

# Monitoring International Trends

## January 2021

The NBA monitors international developments that may influence the management of blood and blood products in Australia. Our focus is on:

- Potential new product developments and applications;
- Global regulatory and blood practice trends;
- Events that may have an impact on global supply, demand and pricing, such as changes in company structure, capacity, organisation and ownership; and
- Other emerging risks that could put financial or other pressures on the Australian sector.

The healthcare sector worldwide remained heavily focussed on the COVID-19 pandemic, and the development and rollout of vaccines and other suitable treatments. Of note: tensions arose in Europe where vaccine supply was unable to meet demand (page 17); concerns increased worldwide about emerging mutant strains of the virus and how effective the current vaccines and treatments will be against these new strains (pages 12 - 13); the US FDA has given emergency authorisation to a sensitive antibody test for COVID-19 that can predict if a patient will experience mild or severe COVID symptoms (page 7); and promising results have shown that high-titre convalescent plasma can lower the mortality risk from COVID-19 (page 8).

In other news, unrelated to COVID-19, BioMarin's phase 3 gene therapy trial for adults with severe haemophilia A has produced very positive results. The mean annualised bleeding rate was reduced by 84% and the mean annualised Factor VIII infusion rate was reduced by 99% (page 4).

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## 1. Treating blood disorders

### Haemophilia

- BioMarin Pharmaceutical announced positive top-line results from its ongoing international phase 3GENEr8-1 trial of valoctocogene roxaparvovec, an investigational gene therapy for the treatment of adults with severe haemophilia A. The trial enrolled 134 participants, all of whom received a single dose and completed at least one year of follow-up<sup>1</sup>.
- A commercial status report on seven gene therapies under development for haemophilia A and B is available<sup>2</sup>. Four of the seven potential therapies are in phase 3 trials, with BioMarin and Uniqure's programs the most progressed.
- Generation Bio announced data from a trial demonstrating tolerability and targeted factor VIII expression levels in haemophilia A mice with a single dose of closed-ended DNA delivered via a cell-targeted lipid nanoparticle system. A dose response was observed across three cohorts, with the highest dose showing a mean human factor VIII expression 23 per cent of normal<sup>3</sup>.

### Sickle cell disease and thalassemia

- The European Medicines Agency is reviewing an application from Global Blood Therapeutics for marketing approval of oral therapy Oxbryta (voxelotor) for people, aged 12 and over, with sickle cell disease<sup>4</sup>.
- Imara reported results from its phase 2a clinical trial of IMR-687 in adult patients with sickle cell disease. The data showed that the drug was well tolerated as a monotherapy, and in combination with hydroxyurea, at all dose levels<sup>5</sup>.

### Other blood disorders

- Veralox Therapeutics submitted an Investigational New Drug application to the US Food and Drug Administration (FDA) for initiation of a phase 1 clinical trial of VLX-1005, a small molecule inhibitor of 12-lipoxygenase, in development for the treatment of heparin-induced thrombocytopenia.<sup>6</sup>
- Swedish Orphan Biovitrum (Sobi™) announced that the European Commission had approved an extension of the indication for Doptelet (avatrombopag) to include the treatment of primary chronic immune thrombocytopenia in adult patients who are

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<sup>1</sup> <https://pipelinereview.com/index.php/2021011177124/DNA-RNA-and-Cells/BioMarin-Announces-Positive-Phase-3-Gene-Therapy-Trial-Results-in-Adults-with-Severe-Hemophilia-A-Study-Met-All-Primary-and-Secondary-Efficacy-Endpoints-in-One-Year-Dat.html> and

<https://www.biopharmadive.com/news/biomarin-hemophilia-gene-therapy-phase-3-data/593118/>  
<sup>2</sup> <https://www.biopharmadive.com/news/hemophilia-gene-therapy-biomarin-uniqure-pfizer-roche/594168/>

<sup>3</sup> <https://pipelinereview.com/index.php/2021010577066/DNA-RNA-and-Cells/Generation-Bio-Announces-Two-Non-Viral-Gene-Therapy-Milestone-Achievements-Target-Levels-of-Factor-VIII-Expression-in-Hemophilia-A-Mice-and-Translation-of-Expression-fr.html>

<sup>4</sup> <https://sicklecellanemianews.com/2021/01/28/ema-reviews-oxbryta-would-be-first-eu-therapy-targeting-scd-root-cause/>

<sup>5</sup> <https://pipelinereview.com/index.php/2021010677094/Small-Molecules/Imara-Reports-Phase-2a-Clinical-Trial-Results-of-IMR-687-in-Adult-Patients-with-Sickle-Cell-Disease.html>

<sup>6</sup> <https://pipelinereview.com/index.php/2021011277154/Small-Molecules/Veralox-Therapeutics-Announces-IND-Submission-for-VLX-1005-to-Treat-Heparin-Inducted-Thrombocytopenia.html>

refractory to other treatments (e.g. corticosteroids, immunoglobulins) in all European Union member states<sup>7</sup>.

## 2. Safety and Patient blood management

- A large, randomised trial found that women given tranexamic acid after a caesarean section showed reduced postpartum haemorrhage according to specific measures<sup>8</sup>.
- A New Zealand study reported that a single 1gm infusion of intravenous iron is adequate in most patients with iron deficiency anaemia<sup>9</sup>.

## 3. Antibodies and COVID-19

- Researchers say that even though pregnant women with COVID-19 can produce a robust antibody response, there is limited transfer across the placenta of these antibodies<sup>10</sup>, consequently, children born to infected mothers may be at risk of infection<sup>11</sup>.
- Eli Lilly's first COVID-19 antibody, bamlanivimab, earned \$US 871 million in revenue in the fourth quarter of 2020<sup>12</sup>; and the US government has placed another large order<sup>13</sup>. According to Eli Lilly, its antibody reduces the risk of nursing home residents contracting COVID-19 by up to 80 per cent<sup>14</sup>. However, laboratory tests showed COVID-19 antibody drugs made by Eli Lilly may be less effective against a new coronavirus variant found in South Africa, so the company is testing it in combination with another treatment by Vir Biotechnology and its partner GlaxoSmithKline<sup>15</sup>.
- Regeneron released preliminary data from an ongoing phase 3 trial of its antibody cocktail REGEN-COV (previously REGN-COV2) in people at high risk of contracting

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<sup>7</sup> <https://pipelinereview.com/index.php/2021012077194/Small-Molecules/Doptelet-avatrombopag-approved-in-the-EU-for-treatment-of-ITP.html>

<sup>8</sup> <https://www.medpagetoday.com/meetingcoverage/smf/90957>

<sup>9</sup> <https://thelimbic.com/haematology/one-off-iron-infusion-works-for-most-ida/>

<sup>10</sup> <https://www.medpagetoday.com/meetingcoverage/smf/90937>

<sup>11</sup> <https://www.healio.com/news/primary-care/20210114/ga-pregnant-women-with-covid19-pass-few-antibodies-to-infants> and [Assessment of Maternal and Neonatal SARS-CoV-2 Viral Load, Transplacental Antibody Transfer, and Placental Pathology in Pregnancies During the COVID-19 Pandemic | Infectious Diseases | JAMA Network Open](#) and [Protecting Pregnant Women and Their Infants From COVID-19: Clues From Maternal Viral Loads, Antibody Responses, and Placentas | Infectious Diseases | JAMA Network Open](#) and [Compromised SARS-CoV-2-specific placental antibody transfer: Cell](#)

<sup>12</sup> [Q420LillySalesandEarningsPressRelease](#)

<sup>13</sup> <https://www.fiercepharma.com/pharma/lilly-picks-up-871m-covid-antibody-sales-projects-blockbuster-contribution-2021>

<sup>14</sup> <https://www.biopharmadive.com/news/lilly-covid-antibody-drug-combination-study/593704/> and [Lilly's neutralizing antibody bamlanivimab \(LY-CoV555\) prevented COVID-19 at nursing homes in the BLAZE-2 trial, reducing risk by up to 80 percent for residents | Eli Lilly and Company](#) and [Eli Lilly's COVID-19 antibody shows it can prevent the disease. But will doctors use it? | FiercePharma](#) and [Drugmaker: Antibody Prevents COVID in Nursing Home Patients | MedPage Today](#)

<sup>15</sup> <https://www.reuters.com/article/health-coronavirus-lilly-vir-biotech/update-1-eli-lilly-testing-covid-19-antibody-treatment-with-vir-biotechs-drug-idUSL4N2K22VA> and <https://www.medscape.com/viewarticle/944742> and <https://www.fiercebitech.com/biotech/eli-lilly-teams-up-pharma-rival-gsk-and-partner-vir-for-covid-antibody-cocktail-test> and <https://www.reuters.com/article/healthcoronavirus-glaxosmithkline/update-1-gsk-vir-to-test-antibody-for-covid-19-treatment-idUSL4N2JN1ZB> and <https://pipelinereview.com/index.php/2021011277147/Antibodies/ir-Biotechnology-and-GSK-Announce-NHS-Supported-AGILE-Study-to-Evaluate-VIR-7832-in-the-Early-Treatment-of-COVID-19.html>

COVID-19 due to having family members with the disease. The company said these results justify using the drug for 'passive vaccination'<sup>16</sup>.

- In September 2020, Regeneron Pharmaceuticals announced that the combination of casirivimab and imdevimab reduced viral loads and ameliorated symptoms in non-hospitalised COVID-19 patients. The US FDA later issued emergency use authorisation for the antibody cocktail in patients with mild to moderate COVID-19 who are not currently hospitalised. More recently, Regeneron reported that early data, from its continuing study of the cocktail (in hospitalised patients needing low-flow oxygen), suggest the drug is effective enough to justify continuing the trial. Trial participants included both seropositive and seronegative patients (those who had produced their own antibodies and those who had not. The company said seronegative patients who received the antibody cocktail were at lower risk of death or needing mechanical ventilation<sup>17</sup>.
- AvantGen announced licensing of its anti-SARS-CoV-2 antibodies to IGM Biosciences to develop as COVID-19 therapies<sup>18</sup>.
- DiosCURE Therapeutics announced a publication<sup>19</sup> describing its core technology of multivalent single-chain antibodies with a unique molecular mode-of-action to inactivate SARS-CoV-2 virions<sup>20</sup>.
- Jemincare began its phase 1 trial of anti-SARS-CoV-2 neutralizing antibody JMB2002<sup>21</sup>.
- The US Centers for Disease Control and Prevention (CDC) found that a specific rapid antigen test may fail to identify two-thirds of asymptomatic cases<sup>22</sup>.
- Celltrion's anti-SARS-CoV-2 antibody CT-P59 in a phase 2 / 3 clinical trial improved outcomes in patients with mild to moderate COVID-19.<sup>23</sup> Celltrion Group then applied for conditional marketing authorisation to the Korean Ministry of Food and Drug Safety <sup>24</sup>.
- A potential COVID-19 treatment that fuses tiny antibodies from llamas and alpacas has been reported to show promise.<sup>25</sup>
- Scientists in South Africa reported that the new South African variant of SARS-CoV-2 "can evade the antibodies that attack it in treatments using blood plasma from

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<sup>16</sup> <https://www.fiercepharma.com/pharma/regeneron-pitches-covid-antibody-cocktail-for-passive-vaccination-fresh-trial-data> and <https://www.biopharmadive.com/news/regeneron-lilly-antibodies-prevent-treat-covid/593991/>

<sup>17</sup> <http://bit.ly/3pA1AsI> and [Regeneron Announces Encouraging Initial Data from COVID-19 Antibody Cocktail Trial in Hospitalized Patients on Low-flow Oxygen | Regeneron Pharmaceuticals Inc.](https://www.regeneron.com/news/initial-data-covid-19-antibody-cocktail-trial)

<sup>18</sup> <https://pipelinereview.com/index.php/2021011277144/Antibodies/AvantGen-Announces-Licensing-of-Its-Anti-SARS-CoV-2-Antibodies-to-IGM-Biosciences-for-COVID-19-Therapy-Development.html>

<sup>19</sup> [Structure-guided multivalent nanobodies block SARS-CoV-2 infection and suppress mutational escape | Science \(sciencemag.org\)](https://www.sciencemag.org/science/2020/11/27/structure-guided-multivalent-nanobodies-block-sars-cov-2-infection-and-suppress-mutational-escape)

<sup>20</sup> <https://pipelinereview.com/index.php/2021011277151/Antibodies/DiosCURE-to-Develop-Highly-Specific-Single-Chain-Antibodies-Against-SARS-CoV-2-Lead-Candidates-Described-in-Science-Publication.html>

<sup>21</sup> <https://pipelinereview.com/index.php/2021012077202/Antibodies/Jemincare-initiates-phase-I-clinical-trial-of-anti-SARS-CoV-2-neutralizing-antibody-JMB2002.html>

<sup>22</sup> <https://www.fiercebiotech.com/medtech/cdc-study-says-abbott-s-rapid-covid-19-antigen-test-may-miss-two-thirds-asymptomatic-cases>

<sup>23</sup> <https://www.fiercebiotech.com/biotech/celltrion-s-covid-19-antibody-improves-outcomes-phase-2> and <https://pipelinereview.com/index.php/2021011377161/Antibodies/Celltrion-Group-announces-positive-top-line-efficacy-and-safety-data-from-global-Phase-II/III-clinical-trial-of-COVID-19-treatment-candidate-CT-P59.html>

<sup>24</sup> <https://pipelinereview.com/index.php/2020122977014/Antibodies/Celltrion-Submits-Application-for-Conditional-Marketing-Authorisation-of-Its-COVID-19-Treatment-Candidate-CT-P59-to-the-Korean-MFDS.html>

<sup>25</sup> [A COVID-19 treatment candidate that fuses tiny antibodies from llamas and alpacas shows promise | FierceBiotech](https://www.fiercebiotech.com/medtech/a-covid-19-treatment-candidate-that-fuses-tiny-antibodies-from-llamas-and-alpacas-shows-promise)

previously recovered patients, and it may reduce the efficacy of the current line of vaccines.”<sup>26</sup>

- Some US officials have been arguing for the increased use of authorised antibody drugs to help keep COVID-19 patients out of the crowded hospital system<sup>27</sup>.
- Researchers from the University of Denver's Knoebel Institute for Healthy Aging, and others, have developed a sensitive antibody test for COVID-19 that can predict if a patient will experience mild or severe COVID symptoms. The US FDA has given it emergency use authorisation.<sup>28</sup>
- A study of SARS-CoV-2 antibody responses in healthcare workers found that “SARS-CoV-2 anti-nucleocapsid antibodies wane within months, and faster in younger adults and in those without symptoms; whereas, the anti-spike IgG remains stably detected. Ongoing longitudinal studies are required to track the long-term duration of antibody levels and their association with immunity to SARS-CoV-2 reinfection.”<sup>29</sup>

#### 4. Use of convalescent plasma in COVID-19

- The REMAP-CAP trial, testing convalescent plasma in COVID-19 patients who were moderately or severely ill, has discontinued the enrolment of severely ill patients as they received no benefit<sup>30</sup>.
- The chief investigators in the RECOVERY trial (randomised evaluation of COVID-19 therapy) closed<sup>31</sup> recruitment of the convalescent plasma arm after an independent board determined there was no evidence that patients were benefiting<sup>32</sup>.
- In an interview<sup>33</sup>, Dr Dorothy Scott<sup>34</sup> of the US FDA discussed COVID-19 convalescent plasma as “a unique source for manufacturing polyclonal COVID-Ig because it contains antibodies that can bind and neutralize the virus by targeting a variety of SARS-CoV-2 viral protein epitopes. This way, COVID-Ig differs from monoclonal antibodies developed against a single SARSCoV-2 viral protein epitope or a monoclonal antibody cocktail that might contain two or more epitope-specific antibodies. In humans, the COVID-Ig is synthesised by multiple plasma cells of B cell lineages (a type of white blood cells). Many plasma cells each make slightly different antibodies to different regions of SARS-CoV-2 proteins. In contrast, monoclonal antibodies are made by specific manipulations to make a cell that can reproduce indefinitely and produce an antibody of desired specificity against one portion of one viral protein. As with every plasma derived protein therapy (PPT), the first step in manufacturing COVID-Ig is to collect a sufficient volume of plasma from donors to

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<sup>26</sup> <https://www.medscape.com/viewarticle/944427>

<sup>27</sup> <https://www.biopharmadive.com/news/coronavirus-antibody-drugs-underused-regeneron-lilly/593476/> and <https://www.fiercepharma.com/pharma/regeneron-inks-sizable-new-coronavirus-antibody-supply-deal-worth-up-to-2-6b> and <https://www.fiercepharma.com/pharma/jpm-regeneron-execs-say-it-s-a-problem-how-few-covid-19-patients-are-getting-antibody> and <https://www.fiercepharma.com/pharma/astrazeneca-biotechs-advance-new-covid-19-antibodies-eyes-dosing-mutation-challenges>

<sup>28</sup> <https://www.kvue.com/article/life/colorado-covid-university-of-denver-covid-test/73-fd032677-b592-462f-953c-555f2cb86789>

<sup>29</sup> <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab004/6064824>

<sup>30</sup> <https://www.medscape.com/viewarticle/943873>

<sup>31</sup> [RECOVERY trial closes recruitment to convalescent plasma treatment for patients hospitalised with COVID-19 — RECOVERY Trial](https://www.fda.gov/news-events/press-announcements/recovery-trial-closes-recruitment-to-convalescent-plasma-treatment-for-patients-hospitalised-with-covid-19)

<sup>32</sup> <https://www.healio.com/news/infectious-disease/20210115/trial-evaluating-convalescent-plasma-for-covid19-ends-after-board-finds-no-benefit>

<sup>33</sup> [WINTER 2020 Special FDA \(netvoyage.com\)](https://www.netvoyage.com/winter-2020-special-fda)

<sup>34</sup> Chief, Plasma Derivatives Branch, Division of Plasma Protein Therapeutics, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research

make enough product to conduct clinical trials to study safety and efficacy of the investigational product”.

- A study<sup>35</sup> has suggested that administering convalescent plasma with high levels of antibodies against SARS-CoV-2 to COVID-19 patients within the first 3 days of symptoms is associated with significantly lower chances of progression to severe disease. In a trial with 160 participants (older adults with COVID-19), half were randomly assigned to receive plasma and half to receive placebo infusion. Treatment with high-titre plasma lowered the relative risk for severe disease by 48 per cent. Senior author Dr Fernando Polack<sup>36</sup> said that it is important to select plasma in the upper 28th percentile of IgG antibody concentrations and to infuse it before the disease progresses.
- Researchers reported that in hospitalised patients not on mechanical ventilation, high-titre convalescent plasma was more effective at lowering their mortality risk than plasma with lower antibody levels<sup>37</sup>.

## 5. Clinical experience in COVID-19

- Some COVID-19 patients have experienced post-infection immune thrombocytopenia<sup>38</sup>.
- The US National Institutes of Health has established a database to collect data about COVID-19-related neurological symptoms, complications and outcomes and data about the impact of COVID-19 on pre-existing neurological conditions<sup>39</sup>.
- Researchers are examining explanations of how SARS-CoV-2 causes neurological symptoms<sup>40</sup>.
- A study found that men are more likely than women to test positive for COVID-19, to require ICU admission and mechanical ventilation, and to die in hospital<sup>41</sup>.
- Clinicians say that “impairment of the central olfactory pathway, mainly involving the orbitofrontal cortex (OFC), may underlie persistent impairment in smell and taste in patients after COVID-19 infection”<sup>42</sup>.
- Researchers say that atrial fibrillation in COVID-19 patients at hospital admission predicts mortality<sup>43</sup>.
- A survey found that people with the UK variant were less likely to lose their sense of taste and/or smell, but more likely to suffer coughing, sore throat and exhaustion<sup>44</sup>.
- Surveys have shown that a common report from people infected with SARS-CoV-2 is that their sleep quality and sleep patterns have been disturbed<sup>45</sup>.

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<sup>35</sup> [Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults | NEJM](#)

<sup>36</sup> an infectious disease specialist and scientific director at Fundacion INFANT and professor of paediatrics at the University of Buenos Aires School of Medicine, Buenos Aires, Argentina.

<sup>37</sup> <https://www.healio.com/news/infectious-disease/20210114/hightiter-convalescent-plasma-associated-with-lower-risk-for-death-from-covid19> and [Covid-19: Convalescent plasma may cut deaths in patients not on ventilation, study indicates | The BMJ](#) and <https://www.medscape.com/viewarticle/944173>

<sup>38</sup> <https://www.medscape.com/viewarticle/944801>

<sup>39</sup> <https://www.drugtargetreview.com/news/81771/new-database-to-track-neurological-symptoms-of-covid-19/> and <https://www.nih.gov/news-events/news-releases/nih-launches-database-track-neurological-symptoms-associated-covid-19>

<sup>40</sup> <https://www.the-scientist.com/news-opinion/covid-19s-effects-on-the-brain-68369>

<sup>41</sup> [Men more likely to test positive for COVID-19, have worse outcomes \(healio.com\)](#)

<sup>42</sup> <https://www.medscape.com/viewarticle/944608>

<sup>43</sup> <https://www.medscape.com/viewarticle/944802>

<sup>44</sup> <https://www.medscape.com/viewarticle/944770>

<sup>45</sup> <https://www.medscape.com/viewarticle/944631>

- A US study found that pulmonary dysfunction and septic shock were the most common causes of death in a cohort of patients hospitalised with COVID-19<sup>46</sup>.
- In a global trial, full dose anti-coagulant given to moderately ill patients hospitalised for COVID-19 reduced the need for life support and improved outcomes<sup>47</sup>. The appropriate use of anticoagulants in COVID-19 remains a matter for continued discussion and research<sup>48</sup>.
- A study<sup>49</sup> found that anticoagulants/ antiplatelet agents are not risk factors for gastrointestinal bleeding in hospitalised COVID-19 patients<sup>50</sup>.
- Researchers have developed a DNA test to help identify secondary infections that may take hold during COVID-19 treatment<sup>51</sup>.
- Alexion paused enrolment in a phase 3 Ultomiris trial in patients with severe COVID-19. The independent monitoring committee said interim analysis found Ultomiris did not benefit patients any more than supportive care<sup>52</sup>.
- Gilead has been testing whether remdesivir, which is currently in use for half the COVID-19 patients hospitalised in the US,<sup>53</sup> is effective in treating the new SARS-COV-2 strains that have emerged<sup>54</sup>.
- A study found that sickle cell disease was associated with worse COVID-19 outcomes<sup>55</sup>.
- Research suggests that a COVID-19 patient's gut microbiome may affect the severity of their disease and the strength of their immune response<sup>56</sup>.
- A new study supports the view that "people with type 2 diabetes who develop COVID-19 show a substantially reduced risk of dying if they are taking metformin"<sup>57</sup>.
- A study in Greece suggested that upper respiratory tract viral load in patients with COVID-19 could be used to identify those at higher risk for severe outcomes<sup>58</sup>.

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<sup>46</sup> [COVID-19 deaths really are different. But best practices for ICU care should still apply | EurekAlert! Science News](#) and <https://www.healio.com/news/pulmonology/20210127/death-due-to-pulmonary-dysfunction-common-in-covid19>

<sup>47</sup> <https://www.nih.gov/news-events/news-releases/full-dose-blood-thinners-decreased-need-life-support-improved-outcome-hospitalized-covid-19-patients> and <https://www.medpagetoday.com/infectiousdisease/covid19/90840>

<sup>48</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/90726> and <https://www.medscape.com/viewarticle/944584> and <https://www.cbc.ca/news/health/covid-19-blood-thinners-uhn-1.5884230>

<sup>49</sup> [Gastrointestinal Bleeding in Hospitalized COVID-19 Patients: A Propensity Score Matched Cohort Study - Trindade - - Journal of Internal Medicine - Wiley Online Library](#)

<sup>50</sup> <https://www.healio.com/news/gastroenterology/20210104/anticoagulants-do-not-increase-gi-bleeding-in-covid19>

<sup>51</sup> <https://www.fiercebiotech.com/medtech/cambridge-univ-researchers-develop-dna-test-for-covid-19-s-secondary-hospital-acquired>

<sup>52</sup> <https://www.fiercepharma.com/pharma/alexion-s-ultomiris-fails-to-show-promise-covid-19-trial-after-months-testing-severe> and <https://pipelinereview.com/index.php/2021011477170/Antibodies/Alexion-Provides-Update-on-Phase-3-Study-of-ULTOMIRIS-ravulizumab-cwvz-in-Hospitalized-Patients-with-Severe-COVID-19.html>

<sup>53</sup> <https://www.fiercepharma.com/pharma/jpm-gilead-s-veklury-now-used-half-hospitalized-u-s-covid-patients-delivers-big-revenue-bump>

<sup>54</sup> <https://www.cnbc.com/2021/01/11/remdesivir-likely-works-against-covid-strains-found-in-uk-south-africa-gilead-ceo.html>

<sup>55</sup> <https://www.medpagetoday.com/meetingcoverage/ashvideopearlsrbd/90628>

<sup>56</sup> <https://www.medscape.com/viewarticle/943939>

<sup>57</sup> <https://www.medscape.com/viewarticle/944386>

<sup>58</sup> <https://www.healio.com/news/infectious-disease/20210119/upper-respiratory-tract-viral-load-could-identify-highrisk-patients-with-covid19>

- A study suggests that the oral anti-inflammatory drug Colchicine, given to outpatients newly diagnosed with COVID-19, can prevent their hospitalisation<sup>59</sup>.
- The US CDC has published a report suggesting that multisystem inflammatory syndrome in adults is more complicated than in children<sup>60</sup>.
- Researchers in Argentina found that for a small number of patients who were co-infected with dengue and COVID-19, outcomes did not seem to be worse than for those having either infection alone.<sup>61</sup>
- A study<sup>62</sup> reported that fatigue, post-exercise malaise and cognitive dysfunction are commonly reported by COVID-19 long haulers 6 months after their infection;<sup>63</sup> but that this does not appear to correlate with the severity of the infection.<sup>64</sup>
- Researchers said that it is safe for hospitalised COVID-19 patients to continue taking renin-angiotensin system inhibitors<sup>65</sup>.
- It is now thought that having an understanding of the viral load in COVID-19 patients can help to predict the course of their disease<sup>66</sup>.
- Human foetuses can be infected by the SARS-CoV-2 virus; but compared with Zika and cytomegalovirus, it is a rare event<sup>67</sup>.
- Scientists from the US National Institutes of Health conducted brain scans of COVID-19 patients and found damage caused by thinning and leaking blood vessels in samples from patients who died soon after becoming infected. Interestingly, they found no sign of SARS-CoV-2 in the tissue samples, suggesting that the damage was not the result of a direct viral attack on the brain, but perhaps a result of the body's inflammatory response to the virus<sup>68</sup>.
- A large international study will investigate the relationship between COVID-19 and cognitive decline in older members of the population<sup>69</sup>.

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<sup>59</sup> <https://www.medscape.com/viewarticle/944593> and [Colchicine reduces the risk of COVID-19-related complications | Montreal Heart Institute \(icm-mhi.org\)](https://www.medscape.com/viewarticle/943755)

<sup>60</sup> <https://www.cdc.gov/mis-c/mis-a.html>

<sup>61</sup> [https://wwwnc.cdc.gov/eid/article/27/2/20-3439\\_article](https://wwwnc.cdc.gov/eid/article/27/2/20-3439_article)

<sup>62</sup> [Characterizing Long COVID in an International Cohort: 7 Months of Symptoms and Their Impact \(medrxiv.org\)](https://www.medrxiv.org/content/10.1101/2021.01.05.21010801v1) (not yet peer reviewed)

<sup>63</sup> <https://www.medscape.com/viewarticle/943755> and <https://emedicine.medscape.com/article/2500114-clinical> and <https://www.medscape.com/viewarticle/942893>

<sup>64</sup> <https://www.healio.com/news/pulmonology/20210108/persistent-poor-health-after-covid19-appears-unrelated-to-initial-severity-of-infection>

<sup>65</sup> <https://www.healio.com/news/cardiology/20210108/reninangiotensin-inhibitors-safe-in-patients-hospitalized-with-covid19-replace-covid>

<sup>66</sup> <https://www.nytimes.com/2020/12/29/health/coronavirus-viral-load.html>

<sup>67</sup> <https://www.the-scientist.com/features/human-fetuses-can-contract-sars-cov-2-but-its-rare-68293>

<sup>68</sup> Myoung-Hwa Lee et al., Microvascular Injury in the Brains of Patients with Covid-19, New England Journal of Medicine (2020). DOI: [10.1056/NEJMc2033369](https://doi.org/10.1056/NEJMc2033369) and <https://www.medscape.com/viewarticle/943445>

<sup>69</sup> [https://www.washingtonpost.com/local/social-issues/covid-alzheimers-dementia-study/2021/01/05/998caf18-4cc9-11eb-a9f4-0e668b9772ba\\_story.html](https://www.washingtonpost.com/local/social-issues/covid-alzheimers-dementia-study/2021/01/05/998caf18-4cc9-11eb-a9f4-0e668b9772ba_story.html) and [SARS-CoV-2 \(COVID-19\) Impact on the Brain | alz.org](https://www.alz.org/newsroom/2021/01/05/sars-cov-2-covid-19-impact-on-the-brain)

## 6. Other potential treatments for COVID-19

- A study found that plitidepsin (the antiviral Aplidin) can prevent proliferation of the SARS-CoV-2 virus in different cell lines and in mouse lungs<sup>70</sup>.
- Synairgen's SNG001 is a nebulizer containing interferon beta-1a. In a recent phase 2 trial, volunteers who received the drug were more likely to recover from COVID-19 than were placebo controls<sup>71</sup>.
- In a small single-centre observational study, antithrombotic prophylaxis for hospitalised patients (informed by thromboelastography findings on coagulopathy) was associated with more satisfactory outcomes.<sup>72</sup>
- Two new studies found no significant association between blood group and COVID-19 severity.<sup>73</sup>
- A trial to see if tocilizumab plus standard care could improve outcomes in critical covid-19 was stopped early after an increase in deaths<sup>74</sup>.
- Another study found that treating critically ill COVID-19 patients with the immunosuppressants tocilizumab or sarilumab significantly improved survival rates and reduced time in ICU<sup>75</sup>.
- A research team from the Chinese Academy of Sciences' Shenzhen Institutes of Advanced Technology have claimed that pralatrexate, a chemotherapy developed to treat lymphoma, can more strongly inhibit SARS-CoV-2 replication than does Gilead Sciences' remdesivir under the same conditions<sup>76</sup>.
- RedHill Biopharma presented phase 2 data on its oral SK2 inhibitor opaganib<sup>77</sup> in COVID-19 patients receiving supplemental oxygen. The trial suggested improvement in oxygen requirement but was too small to be conclusive; a larger phase 2 /3 trial will report soon<sup>78</sup>.

## 7. Developing vaccines for COVID-19

### Approved or close to submission for approval

- A number of countries have been vaccinating their populations. Concerns have included inadequate supplies of vaccine, inefficient distribution, and delays in administration. There was concern round the world about whether recently emerged and potentially emerging strains of the SARS-CoV-2 virus would be able to escape

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<sup>70</sup> <https://www.medscape.com/viewarticle/944807> and [Plitidepsin has potent preclinical efficacy against SARS-CoV-2 by targeting the host protein eEF1A | Science \(sciencemag.org\)](#) and [Cancer drug derived from sea squirts outperforms remdesivir in COVID-19 preclinical models | FierceBiotech](#)

<sup>71</sup> [Another crucial coronavirus mystery was just explained – BGR](#) and [A breakthrough coronavirus therapy might help patients recover faster – BGR](#)

<sup>72</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/90615>

<sup>73</sup> <https://www.healio.com/news/hematology-oncology/20210108/studies-contradict-earlier-findings-on-blood-group-and-covid19-severity-mortality>

<sup>74</sup> [Covid-19: Arthritis drug trial for severe illness is stopped early after increase in deaths | The BMJ](#)

<sup>75</sup> [Sickest coronavirus patients to be treated with arthritis drugs after study finds reduction in death rates - ABC News](#)

<sup>76</sup> [A novel virtual screening procedure identifies Pralatrexate as inhibitor of SARS-CoV-2 RdRp and it reduces viral replication in vitro \(plos.org\)](#) and <https://www.fiercebiotech.com/research/ai-spots-lymphoma-chemotherapy-as-stronger-covid-19-drug-than-gilead-s-remdesivir>

<sup>77</sup> [RedHill Biopharma Announces Positive Top-Line Safety and Efficacy Data from Phase 2 COVID-19 Study of Opaganib | RedHill Biopharma Ltd.](#)

<sup>78</sup> <https://www.fiercebiotech.com/biotech/redhill-posts-data-covid-19-patients-supplemental-oxygen>

currently approved vaccines, and if so, how this could be dealt with expeditiously.<sup>79</sup> Booster shots have been mooted as a way of ensuring vaccines cope with mutant strains<sup>80</sup>.

- In the US, researchers tested vaccinated people to see how well they are protected against new variants. Two teams reported that “while the mutations in the new variants of the virus – one first seen in Britain, and another first identified in South Africa – did allow them to evade some of the immunity induced by vaccination, it was far from a complete escape”<sup>81</sup>. US agencies will co-operate to study vaccine effectiveness against mutant strains<sup>82</sup>.
- Experts warned that a vaccine’s protection from COVID-19 can take up to two weeks to develop, so precautions against the disease should continue<sup>83</sup>.
- An international poll found that people were more likely to trust vaccines made in Germany or the US, rather than in Russia or China<sup>84</sup>.
- The US CDC, in updated interim guidance on contraindications to COVID-19 vaccination, has said “anyone with a history of immediate allergic reaction of any severity to any component of mRNA COVID-19 vaccines or to polysorbate should not be vaccinated”.<sup>85</sup> On 7 January, the US CDC said 21 people in the US had by then had serious allergic reactions to one of the vaccines being administered. It said that in the rare cases where a reaction occurred to the first dose, it was inadvisable to proceed to the second dose<sup>86</sup>. The CDC reported in mid-January that the rate of anaphylaxis following COVID-19 mRNA vaccines appeared about 10 times that documented for flu shots, but no deaths had been reported.<sup>87</sup>
- Discussion continues over whether the interval between two vaccine doses can be varied<sup>88</sup>.
- The UK, working with two-dose vaccines, decided to space the doses further apart than originally planned, to increase early coverage. Other countries also contemplated this move;<sup>89</sup> however, it was controversial, as that was not the regimen that had been trialled and it was unclear what the impact of the change

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<sup>79</sup> [Emerging evidence suggests new coronavirus variant could pose a problem for current vaccines | 7NEWS.com.au](https://www.7news.com.au/news/2021/01/20/emerging-evidence-suggests-new-coronavirus-variant-could-pose-a-problem-for-current-vaccines/) and <https://www.the-scientist.com/news-opinion/coronavirus-variant-linked-to-covid-19-outbreaks-in-california-68365>

<sup>80</sup> <https://www.fiercepharma.com/pharma/first-moderna-now-pfizer-biontech-also-working-booster-shot-amid-rise-covid-19-variants> and <https://www.cnbc.com/2021/01/25/covid-vaccine-moderna-working-on-covid-booster-shots-for-south-african-strain.html> and [Vaccine makers prepare response as coronavirus mutations raise alarms | BioPharma Dive](https://www.biopharmadive.com/news/pfizer-moderna-covid-19-vaccines-shield-against-new-variants-analysts/) and [Pfizer and Moderna haven't proven their COVID-19 vaccines shield against new variants: analysts | FiercePharma](https://www.fiercepharma.com/pharma/pfizer-moderna-covid-19-vaccines-shield-against-new-variants-analysts/)

<sup>81</sup> <https://edition.cnn.com/2021/01/20/health/covid-vaccines-protect-from-variants/index.html>

<sup>82</sup> <https://www.cnbc.com/2021/01/27/federal-agencies-will-study-covid-vaccine-effectiveness-on-mutant-strains-fauci-says.html> and <https://edition.cnn.com/2021/01/28/health/us-coronavirus-thursday/index.html> and <https://www.cnbc.com/2021/01/21/dr-fauci-says-covid-vaccines-appear-to-be-less-effective-against-some-new-strains.html> and <https://www.the-scientist.com/news-opinion/a-guide-to-emerging-sars-cov-2-variants-68387> and <https://www.medscape.com/viewarticle/944718>

<sup>83</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/90584>

<sup>84</sup> <https://www.medscape.com/viewarticle/944198>

<sup>85</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/90501> and [Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine | CDC](https://www.cdc.gov/media/releases/2021/s0128-covid-19-vaccine.html)

<sup>86</sup> <https://www.fiercehealthcare.com/practices/here-s-latest-cdc-update-clinicians-should-know-when-it-comes-to-covid-19-vaccine> and <https://www.fiercepharma.com/pharma/watch-out-pharma-a-tidal-wave-adverse-event-reports-coming-amid-covid-19-vaccine-rollouts>

<sup>87</sup> <https://www.medpagetoday.com/infectiousdisease/covid19/90556>

<sup>88</sup> <https://www.bmj.com/content/372/bmj.n226>

<sup>89</sup> <https://www.fiercepharma.com/pharma/feds-consider-half-dose-moderna-covid-19-vaccine-as-u-k-spaces-out-pfizer-astrazeneca-shots>

would be.<sup>90</sup> The UK government also said that in some circumstances people might find themselves having a second dose of a vaccine different from the first one they had received, and again this was criticised for having an uncertain impact on efficacy.<sup>91</sup>

### Astra Zeneca

- First approval for emergency use of the AstraZeneca / Oxford University vaccine was in the UK; whereas authorisation in the US is not expected until April<sup>92</sup>.
- Media in mid-January quoted the president of the Australian and New Zealand Immunology Society as saying the group supported pausing the rollout of the AstraZeneca vaccine in favour of the reportedly more effective Pfizer vaccine. The society distanced itself from its president's comments. The Chief Medical Officer said while the Pfizer vaccine is in limited supply, the AstraZeneca vaccine will be manufactured locally in sufficient quantities required to vaccinate the national population<sup>93</sup>. The head of the Oxford Vaccine Group, Professor Andrew Pollard, said "one of the most significant findings from the clinical trials was that after receiving the first dose of the Oxford vaccine no participant was hospitalised or had severe disease"<sup>94</sup>.
- Germany recommended the Astra Zeneca vaccine only for people aged below 65<sup>95</sup>. Meanwhile, Astra Zeneca has denied reports that its vaccine has low efficacy in the elderly.<sup>96</sup>
- The Brazilian Government has approved emergency use of AstraZeneca and Sinovac vaccines.<sup>97</sup>

### Johnson & Johnson

- Johnson & Johnson found its vaccine had lower efficacy in South African phase 3 trial participants<sup>98</sup>. The company reported that its vaccine efficacy was 72 per cent in

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<sup>90</sup> <https://www.medscape.com/viewarticle/943533> and <https://www.fiercepharma.com/pharma/not-so-fast-fda-warns-premature-changes-to-covid-19-vaccine-dosing-clash-slaoui> and <https://www.biopharmadive.com/news/fda-coronavirus-vaccine-dosing-schedule/592811/> and <https://www.washingtonpost.com/health/2021/01/04/covid-vaccine-one-shot/>

<sup>91</sup> <https://www.medscape.com/viewarticle/943562> and [http://www.pharmatimes.com/news/astrazenecaoxford\\_university\\_covid-19\\_vaccine\\_set\\_for\\_uk\\_rollout\\_1360680](http://www.pharmatimes.com/news/astrazenecaoxford_university_covid-19_vaccine_set_for_uk_rollout_1360680) and <https://pipelinereview.com/index.php/2020123077030/Vaccines/AstraZenecas-COVID-19-vaccine-authorised-for-emergency-supply-in-the-UK.html>

<sup>92</sup> <https://thehill.com/policy/healthcare/532163-astrazeneca-vaccine-likely-wont-be-authorized-in-us-until-april> and <https://www.fiercepharma.com/pharma/astrazeneca-has-a-winning-formula-for-its-covid-19-vaccine-ceo-says>

<sup>93</sup> [CMO wades into AstraZeneca, Pfizer vaccine debate saying 'choice is not whether one is better than the other' - ABC News](#) and [Most people in Australia will get AstraZeneca COVID-19 vaccine, Chief Medical Officer Paul Kelly says - ABC News](#)

<sup>94</sup> [Oxford-AstraZeneca vaccine boss warns against delaying immunisation rollout in Australia - ABC News](#)

<sup>95</sup> <https://www.medscape.com/viewarticle/944838>

<sup>96</sup> [AstraZeneca says reports its COVID-19 vaccine has low efficacy in elderly people are 'completely incorrect' - ABC News](#) and [Germany questions efficacy of AstraZeneca vaccine in the elderly - ABC News](#) and <https://www.medscape.com/viewarticle/944670>

<sup>97</sup> <https://www.bloombergquint.com/onweb/brazil-poised-to-approve-emergency-use-of-first-covid-vaccines>

<sup>98</sup> [J&J COVID-19 Vax Effective Against Severe Disease | MedPage Today](#) and <https://www.medpagetoday.com/infectiousdisease/covid19/90954>

the US, 66 per cent in Latin America, and 57 per cent in South Africa.<sup>99</sup> Results of early-stage trials for the Johnson & Johnson single dose vaccine showed all participants had neutralizing antibodies in their system after 57 days.<sup>100</sup> Johnson & Johnson may apply for EU approval in February<sup>101</sup>.

#### Moderna

- The European Commission awarded a conditional marketing authorisation for Moderna's vaccine<sup>102</sup>.
- The US CDC reported that after 4 million doses of the Moderna vaccine had been administered, severe allergic reactions appeared rare<sup>103</sup>.
- Moderna announced that the first participant had been dosed in a phase 1 /2 study of the company's COVID-19 vaccine in Japan<sup>104</sup>. The CEO is reported as saying the company's vaccine will 'potentially' protect against COVID-19 for several years<sup>105</sup>; however, this remains to be seen.
- Moderna will test a second booster shot against the South African variant of the SARS-CoV-2 virus<sup>106</sup>.
- In phase 3 trials of the Moderna vaccine, one side effect observed was facial swelling in people carrying facial fillers<sup>107</sup>.
- The UK approved the Moderna vaccine to be given in two doses a month apart<sup>108</sup>.
- Scientists at Moderna and the US National Institutes of Health said it may take two months to test whether doses of their vaccine can be halved to extend supply<sup>109</sup>.

#### Novavax

- Phase 3 trials of the Novavax vaccine began in Utah. The vaccine requires refrigeration but does not need to be stored at extremely low temperatures<sup>110</sup>.
- Novavax said its vaccine candidate was almost 90 per cent effective in a phase 3 trial in the UK; however, in a phase 2lb trial in South Africa, where most of the cases that

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<sup>99</sup> <https://www.healio.com/news/infectious-disease/20210129/oneshot-jj-vaccine-85-effective-against-severe-disease-66-effective-overall>

<sup>100</sup> <https://thehill.com/policy/healthcare/534217-gottlieb-johnson-johnson-vaccine-looks-like-promising-third-entrant> and [Johnson & Johnson vaccine has promising immune response in early trial | TheHill](https://www.medscape.com/viewarticle/944013)

<sup>101</sup> <https://www.medscape.com/viewarticle/944013>

<sup>102</sup> <https://www.businesswire.com/news/home/20210106005629/en/> and <https://www.fiercepharma.com/pharma/moderna-scores-covid-19-vaccine-backing-europe-setting-off-another-major-vaccination-push> and <https://www.medscape.com/viewarticle/943467> and <https://pipelinereview.com/index.php/2021010277038/Vaccines/Moderna-Announces-Publication-of-Results-from-the-Pivotal-Phase-3-Trial-of-the-Moderna-COVID-19-Vaccine-in-The-New-England-Journal-of-Medicine.html>

<sup>103</sup> <https://www.reuters.com/article/health-coronavirus-vaccine-allergy/severe-allergic-reactions-to-moderna-vaccine-appear-rare-cdc-report-idUSL4N2JX3EN> and [Anaphylaxis Cases With Moderna COVID-19 Vax Follow Similar Pattern | MedPage Today](https://www.medscape.com/viewarticle/943736)

<sup>104</sup> <https://pipelinereview.com/index.php/2021012177218/Vaccines/Moderna-Announces-First-Participant-Dosed-in-Phase-1/2-Study-of-Moderna-COVID-19-Vaccine-in-Japan-Led-by-Takeda.html>

<sup>105</sup> <https://www.medscape.com/viewarticle/943736>

<sup>106</sup> <https://www.fiercepharma.com/pharma/moderna-develops-booster-shot-for-new-covid-strain-affirms-current-vaccine-effectiveness>

<sup>107</sup> <https://www.healio.com/news/dermatology/20210119/qa-reaction-to-facial-fillers-may-be-seen-with-moderna-covid19-vaccine>

<sup>108</sup> [Covid-19: UK approves Moderna vaccine to be given as two doses 28 days apart | The BMJ](https://www.bmj.com/news/covid-19-uk-approves-moderna-vaccine-to-be-given-as-two-doses-28-days-apart)

<sup>109</sup> [Covid-19 vaccination: What's the evidence for extending the dosing interval? | The BMJ](https://www.bmj.com/news/covid-19-vaccination-what-s-the-evidence-for-extending-the-dosing-interval) and <https://www.medscape.com/viewarticle/943596>

<sup>110</sup> [Clinical trials of new COVID-19 vaccine begin in Utah, promises easier storage, transit \(kutv.com\)](https://www.kutv.com/news/clinical-trials-of-new-covid-19-vaccine-begin-in-utah-promises-easier-storage-transit)

occurred during the trial involved the South African strain, the efficacy was much lower<sup>111</sup>.

#### Pfizer/ BioNTech

- Australia's Therapeutic Goods Administration approved the Pfizer/ BioNTech COVID-19 vaccine<sup>112</sup>.
- Norway raised its concern<sup>113</sup> about the safety of the Pfizer/ BioNTech vaccine in people aged over 75 with co-morbidities. Its Medicines Agency investigated deaths in the frail elderly, following (but not necessarily caused by) their vaccination.<sup>114</sup> As of 19 January there had been 71 such deaths<sup>115</sup>. Doctors in Norway were then told to assess frail patients prior to vaccination, as possible side effects may outweigh possible benefit<sup>116</sup>.
- A preliminary study from Israel has suggested that after receiving one dose of the Pfizer vaccine, up to 70 per cent of people can still be infected by SARS-CoV-2<sup>117</sup>.
- Pfizer's vaccine trial in participants aged 12 to 15 is fully enrolled<sup>118</sup>.
- According to WHO, the two doses of the Pfizer vaccine should be given within 21 to 28 days; but it acknowledged some countries would delay the second dose to maximise the number of people benefiting from the first dose<sup>119</sup>.

#### Sinopharm

- Sinopharm (owned by the Chinese Government) reported 79 per cent efficacy of its vaccine in phase 3 trials which took place in China, UAE and Bahrain<sup>120</sup>. The vaccine has been granted conditional marketing approval by Chinese health authorities.<sup>121</sup>
- Sinopharm says its vaccine is safe for children from the age of three<sup>122</sup>.

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<sup>111</sup> <https://www.healio.com/news/primary-care/20210129/novavax-vaccine-89-effective-in-uk-trial-less-effective-in-south-africa> and <https://thehill.com/policy/healthcare/536377-novavax-vaccine-almost-90-percent-effective-in-trial-but-not-against-south> and [Novavax COVID-19 vaccine 89 per cent effective, according to early UK trials - ABC News](https://www.abc.net.au/news/2021-01-25/pfizer-covid-19-vaccine-approved-australia-tga/13087990) and <https://www.biopharmadive.com/news/novavax-vaccine-prevents-covid-19-in-studies-but-less-effective-against-ne/594175/>

<sup>112</sup> [TGA approves Pfizer and BioNTech's COVID-19 vaccine \(labonline.com.au\)](https://www.abc.net.au/news/2021-01-25/pfizer-covid-19-vaccine-approved-australia-tga/13087990) and

<https://www.abc.net.au/news/2021-01-25/pfizer-covid-19-vaccine-approved-australia-tga/13087990>

<sup>113</sup> <https://www.bloomberg.com/news/articles/2021-01-16/norway-vaccine-fatalities-among-people-75-and-older-rise-to-29>

<sup>114</sup> [Covid-19 vaccination associated with adverse drug reactions in elderly people who are frail - Legemiddelverket](https://www.legemiddelverket.no/nyheter/2021-01-19-covid-19-vaccination-associated-with-adverse-drug-reactions-in-elderly-people-who-are-frail)

<sup>115</sup> <https://www.medscape.com/viewarticle/944478>

<sup>116</sup> [Covid-19: Doctors in Norway told to assess severely frail patients for vaccination | The BMJ](https://www.bmj.com/content/362/n8041/norway-covid-19-vaccine-fatalities-among-people-75-and-older-rise-to-29)

<sup>117</sup> <https://www.forbes.com/sites/williamhaseltine/2021/01/27/israeli-study-shows-majority-of-those-vaccinated-can-be-infected-by-sars-cov-2>

<sup>118</sup> <https://www.cnbc.com/2021/01/22/pfizer-says-its-covid-vaccine-trial-for-kids-ages-12-to-15-is-fully-enrolled.html>

<sup>119</sup> <https://www.medscape.com/viewarticle/943572>

<sup>120</sup> <https://www.fiercebiotech.com/biotech/matching-sinopharm-fellow-china-biotech-sinovac-sees-78-covid-vaccine-efficacy>

<sup>121</sup> [http://www.pmlive.com/pharma\\_news/sinopharms\\_covid-19\\_vaccine\\_scores\\_approval\\_in\\_china\\_1360725](http://www.pmlive.com/pharma_news/sinopharms_covid-19_vaccine_scores_approval_in_china_1360725) and <https://www.fiercebiotech.com/biotech/china-sinopharm-sees-79-covid-vaccine-efficacy-picking-up-rear-behind-rivals>

<sup>122</sup> <https://www.fiercebiotech.com/biotech/sinopharm-claims-covid-19-vaccine-safe-kids-aged-3-and-up> and [Sinopharm claims COVID-19 vaccine safe in kids aged 3 and up | FierceBiotech](https://www.fiercebiotech.com/biotech/sinopharm-claims-covid-19-vaccine-safe-kids-aged-3-and-up)

## Sales, manufacturing and distribution

- Information is emerging about prices individual countries are paying for vaccines<sup>123</sup> eg that South Africa is paying more than twice the cost per dose of the Astra Zeneca dose charged to the EU. The EU is paying significantly less for the Pfizer/ BioNTech vaccine than the US, while the reverse is true for the Moderna vaccine, with the explanation given relating to government funding of development.
- The EU announced it had secured nearly half of Pfizer's expected 2021 output of its COVID-19 vaccine<sup>124</sup>. By 12 January the European Union had ordered 2.3 billion doses from six vaccine makers. Only two vaccines had been approved in the EU at that stage. Talks were underway to secure more of the Moderna vaccine (although the price had increased since the initial order), and the EU was in talks with Valneva and Novavax.<sup>125</sup>
- AstraZeneca advised the EU that it was facing a supply shortfall because there had been "reduced yields at a manufacturing site within (its) European supply chain"<sup>126</sup>. Pfizer/BioNTech also reduced their EU vaccine delivery plan. European politicians have reacted strongly<sup>127</sup> to news of reduced deliveries. The EU continued its disputes with Astra Zeneca and Pfizer/ BioNTech over alleged delayed deliveries,<sup>128</sup> and imposed export registration.<sup>129</sup> This led to concern in Australia about delays to expected vaccine shipments.<sup>130</sup>
- Sanofi will assist Pfizer/ BioNTech to produce 100 million vaccine doses.<sup>131</sup>
- Novavax has arranged for Baxter BioPharma Solutions to undertake commercial scale vaccine manufacturing in Germany for the European and UK markets.<sup>132</sup>
- CureVac has partnered with Bayer on its mRNA vaccine, which began phase 3 trials in December.<sup>133</sup>
- Last August, Johnson & Johnson signed a contract with the US Government, agreeing to have 12 million doses available by the end of February and 100 million doses by the end of June. The company was reported to be two months behind schedule,<sup>134</sup> but gave assurances that it would be able to meet its delivery promises.<sup>135</sup>

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<sup>123</sup> <https://www.bmj.com/content/372/bmj.n281>

<sup>124</sup> <https://www.medscape.com/viewarticle/943815>

<sup>125</sup> <https://www.medscape.com/viewarticle/943888>

<sup>126</sup> [AstraZeneca's surprise COVID-19 vaccine shortfall prompts Europe to press for answers | FiercePharma](#)

<sup>127</sup> <https://www.fiercepharma.com/pharma/astrazeneca-covid-19-vaccine-deliveries-europe>

<sup>128</sup> <https://www.medscape.com/viewarticle/944804> and [AstraZeneca, EU officials duke it out in the press as COVID-19 vaccine supply battle heats up | FiercePharma](#)

<sup>129</sup> [COVID-19 VACCINE: EU grants AstraZeneca approval, imposes vaccine export restrictions \(news.com.au\)](#) and [EU gives itself power to block coronavirus vaccine shipments to Australia - ABC News](#)

<sup>130</sup> [Coronavirus: Europe gives itself power to block vaccine shipments to Australia \(theage.com.au\)](#) and [Pfizer getting more information about reports European Union will block coronavirus vaccine exports - ABC News](#)

<sup>131</sup> <https://www.fiercepharma.com/pharma/sanofi-after-r-d-setback-lends-a-hand-to-vaccine-rival-pfizer-for-coronavirus-sho>

<sup>132</sup> <https://www.fiercepharma.com/manufacturing/novavax-taps-baxter-for-commercial-production-as-covid-19-vaccine-nears-finish-line>

<sup>133</sup> <https://www.fiercepharma.com/vaccines/mrna-latecomer-curevac-finds-bayer-as-covid-19-vaccine-partner>

<sup>134</sup> <https://www.nytimes.com/2021/01/13/health/covid-vaccine-johnson-johnson.html>

<sup>135</sup> <https://www.fiercepharma.com/pharma/j-j-ahead-phase-3-covid-19-vaccine-data-release-comfortable-meeting-its-delivery-commitment>

- The US has joined Covax, the World Health Organization (WHO)-led project to distribute coronavirus vaccine to poorer countries.<sup>136</sup>
- Pfizer has agreed to supply up to 40 million doses to the Covax immunisation program for poorer countries.<sup>137</sup>
- The US CDC vaccine tally on 13 January was 30.6 million doses of vaccine distributed and 11.1 administered.<sup>138</sup>

### At an earlier stage of development

- Gritstone is working on a vaccine with funding for preclinical work from the Bill and Melinda Gates Foundation. The US Institute of Allergy and Infectious Diseases will conduct the phase 1 study.<sup>139</sup>
- Merck has halted development of both its vaccine candidates after seeing phase 1 data<sup>140</sup>.
- Two experimental vaccines built from gene-therapy technology led to robust immune responses in mouse and nonhuman primate models. The researchers received a grant of up to \$US 2.1 million from the Bill & Melinda Gates Foundation to develop the vaccine technology, known as AAVCOVID<sup>141</sup>.
- Valneva has completed enrolment in its phase 1 / 2 study of its inactivated, adjuvanted vaccine.<sup>142</sup>
- Codagenix and the Serum Institute of India announced that the first patient has been dosed in the phase 1 clinical trial of COVI-VAC, a single-dose, intranasal, live attenuated vaccine against SARS-CoV-2.<sup>143</sup>
- UK company iosBio signed a global licensing agreement granting ImmunityBio rights to OraPro™ oral vaccine platform technology for COVID-19.<sup>144</sup>
- VBI Vaccines reported progress of its coronavirus vaccine program, which has two candidates: VBI-2901 is a trivalent candidate expressing the SARS-CoV-2 (COVID-19), SARS-CoV (SARS), and MERS-CoV (MERS) spike proteins; whereas VBI-2902 is a monovalent vaccine candidate expressing the SARS-CoV-2 spike protein.<sup>145</sup>
- Vaxess Technologies was awarded a grant from the US National Science Foundation and a subcontract from the US Defense Advanced Research Projects Agency

<sup>136</sup> <https://thehill.com/policy/healthcare/534928-biden-will-join-who-backed-vaccine-initiative>

<sup>137</sup> <https://www.cnbc.com/2021/01/22/pfizer-to-supply-40-million-covid-vaccine-doses-to-covax-global-immunization-program.html>

<sup>138</sup> <https://www.reuters.com/article/us-health-coronavirus-usa-cdc/30-6-million-doses-of-covid-19-vaccines-distributed-11-1-million-administered-u-s-cdc-idUSKBN29J2M4>

<sup>139</sup> <https://www.fiercebiotech.com/biotech/gritstone-adds-covid-19-to-pipeline-niaid-supported-vaccine>

<sup>140</sup> [Merck cans both its COVID-19 vaccines due to weak clinical data | FierceBiotech](#)

<sup>141</sup> [Immunogenicity of an AAV-based, room-temperature stable, single dose COVID-19 vaccine in mice and non-human primates | bioRxiv](#) and [One-dose COVID-19 vaccine candidate that can be stored at room temperature prompts immunity in animals | FierceBiotech](#)

<sup>142</sup> <http://www.pharmatimes.com/news/valneva-completes-recruitment-for-phase-iii-covid-19-vaccine-study-1362313>

<sup>143</sup> <https://pipelinereview.com/index.php/2021011177138/Vaccines/Codagenix-and-Serum-Institute-of-India-Initiate-Dosing-in-Phase-1-Trial-of-COVI-VAC-a-Single-Dose-Intranasal-Live-Attenuated-Vaccine-for-COVID-19.html>

<sup>144</sup> <https://pipelinereview.com/index.php/2021011277148/Vaccines/iosBio-signs-exclusive-worldwide-licensing-agreement-granting-ImmunityBio-rights-to-OraPro-oral-vaccine-platform-technology-for-COVID-19.html>

<sup>145</sup> <https://pipelinereview.com/index.php/2021012177222/Vaccines/VBI-Vaccines-Announces-Progress-of-Coronavirus-Vaccine-Program.html>

(DARPA) to advance two separate projects aimed at developing mRNA-based vaccines and other medical countermeasures with three characteristics:<sup>146</sup>

- refrigeration-free, using the patented Silk Protein Matrix stabilization technology
- single dose administration, enabled by MIMIX™ sustained release formulation
- painless application via MIMIX™ skin patch.
- There are still 200 vaccines in development, some of which are being designed to target mutant strains or particular population groups such as the elderly.<sup>147</sup>
- Companies working on COVID-19 vaccines include:
  - Emergex Vaccines and Brazil's Bio-Manguinhos/ Fiocruz<sup>148</sup>
  - Akston Biosciences and LakePharma<sup>149</sup>
  - Arcturus Therapeutics<sup>150</sup>
- The US FDA placed a clinical hold on Altimune's intranasal vaccine trial,<sup>151</sup> requiring modifications to the protocol and further data on chemistry, manufacturing and controls.
- Australian researchers will trial two COVID-19 vaccines (an mRNA-based vaccine and a recombinant protein vaccine) which can be modified if the virus mutates.<sup>152</sup>
- EpiVax and EpiVax Therapeutics provided an update on the advancement of their peptide-based COVID-19 vaccine, EPV-CoV-19. This T cell epitope-based vaccine has progressed through preclinical validation studies and is expected to be in a phase 1 clinical trial in early 2021.<sup>153</sup>

## 8. Managing the pandemic

### Individual country experience

- Once Australia is distributing the Astra Zeneca vaccine for which refrigerator storage is adequate, GP clinics and pharmacies will participate in the rollout.<sup>154</sup>

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<sup>146</sup> <https://pipelinereview.com/index.php/2021012477237/Vaccines/Vaxess-Technologies-Awarded-NSF-and-DARPA-Funding-for-Development-of-mRNA-Based-Single-Dose-Refrigeration-Free-Vaccine-Patch.html>

<sup>147</sup> [More than 200 COVID-19 vaccines are still in development, with some now focusing on mutant strains and older people - ABC News](#)

<sup>148</sup> [Emergex Vaccines signs Collaboration Agreement with Brazil's Bio-Manguinhos/Fiocruz for the Development of a COVID-19 Vaccine | Vaccines | News Channels \(pipelinereview.com\)](#)

<sup>149</sup> <https://pipelinereview.com/index.php/2021010677074/Vaccines/Akston-Biosciences-and-LakePharma-Announce-Strategic-Partnership-to-Manufacture-Second-Generation-COVID-19-Vaccine.html>

<sup>150</sup> <https://pipelinereview.com/index.php/2021010577048/DNA-RNA-and-Cells/Arcturus-Therapeutics-Receives-FDA-Allowance-to-Proceed-with-Phase-2-Study-of-ARCT-021-LUNAR-COV19-Vaccine-Candidate-in-the-United-States.html>

<sup>151</sup> <https://www.fiercepharma.com/drug-delivery/fda-puts-altimmune-s-intranasal-covid-19-vaccine-trial-hold>

<sup>152</sup> [Australia to trial 'backup' COVID-19 vaccines that can be modified to fight virus mutations - ABC News](#)

<sup>153</sup> <https://pipelinereview.com/index.php/2021010277039/Vaccines/EpiVax-and-EpiVax-Therapeutics-Advance-COVID-19-Vaccine-Program-EPV-CoV-19.html>

<sup>154</sup> [Pharmacies and GPs to participate in coronavirus vaccine rollout from phase 2a - ABC News](#)

- On 8 January Australia’s national cabinet met to tighten precautions on international arrivals<sup>155</sup> in order to prevent further spread of the more infectious mutant strain<sup>156</sup> from hotel quarantine into the community<sup>157</sup>.
- In late January, New Zealand reported its first COVID-19 case in the community for two months, in a returned traveller who had completed her quarantine requirements.<sup>158</sup>
- Researchers<sup>159</sup> have argued based on the New Zealand and Australian experience that “aiming for elimination of community transmission of the SARS-CoV-2 virus could offer important advantages over a suppression or mitigation strategy with ongoing transmission.”<sup>160</sup>
- A ‘No-COVID strategy’ has been discussed in Germany<sup>161</sup>. On 8 January Germany recorded a record 1,188 deaths from COVID-19.<sup>162</sup>
- The EU reported almost 300,000 ‘excess’ deaths from March to October 2020 (more than usual but not at the time attributed to COVID-19, possibly suggesting missed diagnoses)<sup>163</sup>.
- There has been some tension between EU countries about vaccine rollout<sup>164</sup>.
- In March 2020 the SARS-Co-V variant L452R was first detected in Denmark. By late December it was responsible for 25 per cent of recent infections in California<sup>165</sup>.
- On 18 January France’s average number of daily new infections reached 18,270, its highest level in almost seven weeks.<sup>166</sup>
- A study reported that “in Europe, countries that implemented strict COVID-19 mitigation policies early in the pandemic, including cancellation of public events, gathering restrictions, school closures and recommendations to stay at home, saw a lower death toll compared to those with less stringent policies.”<sup>167</sup>
- Most of Spain’s care home residents by late January had received at least one dose of vaccine<sup>168</sup>. Data so far shows that white Americans are being vaccinated at a faster rate than black Americans<sup>169</sup>.
- A US study found that “the more packed a hospital intensive care unit is with COVID-19 patients, the greater likelihood those patients will die.”<sup>170</sup>

<sup>155</sup> <https://www.msn.com/en-au/news/australia/national-cabinet-makes-masks-mandatory-on-flights-announces-new-coronavirus-strain-rapid-testing-for-travellers-from-uk/ar-BB1czgDO>

<sup>156</sup> <https://www.the-scientist.com/news-opinion/south-african-sars-cov-2-variant-alarms-scientists-68317>

<sup>157</sup> [Coronavirus Australia: National cabinet to consider tighter rules on UK arrivals \(smh.com.au\)](https://www.smh.com.au/news/australia/national-cabinet-to-consider-tighter-rules-on-uk-arrivals-20200108)  
[Three-day lockdown imposed on Greater Brisbane to stop spread of mutant COVID strain \(msn.com\)](https://www.msn.com/en-au/news/australia/three-day-lockdown-imposed-on-greater-brisbane-to-stop-spread-of-mutant-covid-strain/ar-BB1czgDO)

<sup>158</sup> [New Zealand reports first case of coronavirus in community in months - ABC News](https://www.abc.net.au/news/2020-01-17/new-zealand-reports-first-case-of-coronavirus-in-community-in-months/11811110)

<sup>159</sup> Michael Baker and Nick Wilson, both professors of public health, and Tony Blakely, professor of epidemiology

<sup>160</sup> [Elimination could be the optimal response strategy for covid-19 and other emerging pandemic diseases | The BMJ](https://www.bmj.com/content/361/n8022/e003053)

<sup>161</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00186-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00186-0/fulltext)

<sup>162</sup> [Germany Reports Record COVID-19 Deaths, Concerns About New Variant Grow \(medscape.com\)](https://www.medscape.com/viewarticle/943630)

<sup>163</sup> [EU Reports Nearly 300,000 Excess Deaths in 8 Months of 2020 \(medscape.com\)](https://www.medscape.com/viewarticle/943630)

<sup>164</sup> <https://www.medscape.com/viewarticle/943630>

<sup>165</sup> [COVID-19 Variant First Found in Other Countries and States Now Seen More Frequently in California - Novel Coronavirus \(COVID-19\) - County of Santa Clara \(sccgov.org\)](https://www.sccgov.org/newsroom/press-releases/2020-03-11-covid-19-variant-first-found-in-other-countries-and-states-now-seen-more-frequently-in-california)

<sup>166</sup> [France's daily new COVID-19 infections at a more than six-week high | Reuters](https://www.reuters.com/article/health-covid-19/frances-daily-new-covid-19-infections-at-a-more-than-six-week-high-idCAKBN200001)

<sup>167</sup> <https://www.medscape.com/viewarticle/944162> and [Mitigation Policies and COVID-19–Associated Mortality — 37 European Countries, January 23–June 30, 2020 | MMWR \(cdc.gov\)](https://www.cdc.gov/mmwr/preview/mmwrhtml/6001a1.htm)

<sup>168</sup> <https://www.medscape.com/viewarticle/943957>

<sup>169</sup> [https://khn.org/news/article/black-americans-are-getting-vaccinated-at-lower-rates-than-white-americans/](https://www.khn.org/news/article/black-americans-are-getting-vaccinated-at-lower-rates-than-white-americans/)

<sup>170</sup> <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2775236> and <https://www.healthcarediver.com/news/study-links-hospital-icu-capacity-to-covid-19-mortality-rates/593533/>

- The US established the Multistate Assessment of SARS-CoV-2 Seroprevalence (MASS) study to analyse blood donations, and the data suggested that many more people had had Covid-19 than had been diagnosed.<sup>171</sup>
- Serological screening of archived samples of blood donations suggested SARS-CoV-2 may have been in the US before the first case was reported on 19 January 2020 in Washington State<sup>172</sup>.
- The US CDC announced that effective 26 January, all passengers flying into the US would need to show proof of a negative COVID-19 test within 3 days of boarding their flight<sup>173</sup>. However, a New Zealand study has found genomic evidence of in-flight transmission of the SARS-CoV-2 virus despite predeparture testing.<sup>174</sup>
- Data from 22 US states show a more than eightfold increase in the rate of hospitalisation of children with COVID-19 over the course of 6 months.<sup>175</sup>
- On 6 January the CDC said that over 52 cases of infection with a mutant Sars-CoV-2 virus, initially identified in the UK, had been found in the US. The CDC said these figures did not represent the total number of cases circulating in the US and substantially increased the number of positive samples it sequences.<sup>176</sup> A further variant had also been reported<sup>177</sup>.
- On 7 January when the daily death toll exceeded 4,000,<sup>178</sup> the CDC predicted up to 438,000 deaths by the end of January. By then almost 6 million people had received their first dose of vaccine, and a further 21.4 million doses had been distributed. This was far short of totals that had been promised by the end of December.<sup>179,180</sup> On 12 January, more than 4,400 people, nationally, died of COVID-19<sup>181</sup>.
- In the last few days of January, the number of daily cases in the US began to decline, as total recorded deaths from COVID-19 passed 420,000<sup>182</sup>. The US ordered a further 200 million doses of vaccine<sup>183</sup>. By 27 January, 24,652,634 doses of COVID-

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<sup>171</sup> [Multistate Assessment of SARS-CoV-2 Seroprevalence in Blood Donors | CDC](https://www.medscape.com/viewarticle/944035) and <https://www.medscape.com/viewarticle/944035>

<sup>172</sup> <https://transfusionnews.com/2020/12/22/serological-screening-of-blood-donations-suggests-sars-cov-2-may-have-been-introduced-in-the-us-before-january-2020/>

<sup>173</sup> [CDC Expands Negative COVID-19 Test Requirement to All Air Passengers Entering the United States | CDC Online Newsroom | CDC](https://www.cdc.gov/media/releases/2021/s0126-covid-19-test-requirement.html) and <https://www.medscape.com/viewarticle/944040>

<sup>174</sup> [https://wwwnc.cdc.gov/eid/article/27/3/20-4714\\_article](https://wwwnc.cdc.gov/eid/article/27/3/20-4714_article)

<sup>175</sup> <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2775008> and

<https://www.healio.com/news/primary-care/20210111/rate-of-pediatric-covid19-hospitalizations-has-increased>

<sup>176</sup> [New Covid variant: CDC has found more than 50 US cases of variant first identified in UK - CNN](https://www.cnn.com/2021/01/02/health/covid-19-variant-uk/index.html) and <https://www.usatoday.com/story/news/health/2021/01/02/new-covid-strain-b-117-explained/4112125001/> and <https://www.medpagetoday.com/infectiousdisease/covid19/90499> and <https://www.fiercebiotech.com/medtech/labcorp-to-help-cdc-track-covid-19-mutations-as-new-strain-spreads-u-s>

<sup>177</sup> <https://edition.cnn.com/2021/01/18/health/us-coronavirus-monday/index.html> and <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html>

<sup>178</sup> <https://edition.cnn.com/2021/01/08/health/us-coronavirus-friday/index.html>

<sup>179</sup> <https://edition.cnn.com/2021/01/07/health/us-coronavirus-thursday/index.html>

<sup>180</sup> <https://edition.cnn.com/2021/01/08/health/us-coronavirus-friday/index.html>

<sup>181</sup> [https://www.huffingtonpost.com/entry/coronavirus-record-deaths-united-states-again\\_n\\_5fff4d52c5b66f3f79639cd5](https://www.huffingtonpost.com/entry/coronavirus-record-deaths-united-states-again_n_5fff4d52c5b66f3f79639cd5)

<sup>182</sup> <https://www.reuters.com/article/us-health-coronavirus-usa-trends/u-s-new-covid-cases-down-21-in-past-week-deaths-fall-from-peak-idUSKBN29U2E5> and

<https://www.reuters.com/article/us-health-coronavirus-usa/hopeful-signs-on-pandemic-lead-some-u-s-states-to-ease-coronavirus-restrictions-idUSKBN29W2Q3>

<sup>183</sup> [US orders 200M additional COVID-19 vaccine doses amid 'wartime effort' to address shortages \(healio.com\)](https://www.healio.com/news/primary-care/20210122/us-orders-200-million-doses-of-covid-19-vaccine) and [Scramble for specialty syringes as Pfizer, feds look to extract 6th vaccine doses | FiercePharma](https://www.fiercepharma.com/news/scramble-for-specialty-syringes-as-pfizer-feds-look-to-extract-6th-covid-19-vaccine-doses) and <https://www.nytimes.com/2021/01/22/health/pfizer-vaccine.html>

19 vaccines had been administered in the US, with 47,230,950 doses distributed<sup>184</sup>. Occasional cases of anaphylaxis were reported after administration of both the Moderna and Pfizer vaccines<sup>185</sup>.

- The US FDA warned that the new strain of SARS-CoV-2 could trigger false negatives in “gold standard” tests.<sup>186</sup> Scientists also raised the possibility that antibody drugs and natural antibodies may not work as well against the mutant strain<sup>187</sup>. A study by Pfizer showed the Pfizer/ BioNTech vaccine was effective against the mutant strain.<sup>188</sup>
- In Japan, airport tests found a coronavirus variant in people arriving from Brazil that differs from the UK and South African mutant strains<sup>189</sup>.
- India began shipping COVID-19 vaccine to Bhutan, Bangladesh and Nepal<sup>190</sup>
- Reports claim that leaked documents show that China underreported COVID-19 numbers significantly at the beginning of the pandemic<sup>191</sup>.
- An independent international panel reported that China “could have applied public health measures more forcefully in January (2020) to curb the initial COVID-19 outbreak”. The panel also criticised the WHO for its tardiness in declaring an international emergency, which it did not do until 30 January 2020<sup>192</sup>.
- On 18 January, 109 new confirmed COVID-19 cases were reported in China, the sixth day the figure was over 100. China does not count asymptomatic cases as confirmed<sup>193</sup>.
- China in mid-January advised its people against travelling during the lunar New Year holiday, in the midst of new COVID-19 outbreaks<sup>194</sup> and parts of the country were in strict lockdown.<sup>195</sup>
- The Chinese Centre of Disease Control and Prevention published the results of a serological study of some 34,000 residents from Wuhan and other Chinese cities. The study was conducted one month after the epidemic was brought under control and found about 4.43 per cent of Wuhan participants had COVID-19 antibodies in their blood. With a population of 11.2 million people, international commentators suggest that Wuhan may have had around 500,000 people with COVID-19. This is 10 times the official count of 50,000 confirmed cases reported by the Wuhan Municipal Health Commission, which excluded asymptomatic cases.<sup>196</sup>

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<sup>184</sup> <https://www.reuters.com/article/health-coronavirus-usa-cdc/47-2-mln-doses-of-covid-19-vaccines-distributed-24-6-mln-administered-u-s-cdc-idUSL4N2K24CO>

<sup>185</sup> <https://www.reuters.com/article/health-coronavirus-vaccines-allergies/u-s-cdc-sees-lower-rates-of-allergic-reaction-after-pfizer-vaccine-idUSFWN2K217A>

<sup>186</sup> <https://www.fiercebiotech.com/medtech/fda-warns-new-coronavirus-variant-could-trigger-false-negatives-among-gold-standard-tests>

<sup>187</sup> <https://www.livescience.com/amp/south-african-coronavirus-variant-antibody-resistant.html>

<sup>188</sup> <https://www.cnbc.com/2021/01/08/pfizer-biontech-vaccine-appears-effective-against-mutation-in-new-strains.html> and <https://www.healio.com/news/infectious-disease/20210108/pfizer-vaccine-appears-effective-against-emerging-sarscov2-variants>

<sup>189</sup> [Japanese Health Ministry Finds New COVID-19 Variant | Time](https://www.nytimes.com/2021/01/08/health/coronavirus-variant-japan.html)

<sup>190</sup> <https://www.medscape.com/viewarticle/944396>

<sup>191</sup> <https://www.independent.co.uk/world/covid19-china-mishandle-pandemic-leaked-documents-b1764276.html> and <https://edition.cnn.com/2020/11/30/asia/wuhan-china-covid-intl/index.html>

<sup>192</sup> [Independent pandemic review panel critical of China, WHO delays | Reuters](https://www.reuters.com/article/whodocuments/whodocuments-independent-pandemic-review-panel-critical-of-china-who-delays-idUSKCN2000001)

<sup>193</sup> [China reports 109 new COVID-19 cases as Government claims virus is found in ice cream - ABC News](https://www.abcnews.com/news/2020/01/18/china-reports-109-new-covid-19-cases-as-government-claims-virus-is-found-in-ice-cream/)

<sup>194</sup> [China warns citizens not to go home for Lunar New Year amid new COVID-19 outbreaks - ABC News](https://www.abcnews.com/news/2020/01/18/china-warns-citizens-not-to-go-home-for-lunar-new-year-amid-new-covid-19-outbreaks/)

<sup>195</sup> [Coronavirus China: Millions sent into lockdown over virus surge \(news.com.au\) and https://www.medscape.com/viewarticle/943713](https://www.news.com.au/health/coronavirus-china-millions-sent-into-lockdown-over-virus-surge/news-story/943713)

<sup>196</sup> [Coronavirus cases in Wuhan may be far higher than thought, according to China CDC study - ABC News](https://www.abcnews.com/news/2020/01/18/coronavirus-cases-in-wuhan-may-be-far-higher-than-thought-according-to-china-cdc-study/)

- China's vaccination rollout (fifty million doses by mid-February) is reported not to include children, those with chronic diseases or the elderly as yet, as the vaccines have been tested only in healthy people.<sup>197</sup>
- China said on 7 January that it was still negotiating about the details of a visit by a World Health Organization team of experts investigating the origins of COVID-19.<sup>198</sup>
- A study of healthcare workers by Public Health England found that people who have been infected with the virus will be immune to it for at least five months; however, even those with antibodies may still be able to carry and transmit the virus to others<sup>199</sup>.
- UK health officials on 6 January said SARS-CoV-2 had recently infected 1 in 50 of the population<sup>200</sup>.
- There is evidence to suggest that the UK variant strain of the virus has increased the average number of people an infected person infects by between 0.4 and 0.7.<sup>201</sup>
- The South African National Institute of Communicable Diseases began testing the Oxford/AstraZeneca, Pfizer/BioNTech, Johnson & Johnson and Novavax<sup>202</sup> vaccines against the variant strain of the virus, 501Y.V2.<sup>203</sup>
- Israel based Scentech-Medical announced a test developed for the analysis and quantification of volatile compounds in breath can detect coronavirus infection in active, symptomatic, and asymptomatic carriers.<sup>204</sup>

## Transmission

- During January the total number of coronavirus infections recorded, globally, passed 100 million.<sup>205</sup>
- As the EU announced it had secured nearly half of Pfizer's 2021 global output of COVID-19 vaccine<sup>206</sup>, the WHO said rich countries should stop jumping the vaccine queue<sup>207</sup>.
- The UK offered its genomic experience globally to assist in identifying new variant strains<sup>208</sup>.
- Brazilian researchers were tracking cases of reinfection with the country's new variant strain<sup>209</sup>.

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<sup>197</sup> [China's coronavirus rollout plan revealed as authorities aim to vaccinate 50 million before Lunar New Year - ABC News](#)

<sup>198</sup> <https://www.cbs19.tv/article/news/health/coronavirus/plans-of-who-expert-visit-to-china-under-negotiation/507-d4c92f14-39af-4831-acda-dd564a381901> and <https://www.medscape.com/viewarticle/943554> and <https://www.abc.net.au/news/2021-01-06/world-health-organization-disappointed-covid-team-not-in-china/13035208>

<sup>199</sup> <https://au.news.yahoo.com/coronavirus-new-immunity-research-may-explain-covid-surge-230427824.html>

<sup>200</sup> [Virus Has Recently Infected 1 in 50 in England - The New York Times \(nytimes.com\)](#)

<sup>201</sup> [How much more contagious is the new strain of COVID B117 detected in the UK? - ABC News](#) and [Australian authorities say we need to assume the UK COVID-19 variant will become the dominant strain. This is where the virus has spread so far - ABC News](#)

<sup>202</sup> <https://www.medscape.com/viewarticle/943832>

<sup>203</sup> [S.Africa testing vaccines on variant, hopes for results within 2 weeks \(yahoo.com\)](#)

<sup>204</sup> <https://www.precisionvaccinations.com/rapid-breath-test-detecting-covid-19-infection-launches-clinical-trial>

<sup>205</sup> <https://www.reuters.com/article/us-health-coronavirus-global-cases/global-covid-19-cases-surpass-100-million-as-nations-tackle-vaccine-shortages-idUSKBN29W0B5>

<sup>206</sup> <https://www.medscape.com/viewarticle/943815>

<sup>207</sup> <https://www.medscape.com/viewarticle/943833>

<sup>208</sup> [http://www.pharmatimes.com/news/uk\\_will\\_offer\\_its\\_genomic\\_expertise\\_worldwide\\_to\\_identify\\_new\\_covid-19\\_variants\\_1362154](http://www.pharmatimes.com/news/uk_will_offer_its_genomic_expertise_worldwide_to_identify_new_covid-19_variants_1362154)

<sup>209</sup> <https://www.medscape.com/viewarticle/944748>

- WHO said the rapid spread of the UK variant through Europe was cause for alarm.<sup>210</sup>
- A nasal spray under development delivers nitric oxide to the nasal passages designed to destroy the SARS-CoV-2 virus at entry.<sup>211</sup>
- Researchers found<sup>212</sup> that over half of COVID-19 transmission may occur through asymptomatic people.

## Testing

- With more than one-third of COVID-19 infections asymptomatic, there are suggestions that more emphasis should be placed on frequent at-home screening with rapid antigen tests.<sup>213</sup>
- Researchers say that a new olfactory dysfunction test may be useful in diagnosing mild COVID-19.<sup>214</sup>

## 9. Miscellaneous news

### Diseases other than COVID-19

- From 1 to 22 January, 18 new cases of Ross River virus were recorded in Australia's southern Riverina<sup>215</sup>.
- A sentinel chicken in Meningie has tested positive to both Murray Valley Encephalitis virus and Kunjin virus during routine monitoring.<sup>216</sup>
- Health authorities in Queensland have issued a warning after three bats tested positive to Australian lyssavirus.<sup>217</sup>
- In 2020, 5784 syphilis cases were reported in Japan, with 26.8 per cent reported in Tokyo and 15.4 per cent in Osaka. This was the fourth year in a row that Japan's National Institute of Infectious Diseases has reported more than 5,000 syphilis cases.<sup>218</sup>
- Researchers demonstrated that infusions of antibodies can prevent infection with HIV<sup>219</sup>.
- A study in Sierra Leone suggests that the Ebola virus can lie in hiding from the immune system before re-emerging later and sparking a new response—although the study did not determine if people were infectious again.<sup>220</sup>

<sup>210</sup> <https://www.theguardian.com/world/2021/jan/07/europe-tipping-point-covid-running-rampant-who-new-variant> and [Germany Reports Record COVID-19 Deaths, Concerns About New Variant Grow \(medscape.com\)](https://www.medscape.com/viewarticle/943762)

<sup>211</sup> <https://www.fiercepharma.com/drug-delivery/covid-19-nasal-spray-starts-clinical-development-u-k>

<sup>212</sup> [SARS-CoV-2 Transmission From People Without COVID-19 Symptoms | Infectious Diseases | JAMA Network Open | JAMA Network](https://www.jama.com/doi/10.1001/jama.2021.01.07) and <https://www.medscape.com/viewarticle/943762> and [https://www.upi.com/Health\\_News/2021/01/07/Study-Symptom-free-infected-people-cause-at-least-half-of-COVID-19-spread/1781610029957/](https://www.upi.com/Health_News/2021/01/07/Study-Symptom-free-infected-people-cause-at-least-half-of-COVID-19-spread/1781610029957/)

<sup>213</sup> <https://www.medscape.com/viewarticle/944662> and [The Proportion of SARS-CoV-2 Infections That Are Asymptomatic: A Systematic Review: Annals of Internal Medicine: Vol 0, No 0 \(acpjournals.org\)](https://www.annals.org/doi/10.1093/annals/abaa000)

<sup>214</sup> <https://www.medscape.com/viewarticle/944244>

<sup>215</sup> <https://www.abc.net.au/news/2021-01-25/ross-river-virus-alert-for-southern-riverina/13088000>

<sup>216</sup> [SA Health mosquito alert | The Advertiser \(adelaidenow.com.au\)](https://www.adelaidenow.com.au/news/south-australia/health/sa-health-mosquito-alert-the-advertiser/news-story/13088000)

<sup>217</sup> [Bat warning issued after officials detect three cases of lyssavirus in Queensland in one month - ABC News](https://www.abc.net.au/news/2021-01-25/bat-warning-issued-after-officials-detect-three-cases-of-lyssavirus-in-queensland-in-one-month-13088000)

<sup>218</sup> [http://outbreaknewstoday.com/japan-ends-the-year-with-5700-syphilis-cases-81828/>](https://www.outbreaknewstoday.com/japan-ends-the-year-with-5700-syphilis-cases-81828/>)

<sup>219</sup> <https://www.healio.com/news/infectious-disease/20210126/in-first-researchers-say-infusions-of-antibodies-can-prevent-hiv-infection>

<sup>220</sup> <https://www.the-scientist.com/news-opinion/antibody-spike-months-after-ebola-infection-surprisingly-common-68391>

- The WHO, UNICEF and others announced the establishment of a global Ebola vaccine stockpile to ensure rapid response when required.<sup>221</sup>
- The European Commission approved Roche's antiviral Xofluza for the treatment of influenza.<sup>222</sup>
- Cocrystal Pharma said "it has completed all research obligations under the Merck exclusive worldwide license and collaboration agreement, and that Merck is now solely responsible for further development of the influenza A/B antiviral compounds that were discovered using Cocrystal's unique structure-based technologies"<sup>223</sup>.
- Researchers reported that "prolonged viremia in Zika-infected mothers is associated with a sevenfold higher risk of neonatal or foetal adverse outcomes compared with pregnancies without prolonged viremia."<sup>224</sup>
- Moderna announced new development programs in three infectious disease vaccines: HIV, Nipah virus and seasonal flu.<sup>225</sup>
- BioNTech's CEO, Ugur Sahin, has led research suggesting that an mRNA vaccine might work in multiple sclerosis.<sup>226</sup>

## Other

- Researchers claim their TALEN gene editing tool has advantages over CRISPR-Cas9.<sup>227</sup>
- Dr Janet Woodcock, previously head of the Center for Drug Evaluation and Research, has been named as interim US FDA Commissioner.<sup>228</sup>
- Merck has purchased Hamburg-based mRNA manufacturer AmpTec to increase its potential to produce vaccines, treatments and diagnostics using that platform.<sup>229</sup>
- Bluebird Bio will spin off its cancer drug business into an independent, publicly traded company,<sup>230</sup> which will include a multiple myeloma treatment under regulatory review and drugs for lymphoma and solid tumours. Bluebird will retain its name and drug development for rare blood and brain diseases, including the beta thalassemia treatment Zynteglo.<sup>231</sup>
- Vir Biotechnology announced that the first patient was dosed in late December 2020 in a phase 1 clinical trial of VIR-1111, an investigational HIV T cell vaccine. It is a

<sup>221</sup> [UN agencies and partners establish global Ebola vaccine stockpile | UN News](#)

<sup>222</sup> <https://pipelinereview.com/index.php/2021011177127/Small-Molecules/Roches-Xofluza-approved-by-the-European-Commission-for-the-treatment-of-influenza-the-first-new-influenza-antiviral-for-patients-in-almost-20-years.html>

<sup>223</sup> <https://pipelinereview.com/index.php/2021012077206/Small-Molecules/Cocrystal-Pharma-Announces-Further-Development-of-Influenza-A/B-Antiviral-Compounds-by-Merck-under-Exclusive-Worldwide-License-and-Collaboration-Agreement.html>

<sup>224</sup> <https://www.healio.com/news/infectious-disease/20210114/prolonged-zika-viremia-in-mothers-a-significant-risk-factor-for-birth-defects> and [Driggers RW, et al. \*N Engl J Med.\* 2016;doi:10.1056/NEJMoa1601824.](#)

<sup>225</sup> [Moderna Provides Business Update and Announces Three New Development Programs in Infectious Disease Vaccines | Moderna, Inc. \(modernatx.com\)](#) and <https://qz.com/1955411/moderna-is-working-on-an-hiv-vaccine-after-its-covid-19-success/>

<sup>226</sup> [A noninflammatory mRNA vaccine for treatment of experimental autoimmune encephalomyelitis | Science \(sciencemag.org\)](#) and <https://www.fiercebiotech.com/research/biontech-ceo-turns-covid-19-vaccine-s-mrna-tech-against-multiple-sclerosis>

<sup>227</sup> <https://www.fiercebiotech.com/research/talen-gene-editing-tool-more-efficient-than-crispr-cas9-certain-dna-study>

<sup>228</sup> <https://www.medicaldesignandoutsourcing.com/reports-cder-head-woodcock-to-lead-fda-for-now/>

<sup>229</sup> <https://www.fiercepharma.com/manufacturing/merck-kqaa-snaps-up-mrna-manufacturer-amptec-as-pandemic-vaccines-unlock-platform-s>

<sup>230</sup> [bluebird bio to Separate Oncology Business into Independent Company - bluebird bio, Inc.](#)

<sup>231</sup> <https://www.biopharmadive.com/news/bluebird-bio-split-company-cancer-drug-spin/593152>

proof-of-concept vaccine designed to test whether its novel vaccine platform yields protective immune responses, and to identify their characteristics.<sup>232</sup>

- A meta-analysis showed that “having a single copy of a genetic variant for sickle cell disease (sickle cell trait) was not associated with coronary heart disease (CHD) in African Americans.”<sup>233</sup>

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<sup>232</sup> [VIR-1111: A Prototype Human CMV-based Vaccine for Human Immunodeficiency Virus \(HIV\) in Healthy Volunteers - Full Text View - ClinicalTrials.gov](#)

<sup>233</sup> [Association of Sickle Cell Trait With Incidence of Coronary Heart Disease Among African American Individuals | Acute Coronary Syndromes | JAMA Network Open | JAMA Network](#) and <https://www.medpagetoday.com/hematologyoncology/hematology/90527>