

Monitoring International Trends

November 2020

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 emphasis within the health sector worldwide has continued to be on the COVID-19 pandemic. Of note, this month's edition provides updates on trials of manufactured antibodies to treat COVID-19 (pages 6-9); the use of convalescent plasma to treat COVID-19 (pages 9); and updates on regulatory submissions for COVID-19 vaccine and supply plans (pages 13-18).

Among items of interest in this month's edition which are unrelated to the COVID-19 pandemic are that: UniQure's gene therapy for haemophilia B showed in a late-stage trial that it could eliminate bleeding events over the six months following infusion with the therapy (page 4); French scientists have discovered possible hepatitis E virus transmission in solvent/detergent-treated plasma (page 5); the US Food and Drug Administration have rejected BioMarin's haemophilia gene therapy, Roctavian, requesting two-year follow-up data from the Phase 3 trial of the product (page 4); and clinicians in Victoria are calling for a deprescribing of antiplatelets in patients taking direct oral anticoagulants after a study found a five-fold higher risk of major bleeding events in patients taking both classes of agent concurrently (page 5).

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1. Treating blood disorders

The ASH annual meeting

- The American Society of Hematology (ASH) 2020 Annual Meeting will be virtual, held from 5 to 8 December. All abstracts can be accessed via the [official ASH website](#).
- Swedish Orphan Biovitrum AB (Sobi) will be amongst companies contributing to this 62nd Annual Meeting:
 - a. In collaboration with Sanofi, final data emphasising the efficacy and safety of Elocta® (efmoroctocog alfa) and Alprolix® (eftrenonacog alfa) in previously untreated patients (PUPs) with haemophilia A and B respectively will be presented.¹
 - b. An overview of the ongoing BIVV001 Phase III study design (the XTEND-1 study) will be provided.²
 - c. Efficacy and safety data for Doptelet® (avatrombopag) in treatment for Chronic Immune Thrombocytopenia (ITP) will be presented.³
 - d. Data will be reported on emapaulumab in patients with primary haemophagocytic lymphohistiocytosis.⁴
- Sobi's collaborating partner Apellis will be reporting to the ASH meeting data supporting the efficacy and safety of pegcetacoplan for the treatment of paroxysmal nocturnal haemoglobinuria (PNH).⁵ Apellis has already announced US Food and Drug Administration (FDA) acceptance and priority review of its new drug application for pegcetacoplan for the treatment of PNH.⁶

¹ #509 Final results of the PUPs A-LONG Study: Evaluating Safety and Efficacy of rFVIII Fc in Previously Untreated Patients with Haemophilia A (oral presentation). #867 Final Results of PUPs B-LONG Study: Evaluating Safety and Efficacy of rFIX Fc in Previously Untreated Patients with Haemophilia B (poster abstract presentation).

² BIVV001 is an investigational once-weekly factor therapy for people with haemophilia A and represents a new class of FVIII therapy that has the potential to provide high sustained factor activity levels. BIVV001 is being developed in collaboration with Sanofi. #856 Evaluating BIVV001, a New Class of Factor VIII Replacement Therapy: A Phase 3 Study (XTEND-1) Design (poster abstract presentation).

³ #848 Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling Providing Guidance for Selecting Avatrombopag (AVA) Dose When Switching from Eltrombopag in Chronic Immune Thrombocytopenia (ITP); #835 Consistent Efficacy Demonstrated by Avatrombopag in Immune Thrombocytopenia (ITP) Regardless of the Number of Lines of Prior ITP Treatment; #844 Characterization of Thromboembolic Events Occurring During the Avatrombopag Immune Thrombocytopenia (ITP) Clinical Development Program; #2660 A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Avatrombopag for the Treatment of Chemotherapy-Induced Thrombocytopenia in Patients with Solid Tumors; #2675 Durability of Initial Platelet Count Response in Patients Treated with Avatrombopag for Immune Thrombocytopenia (ITP): Post-hoc Results from a Phase 3 Clinical Study; and #2677 Efficacy Analyses from the Immune Thrombocytopenia (ITP) Clinical Development Program for Avatrombopag: Comparisons with Placebo and Eltrombopag (all as poster abstract presentations).

⁴ #3266 Sensitivity Analysis of Overall Response Rate (ORR) with Emapalumab in Children with Primary Hemophagocytic Lymphohistiocytosis (HLH); #3273 Population Pharmacokinetic Analysis of Emapalumab, a Fully Human, Anti-Interferon Gamma Monoclonal Antibody, in Children with Primary Hemophagocytic Lymphohistiocytosis; and #3278 Safety of Emapalumab in Children with Primary Hemophagocytic Lymphohistiocytosis: Results of the Primary Analysis of the Pivotal Phase 2/3 Study.

⁵ <https://investors.apellis.com/news-releases/news-release-details/apellis-present-new-data-supporting-efficacy-and-safety>

⁶ <https://pipelinereview.com/index.php/2020/11/776571/Proteins-and-Peptides/Apellis-Announces-FDA-Acceptance-and-Priority-Review-of-the-New-Drug-Application-for-Pegcetacoplan-for-the-Treatment-of-PNH.html>

- Sobi has already announced that the European Commission has approved an update to the Alprolix® (eftrenonacog alfa) Summary of Product Characteristics (SmPC) to include additional information regarding use among PUPs with haemophilia B. The data reinforces its favourable safety profile for use in all age groups.⁷
- Sobi has also announced the commercial launch of Doptelet® in Europe, with the UK as the first country for launch. Doptelet is a thrombopoietin receptor agonist approved for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.⁸

Other haemophilia news

- UniQure's gene therapy for haemophilia B showed in a late-stage trial that it could eliminate bleeding events over six months.⁹
- BioMarin's haemophilia gene therapy was rejected by the US FDA in August.¹⁰ According to the company, the FDA wants to see at least two years of follow-up from the Phase III trial of Roctavian.¹¹
- Bluebird bio is expecting a year's delay in its quest for approval from the US FDA for its LentiGlobin gene therapy for sickle cell disease. The FDA has raised concerns about manufacturing of the therapy.¹²
- Sanofi paused its trial of fitusiran its Alnylam-partnered RNA-silencing haemophilia treatment after new side effects were identified.¹³

Sickle cell and thalassemia news

- The FDA has awarded orphan drug status to Agios Pharmaceuticals' mitapivat, a pyruvate kinase R activator, for sickle cell disease. Agios expects to initiate a Phase III study in 2021.¹⁴
- The Bill and Melinda Gates Foundation is sponsoring a new sickle cell CRISPR approach by Intellia Therapeutics.¹⁵
- The US FDA awarded orphan drug designation to Bausch Health Companies Pharmaceuticals' rifaximin for the treatment of sickle cell disease.¹⁶
- The European Commission has approved Novartis' Adakveo (crizanlizumab) as a preventive treatment for recurrent vaso-occlusive crises in patients aged 16 or more who have sickle cell disease. This approval encompasses use of the drug along with hydroxyurea and as a stand-alone therapy where hydroxyurea treatment is

⁷ <https://www.sobi.com/en/press-releases/favourable-paediatric-data-results-alprolix-r-product-information-update-1860435>

⁸ www.sobi.com.

⁹ <https://www.biopharmadive.com/news/uniqure-hemophilia-b-gene-therapy-hope-trial/589336/>

¹⁰ [In major surprise, FDA rejects high-profile therapies from BioMarin, Gilead](#)

¹¹ <https://www.biopharmadive.com/news/biomarin-fda-roctavian-vosorotide/588549/>

¹² <https://www.biopharmadive.com/news/bluebird-sickle-cell-gene-therapy-manufacturing-delay/588479/> and

¹³ <https://www.hemophilia.org/Newsroom/Industry-News/Global-Dosing-Hold-in-Fitusiran-Trials-Initiated-by-Sanofi-Genzyme-to-Investigate-New-Adverse-Events> and

<https://www.fiercebiotech.com/biotech/sanofi-alnylam-s-hemophilia-med-fitusiran-hold-again>

¹⁴ [Agios Announces FDA Orphan Drug Designation Granted to Mitapivat for Treatment of Sickle Cell Disease | Seeking Alpha](#)

¹⁵ <https://endpts.com/gates-foundation-backs-a-new-sickle-cell-crispr-approach-siddhartha-mukherjees-vor-adds-a-new-car-t/>

¹⁶ <https://seekingalpha.com/pr/18065229-bausch-healths-rifaximin-receives-fda-orphan-designation-for-sickle-cell-disease>

inappropriate. An open-label Phase II trial (NCT03474965) is investigating the best dose of Adakveo for paediatric patients.¹⁷

Other product news

- Alexion Pharmaceuticals announced that the European Commission had approved the new 100 mg/mL intravenous formulation of ULTOMIRIS® (ravulizumab) for the treatment of PNH and atypical haemolytic uremic syndrome.¹⁸
- Pharvaris announced the presentation of two posters at the virtual American College of Asthma, Allergy and Immunology (ACAAI) Annual Scientific Meeting. The data in both posters present the pharmacokinetic, pharmacodynamic, and safety profiles of PHA121 in healthy volunteers. Pharvaris expects to advance PHVS416 (PHA121 in soft capsules) to provide a rapid and convenient on-demand hereditary angioedema treatment using a small oral dosage form.¹⁹

2. Safety and Patient blood management

- French scientists discovered possible hepatitis E virus transmission in plasma treated with solvent/detergent.²⁰
- French researchers investigating whether asymptomatic or pre-symptomatic blood donors positive for SARS-CoV-2 are infectious found no evidence of SARS-CoV-2 transfusion transmission or viral infectivity, but concluded: “further research and haemovigilance is needed in order to determine the SARS-CoV-2 RNA levels needed for viral transmission of this respiratory virus in blood”.²¹
- In Australia, an urgent call for blood was met with increased donations, beating earlier records after the Bali bombings and during bushfires. Lifeblood nevertheless took the opportunity to push for more consistent donors.²²
- LGBTIQ equality advocates want Australia’s governments to abolish the celibacy requirement for gay, bisexual and transgender people who want to give blood. Advocacy group, just.equal, has written to all Australia’s health ministers asking how they responded to the proposal made by the Therapeutic Goods Administration (TGA) in April to reduce the gay, bi and trans celibacy period from twelve months to three.²³
- A Victorian study has led to a call for “deprescribing of antiplatelets in patients taking DOACs (direct oral anticoagulants) after (it) found a five-fold higher risk of major bleeding events in patients taking both classes of agent concurrently”.²⁴

¹⁷ <https://sicklecellanemianews.com/2020/11/03/eu-approves-adakveo-to-treat-pain-crises-in-scd-patients-16-and-older/>

¹⁸ <https://pipelinereview.com/index.php/2020112076611/Antibodies/Alexion-Receives-Marketing-Authorization-from-European-Commission-for-New-Formulation-of-ULTOMIRIS-ravulizumab-with-Significantly-Reduced-Infusion-Time.html>

¹⁹ <https://pipelinereview.com/index.php/2020111376537/Small-Molecules/Pharvaris-Presents-Clinical-Data-at-ACAAI-2020-Demonstrating-Safety-and-Therapeutic-Potential-of-Oral-PHA121-for-the-Treatment-of-HAE.html>

²⁰ <https://transfusionnews.com/2020/11/11/transfusion-transmission-of-hepatitis-e-from-solvent-detergent-treated-plasma>

²¹ <https://transfusionnews.com/2020/10/21/no-evidence-of-sars-cov-2-transfusion-transmission-or-viral-infectivity/>

²² [Australians donate blood in record numbers to meet shortfall - ABC News](#)

²³ [Has completely removing the celibacy period for blood donations been considered](#)

²⁴ <https://thelimbic.com/haematology/bleeding-risk-highlights-need-to-deprescribe-antiplatelets-in-patients-taking-doacs/>

- The RIVER trial demonstrated that Rivaroxaban (Xarelto) appeared equivalent to warfarin for prevention of major cardiovascular events in atrial fibrillation with a bioprosthetic mitral valve.²⁵
- An analysis of stroke admissions at the Canberra Hospital between 2016 and 2018 found 63 per cent of patients with known atrial fibrillation were appropriately dosed with anticoagulants, a substantial improvement on the results from a study a decade earlier.²⁶
- The US FDA has received a supplemental New Drug Application for rivaroxaban (Xarelto®; Janssen) to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease.²⁷
- A UK researcher says that aspirin may increase the chance of survival of COVID-19 patients by preventing blood clots.²⁸
- An Australian-led randomised controlled trial has shown that tranexamic acid does not prevent intracerebral haemorrhage growth in patients with acute intracerebral haemorrhage.²⁹

3. Antibodies, T cells and COVID- 19

- Twist Biosciences' nanobodies (single domain antibodies) were reported to show promise in hamsters for treatment of COVID-19.³⁰
- Adagio Therapeutics pre-published *in vitro* and *in vivo* data demonstrating its lead COVID-19 antibody candidate, ADG2, shows potency against a range of coronaviruses that threaten human health.³¹
- AstraZeneca has initiated a 5,000 participant Phase III trial of its long-acting antibody combination, AZD7442, to see if it will prevent COVID-19 for up to a year. The treatment is designed for immunosuppressed patients.³²

²⁵ <https://www.medpagetoday.com/meetingcoverage/aha/89678>

²⁶ <https://thelimbic.com/haematology/doacs-improve-appropriate-use-of-anticoagulants-in-af/>

²⁷ <https://www.empr.com/home/news/drugs-in-the-pipeline/rivaroxaban-xarelto-reduce-major-vascular-events-peripheral-artery-disease-pad/>

Xarelto is already indicated:

- to decrease the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
- to reduce, in combination with aspirin, the risk of major CV events (CV death, myocardial infarction, and stroke) in patients with chronic coronary artery disease or peripheral artery disease
- to treat deep vein thrombosis (DVT) and pulmonary embolism (PE)
- to reduce the risk of recurrent DVT/PE
- to prevent DVT, which may lead to PE, in patients who have surgery to replace a knee or hip
- to prevent venous thromboembolism (VTE) and VTE-related death during hospitalisation and subsequent discharge in adult patients with an acute medical illness who are at risk for thromboembolic complications due to lack of mobility and other risk factors for VTE and who are not at high risk of bleeding

²⁸ <https://www.medscape.com/viewarticle/940492>

²⁹ <https://thelimbic.com/haematology/tranexamic-acid-does-not-prevent-intracerebral-haemorrhage-growth/>

³⁰ <https://www.fiercebiotech.com/research/twist-bioscience-s-covid-19-nanobodies-inspired-by-llamas-show-promise-hamsters>

³¹ <https://pipelinereview.com/index.php/2020111976600/Antibodies/Adagio-Therapeutics-COVID-19-Antibody-Demonstrates-Best-in-Class-Breadth-and-Potency-Against-a-Range-of-Coronaviruses-that-Pose-Human-Threat.html> and [An Engineered Antibody with Broad Protective Efficacy in Murine Models of SARS and COVID-19 | bioRxiv](https://www.fiercebiotech.com/research/adagio-s-covid-antibody-protects-mice-and-zaps-related-viruses-lab-tests) (not yet peer-reviewed) and

<https://www.fiercebiotech.com/research/adagio-s-covid-antibody-protects-mice-and-zaps-related-viruses-lab-tests>

³² <https://www.medscape.com/viewarticle/941403>

- AstraZeneca has arranged for Lonza to produce its experimental COVID treatment AZD7442, a combination of two long-acting antibodies.³³ AstraZeneca is targeting severely ill patients with its antibody therapy, although both Regeneron and Eli Lilly have not demonstrated their products succeed in that population.³⁴
- The US FDA granted emergency use authorisation for casirivimab and imdevimab for the treatment of mild to moderate COVID-19 to lower the risk of its progressing to severe disease. The monoclonal antibodies are to be administered together intravenously.³⁵
- A small study has found that breast milk from women who have recovered from COVID-19 may contain antibodies which could pass immunity to the SARS-CoV-2 virus to their infants.³⁶
- A report from Italy says a baby, whose mother tested positive for COVID-19 after delivery, did not contract the coronavirus when breast fed.³⁷
- A US study, not yet peer reviewed, reported that for 149 participants who had been infected with COVID-19 all had antibodies to the virus one month after infection. Six months after infection “those antibodies were more potent and better at fighting mutated versions of the virus”.³⁸
- A large UK study has supported the view that coronavirus antibodies developed by COVID-19 patients wane over several months.³⁹
- The US FDA has approved the first COVID-19 test that detects the specific antibodies that prevent the coronavirus from entering human cells.⁴⁰
- Siemens has developed an antibody test which it says can quantify COVID-19 immunity and thus measure the level of immunity a vaccine can provide, and if/ how it falls away over time.⁴¹
- A study has linked recent infections with common cold coronaviruses to less severe cases of COVID-19.⁴²
- The US government will pay Eli Lilly \$US 375 million to buy 300,000 vials of the company's experimental coronavirus drug, bamlanivimab. This is a monoclonal antibody with high affinity for the spike protein of SARS-CoV-2, which blocks viral attachment and entry into human cells. Lilly requested and received⁴³ an emergency clearance from the US FDA for use of the drug, after early study results⁴⁴ showed treatment helped lower virus levels in people with mild or moderate COVID-19, and

³³ <https://www.lonza.com/news/2020-10-30-06-00> and <https://www.fiercepharma.com/manufacturing/astrazeneca-taps-lonza-to-churn-out-drug-substance-for-covid-19-antibody>

³⁴ <https://www.fiercebiotech.com/biotech/astrazeneca-targets-severe-covid-19-patients-for-antibody-therapy-despite-regeneron-lilly>

³⁵ <https://www.healio.com/news/primary-care/2020/11/23/fda-authorizes-emergency-use-of-casirivimab-imdevimab-for-covid19>

³⁶ <https://www.the-scientist.com/news-opinion/breastmilk-harbors-antibodies-to-sars-cov-2-68162>

³⁷ <https://www.medscape.com/viewarticle/941121>

³⁸ <https://consumer.healthday.com/11-17-coronavirus-immunity-might-last-at-least-6-months-2648877437.html>

³⁹ <https://newatlas.com/health-wellbeing/covid19-coronavirus-antibody-uk-study-months-immunity/>

⁴⁰ <https://www.fiercebiotech.com/medtech/fda-greenlights-first-diagnostic-test-for-covid-19-antibodies-block-virus-from-entering>

⁴¹ <https://www.fiercebiotech.com/medtech/siemens-healthineers-to-offer-antibody-test-for-quantifying-covid-19-immunity>

⁴² <https://www.the-scientist.com/news-opinion/common-cold-coronaviruses-tied-to-less-severe-covid-19-cases-68146> and [JCI - Recent endemic coronavirus infection is associated with less severe COVID-19](https://www.jci.org/articles/137/11/1700)

⁴³ <https://transfusionnews.com/2020/11/17/fda-issues-emergency-use-authorization-for-sars-cov-2-monoclonal-antibody-therapy> and <https://www.medpagetoday.com/infectiousdisease/covid19/89581> and [Statement on Bamlanivimab EUA | COVID-19 Treatment Guidelines \(nih.gov\)](https://www.cdc.gov/media/releases/2020/s1117-covid-19-treatment-guidelines.html)

⁴⁴ <https://www.biopharmadive.com/news/lilly-coronavirus-antibody-drug-data/585312/>

suggested the drug may reduce the risk of hospitalisation. Then researchers leading a government-run study of bamlanivimab in patients already hospitalised with COVID-19 determined treatment was unlikely to help and recommended discontinuing study of the drug in that setting.⁴⁵

- Now that Eli Lilly has a US FDA emergency use authorisation for its COVID-19 antibody, the company is bringing in Samsung to help with the scale-up to meet expected global demand.⁴⁶
- Regeneron Pharmaceuticals said its coronavirus antibody cocktail reduced medical visits in a study of around 800 patients with mild-to-moderate COVID-19.⁴⁷ In a Phase III antibody trial, Regeneron discontinued testing the drug on patients needing high-flow oxygen or mechanical ventilation after an independent data monitoring committee raised safety concerns.⁴⁸ Regeneron expects to have 300,000 doses of its COVID-19 antibody cocktail ready by January.⁴⁹
- Sorrento Therapeutics is filing an investigational new drug (IND) application in the US for intravenous COVI-AMG (STI-2020) to treat COVID-19 patients with mild symptoms and to evaluate safety and pharmacokinetics in healthy volunteers. Sorrento earlier submitted an IND for COVI-GUARD™ (STI-1499), the parent antibody for COVI-AMG.⁵⁰
- The UK BioIndustry Association (BIA) Antibody Taskforce has identified differentiated antibody combinations to take further into development as an antibody cocktail to help fight COVID-19.⁵¹
- HiFiBiO Therapeutics announced the successful completion of the first cohort of the Phase I study⁵² of HFB30132A, a SARS-CoV-2 neutralizing antibody designed to treat and prevent COVID-19.⁵³
- A group of researchers say that a T cell test may be more effective than an antibody test in detecting past infections.⁵⁴

⁴⁵ <https://www.biopharmadive.com/news/lilly-coronavirus-antibody-warp-speed-supply-deal/587924/>

⁴⁶ <https://www.fiercepharma.com/pharma/amid-concerns-over-tight-supply-lilly-partners-samsung-to-boost-covid-19-antibody>

⁴⁷ <https://www.reuters.com/article/us-health-coronavirus-regeneron/regeneron-says-its-covid-19-antibody-treatment-cut-medical-visits-in-trial-idUSKBN27D36D> and <https://www.medpagetoday.com/infectiousdisease/covid19/89386> and <https://pipelinereview.com/index.php/2020102976344/Antibodies/Regenerons-COVID-19-Outpatient-Trial-Prospectively-Demonstrates-that-REGN-COV2-Antibody-Cocktail-Significantly-Reduced-Virus-Levels-and-Need-for-Further-Medical-Attention.html>

⁴⁸ <https://www.fiercebiotech.com/biotech/regeneron-hit-by-safety-signal-for-covid-cocktail-as-data-board-tells-pharma-to-stop> and <https://pipelinereview.com/index.php/2020103076355/Antibodies/REGN-COV2-Independent-Data-Monitoring-Committee-Recommend-Holding-Enrollment-in-Hospitalized-Patients-with-High-Oxygen-Requirements-and-Continuing-Enrollment-in-Patients-with.html> and <https://thehill.com/policy/healthcare/523600-regeneron-halts-trial-of-covid-19-antibody-drug-in-sickest-hospitalized>

⁴⁹ <https://www.fiercepharma.com/manufacturing/regeneron-predicts-300-000-covid-19-cocktail-doses-ready-by-january-and-substantially>

⁵⁰ <https://pipelinereview.com/index.php/2020110976463/Antibodies/Sorrento-Announces-FDA-IND-Filing-Today-for-COVI-AMG-Neutralizing-and-High-Potency-Antibody-Against-SARS-CoV-2.html>

⁵¹ http://www.pharmatimes.com/news/uk_biotech_consortium_identifies_covid-19_antibody_combinations_1355340

⁵² [NCT04590430](https://clinicaltrials.gov/ct2/show/study/NCT04590430)

⁵³ <https://pipelinereview.com/index.php/2020102676305/Antibodies/HiFiBiO-Therapeutics-Completes-First-Cohort-of-a-Phase-I-Study-of-its-SARS-CoV-2-Neutralizing-Antibody-for-the-Treatment-and-Prevention-of-COVID-19.html>

⁵⁴ <https://www.medscape.com/viewarticle/941240>

- Qiagen has begun commercialisation in the US of its portable SARS-CoV-2 antigen test which can process 30 samples per hour.⁵⁵ Qiagen is working with startup company TScan to develop its immune system test for COVID-19. Gavin MacBeath, TScan's chief scientific officer, said: "We believe that detecting antiviral T cells based on our discoveries will provide a more reliable way to determine exposure to SARS-CoV-2 over a much longer period following infection." The companies have said that T cells in patients recovering from COVID-19 have been shown not to cross-react to other seasonal coronaviruses, such as the one that causes the common cold.⁵⁶
- Researchers have suggested that an infusion of memory T cells from recovered COVID-19 patients could treat severe disease.⁵⁷
- A study found the T cell response after COVID-19 lasts at least six months, although the magnitude of the response is less in those whose disease is asymptomatic.⁵⁸

4. Use of convalescent plasma in COVID-19

- A study of neutralizing antibody levels in convalescent plasma donors found higher antibody levels in men, in older donors and in patients who had been hospitalised.⁵⁹
- Researchers reported on a randomized trial in Argentina of convalescent plasma in COVID-19 patients with severe pneumonia. They said neither clinical status nor overall mortality was improved by the treatment.⁶⁰
- A randomized Phase II clinical trial found convalescent plasma had no effect on progression to severe disease or all-cause mortality in COVID-19 patients.⁶¹
- At the end of October, the Cochrane Library urged "continuing to collect data on the efficacy and safety of COVID-19 convalescent plasma in a randomized, controlled manner". There were then 135 continuing studies for convalescent plasma and hyperimmune globulin.⁶²
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- A small case series (8 patients) was reported to offer "preliminary evidence that convalescent plasma therapy appears to be a safe and effective late-stage treatment for patients with COVID-19 infection".⁶³

⁵⁵ [QIAGEN Launches Portable Digital SARS-CoV-2 Antigen Test That Can Accurately Analyze Over 30 Samples Per Hour](#)

⁵⁶ <https://www.fiercebiotech.com/medtech/qiagen-joins-t-cell-developer-tscan-to-develop-comprehensive-immune-system-test-for-covid>

⁵⁷ <https://www.the-scientist.com/news-opinion/doctors-consider-convalescent-t-cell-therapy-for-covid-19-68130>

⁵⁸ <https://www.bmj.com/content/371/bmj.m4257>

⁵⁹ https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.45.2001754?TRACK=RSS#html_fulltext and <https://thelimbic.com/haematology/convalescent-plasma-fails-to-improve-outcomes-in-severe-covid-19/>

⁶⁰ <https://www.medpagetoday.com/infectiousdisease/covid19/89878> and [A Randomized Trial of Convalescent Plasma in Covid-19 Severe Pneumonia | NEJM](#)

⁶¹ <https://www.fiercebiotech.com/biotech/convalescent-plasma-fails-phase-2-moderate-covid-19-patients> and [Convalescent plasma in the management of moderate covid-19 in adults in India: open label phase II multicentre randomised controlled trial \(PLACID Trial\) | The BMJ](#)

⁶² <https://transfusionnews.com/2020/10/28/cochrane-living-systematic-review-more-data-needed-to-determine-efficacy-of-covid-19-convalescent-plasma>

⁶³ <https://www.healio.com/news/pulmonology/20201102/convalescent-plasma-may-be-safe-effective-latestage-treatment-for-covid19> and [https://journal.chestnet.org/article/S0012-3692\(20\)32752-5/fulltext](https://journal.chestnet.org/article/S0012-3692(20)32752-5/fulltext)

5. Clinical experience in COVID-19

- UK research suggests that twenty per cent of people who test positive for SARS-CoV-2 are diagnosed with a psychiatric disorder such as anxiety or depression within three months. The study also found that having a psychiatric disorder independently increases the risk of getting COVID-19.⁶⁴
- A study in almost 1000 COVID-19 patients found ten per cent of those with pneumonia had antibodies that disabled interferons, key proteins in the immune system.⁶⁵
- Researchers found relatively high SARS-CoV-2 antibody titres in children with multisystem inflammatory syndrome.⁶⁶
- Regeneron geneticists have linked four gene locations and three specific genes to COVID-19 susceptibility and severity.⁶⁷
- Researchers have offered an explanation as to why elderly COVID-19 survivors are more prone to impaired lung function. Mayo Clinic scientists found that, in mice, T cells that reside in tissues—as compared with circulating T cells—were defective after influenza; so instead of being protective, these T cells in old mice contributed to inflammation. This suggests that a treatment targeted at T cells might yield improved recovery in elderly patients.⁶⁸
- A stroke neurologist and his colleagues reported that lung evaluation by CT angiography is accurate for quick and early detection for COVID-19 infection in patients with acute ischemic stroke.⁶⁹
- Most countries where data is available are seeing a male to female COVID-19 mortality rate greater than one, but in India, Nepal, Vietnam and Slovenia the mortality rate is higher for women.⁷⁰
- In the US, scientists have said that an urgent research focus should be treatments for people with early COVID-19 infection, reducing their chance of developing severe infection and lessening the strain on the hospital system.⁷¹
- The US Centers for Disease Control and Prevention (CDC) said that about 1 in 11 patients hospitalised with COVID-19 were readmitted to the same hospital within two months.⁷²
- Researchers suggested⁷³ that over half the patients hospitalised with COVID-19 have prothrombotic antiphospholipid autoantibodies in their blood, which could explain the venous and arterial thromboembolism many experience.⁷⁴

⁶⁴ <https://www.medscape.com/viewarticle/940922> and <https://www.bmj.com/content/371/bmj.m4386>

⁶⁵ <https://www.medscape.com/viewarticle/940968>

⁶⁶ <https://www.2minutemedicine.com/higher-sars-cov-2-antibody-titers-in-patients-hospitalized-with-mis-c>

⁶⁷ <https://www.abstractsonline.com/pp8/#!/9070/presentation/3855> and

<https://www.fiercebiotech.com/research/regeneron-scientists-pinpoint-genes-related-to-covid-19-susceptibility-and-severity>

⁶⁸ <https://www.fiercebiotech.com/research/t-cell-discovery-points-to-potential-strategy-for-managing-chronic-lung-disease-after>

⁶⁹ <https://www.healio.com/news/cardiology/20201029/ct-angiography-for-ischemic-stroke-accurate-in-covid19-screening>

⁷⁰ [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(20\)30464-2/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30464-2/fulltext)

⁷¹ <https://www.niaid.nih.gov/news-events/treatments-people-early-covid-19-infection-urgent-research-focus> and <https://jamanetwork.com/journals/jama/fullarticle/2773058>

⁷² <https://www.cdc.gov/mmwr/volumes/69/wr/mm6945e2.htm>

⁷³ <https://stm.sciencemag.org/content/early/2020/11/02/scitranslmed.abd3876>

⁷⁴ <https://www.medscape.com/viewarticle/940379>

- Baxter announced data supporting the use of its Oxiris filter set for extracorporeal (outside of the body) blood purification in severely ill COVID-19 patients.⁷⁵
- A researcher reported that a patient with a systemic autoimmune rheumatic disease had a higher risk of adverse outcomes with COVID-19.⁷⁶
- Researchers say that inflammation, cell death and tissue damage, and prerenal electrolyte imbalance may predict cytokine storm in COVID-19 at an early stage.⁷⁷
- A study not yet peer-reviewed⁷⁸ reports that for some patients with severe COVID-19, the body creates "autoantibodies" that target human cells instead of the virus, as in other autoimmune diseases.⁷⁹
- A retrospective analysis in the Chicago area early in the pandemic found that neurologic manifestations occurred often in patients with COVID-19, irrespective of respiratory disease severity. Encephalopathy, which was the third most frequently observed neurological manifestation, correlated independently with worse functional outcomes and greater mortality.⁸⁰
- Scientists have said that spike proteins on the SARS-CoV-2 virus offer a possible explanation of the neurological complications that can accompany COVID-19.⁸¹
- The American Heart Association Scientific Sessions heard⁸² that COVID-19 can cause severe cardiovascular complications, such as arrhythmias, myocardial injury, thromboembolic phenomenon and cardiomyopathies.⁸³

6. Potential treatments for COVID-19 not mentioned elsewhere

- The US National Institute of Allergy and Infectious Diseases announced that the fourth iteration of the Adaptive COVID-19 Treatment Trial (ACTT-4) has begun to enrol hospitalised adults with COVID-19 who require supplemental oxygen. The trial in up to 1,500 patients will take place at around 100 sites in the US and elsewhere. Patients will be randomly assigned to one of two treatment arms of equal size. The first will be given both dexamethasone and remdesivir. The second will be given remdesivir and the rheumatoid arthritis drug baricitinib.⁸⁴
- The Infectious Diseases Society of America (IDSA) says Gilead's antiviral drug remdesivir should be used for hospitalised COVID-19 patients despite a World Health Organization (WHO) recommendation against such use.⁸⁵ Remdesivir has US FDA approval for use in COVID-19 but a WHO study was reported to have found that remdesivir showed no benefits for patients hospitalised with COVID-19.⁸⁶ The president of the European Society of Intensive Care Medicine said the drug is "now

⁷⁵ <https://seekingalpha.com/news/3626439-baxter-blood-filter-shows-potential-benefit-in-severely-ill-covidminus-19-patients>

⁷⁶ <https://www.medpagetoday.com/meetingcoverage/acr/89548>

⁷⁷ <https://www.healio.com/news/rheumatology/20201028/predictive-criteria-identifies-patients-at-risk-for-cytokine-storm-in-covid19>

⁷⁸ <https://www.medrxiv.org/content/10.1101/2020.10.21.20216192v2>

⁷⁹ <https://www.medscape.com/viewarticle/940014>

⁸⁰ <https://www.healio.com/news/neurology/20201020/encephalopathy-other-neurologic-manifestations-occur-frequently-in-covid19>

⁸¹ <https://www.healio.com/news/neurology/20201030/spike-proteins-provide-plausible-explanation-for-neurological-complications-of-covid19>

⁸² From Dr Anthony Fauci, director of the US National Institutes of Allergy and Infectious Diseases.

⁸³ <https://www.healio.com/news/cardiology/20201117/fauci-underlying-cvd-drives-risk-for-covid19-severity-death>

⁸⁴ <https://www.nih.gov/news-events/news-releases/fourth-iteration-covid-19-treatment-trial-underway>

⁸⁵ <https://www.reuters.com/article/health-coronavirus-idsa-guidelines/u-s-infectious-disease-group-backs-gileads-remdesivir-for-covid-19-treatment-idUSL1N2I916W>

⁸⁶ [46718889 \(medrxiv.org\)](https://www.medrxiv.org/abs/2020.11.18.46718889) not peer reviewed

classified as a drug you should not use routinely in COVID-19 patients” requiring intensive care.⁸⁷

- The US FDA approved the use of an oral Janus kinase (JAK) inhibitor, baricitinib, in combination with intravenous remdesivir, in patients hospitalised with severe COVID-19.⁸⁸
- A preliminary randomized controlled trial suggested that early treatment with the antidepressant fluvoxamine may help prevent respiratory deterioration in patients with mild symptomatic COVID-19.⁸⁹ Researchers reported that clinical deterioration was not observed in 80 symptomatic COVID-19 patients dosed with the selective serotonin reuptake inhibitor fluvoxamine in a randomized trial, compared with six of 72 receiving placebo.⁹⁰
- Novartis has acquired a global licence to Mesoblast’s cell therapy remestemcel-L in the treatment of COVID-19.⁹¹ Novartis has taken an option on two drugs being developed by Molecular Partners to treat or prevent COVID-19.⁹²
- Merck is buying Oncolmmune for \$US 425 million for its COVID-19 drug, CD24Fc. This fusion protein is linked to clinical improvements seen in a Phase III trial in severe and critical COVID-19 patients.⁹³
- In April, the US National Institutes of Health launched a clinical trial at 34 US hospitals to determine if hydroxychloroquine was a safe and effective medication for COVID-19. The study was funded by the National Heart, Lung, and Blood Institute (NHLBI). By June, the study was stopped because interim results showed the drug neither caused harm nor improved patient outcomes. The trial had by then enrolled 479 of the expected 510 patients. The FDA had already revoked emergency use authorization for hydroxychloroquine and chloroquine in SARS-CoV-2 infection. Researchers have now completed a final analysis of the study data. Their findings were published in *JAMA* on November 9, 2020.⁹⁴ They concluded that the drug provides no benefit to adults hospitalised with COVID-19.⁹⁵
- A small pilot study in the UK found that hospitalised COVID-19 patients receiving SNG001, inhaled nebulized interferon beta-1a, were more likely to show clinical improvement than those given a placebo.⁹⁶
- AstraZeneca’s blood cancer medication Calquence did not help COVID-19 patients survive and did not reduce respiratory failure any better than supportive care.⁹⁷

⁸⁷ [World's top intensive care body advises against remdesivir for sickest COVID patients | Reuters](#)

⁸⁸ <https://www.medpagetoday.com/infectiousdisease/covid19/89803> and [Baricitinib Receives Emergency Use Authorization from the FDA for the Treatment of Hospitalized Patients with COVID-19 | Eli Lilly and Company](#) and <https://www.fiercepharma.com/pharma/lilly-scores-fda-emergency-authorization-for-olumiant-covid-19-its-second-therapeutic-option>

⁸⁹ <https://www.medscape.com/viewarticle/941292>

⁹⁰ <https://www.medpagetoday.com/infectiousdisease/covid19/89630>

⁹¹ <https://www.fiercebiotech.com/biotech/novartis-licenses-phase-3-covid-19-cell-therapy-from-mesoblast> and [Novartis secures exclusive rights for potential acute respiratory distress syndrome cell therapy | Novartis](#)

⁹² <https://www.biopharmadive.com/news/novartis-molecular-partners-covid-19-drug/587907/> and <https://www.novartis.com/news/media-releases/novartis-announces-collaboration-molecular-partners-develop-two-darpin-therapies-designed-potential-use-against-covid-19>

⁹³ <https://www.fiercebiotech.com/biotech/merck-inks-425m-oncoimmune-buyout-to-bag-covid-19-drug>

⁹⁴ [Effect of Hydroxychloroquine on Clinical Status - For The Media - JAMA Network](#) and

⁹⁵ <https://www.nih.gov/news-events/nih-research-matters/hydroxychloroquine-doesnt-benefit-hospitalized-covid-19-patients>

⁹⁶ <https://www.medpagetoday.com/infectiousdisease/covid19/89636> and [Safety and efficacy of inhaled nebulised interferon beta-1a \(SNG001\) for treatment of SARS-CoV-2 infection: a randomised, double-blind, placebo-controlled, phase 2 trial - The Lancet Respiratory Medicine](#) and <https://www.fiercebiotech.com/biotech/synairgen-stock-climbs-covid-19-treatment-results>

⁹⁷ <https://www.astrazeneca.com/media-centre/press-releases/2020/update-on-calavi-phase-ii-trials-for-calquence-in-patients-hospitalised-with-respiratory-symptoms-of-covid-19.html>

- Inhaled corticosteroids were found not to prevent COVID-19 related death in asthma and in chronic obstructive pulmonary disease.⁹⁸
- Researchers from the Cleveland Clinic have suggested that the sleep aid melatonin may be useful in treating COVID-19.⁹⁹
- Atossa Therapeutics announced blinded preliminary results from a Phase 1 study evaluating AT-301 administered by nasal spray, for the treatment of COVID-19. AT-301 was found to be safe and well tolerated at two different dose levels in both single and multiple dose forms over 14 days. The drug is under development for home use. Atossa also plans to develop its nasal spray to potentially help prevent COVID-19 infection.¹⁰⁰

7. Developing vaccines for COVID-19

In late stage of development

- An investigational vaccine developed by AstraZeneca and the University of Oxford underwent two late-stage, placebo-controlled trials of around 23,000 volunteers across the UK and Brazil. Astra Zeneca said AZD1222 met the primary efficacy endpoint in preventing COVID-19.¹⁰¹ An interim analysis after 131 participants contracted COVID-19 determined that, on average, vaccination was 70 per cent effective in prevention. A lower-dose regimen, with a half-dose given first followed by a full dose one month later, was 90 per cent effective, while two full doses appeared 62 per cent effective.¹⁰² AstraZeneca admits the half-dose primer was a mistake made for a relatively small number of participants, and the improved efficacy may seem surprising, although the small dose could have primed the immune system to react strongly to the second (booster) shot.¹⁰³
- AstraZeneca hopes its vaccine will enjoy a competitive advantage over the two mRNA vaccines which are probably close to regulatory approval, because it has less demanding transport and storage requirements.¹⁰⁴ Astra Zeneca said it expected to be rolling out hundreds of millions of doses by Christmas.¹⁰⁵

⁹⁸ <https://www.healio.com/news/pulmonology/20201116/inhaled-corticosteroids-fail-to-protect-against-covid19related-death-in-asthma-copd>

⁹⁹ <https://www.fiercebiotech.com/research/does-sleep-aid-melatonin-work-as-a-covid-19-treatment>

¹⁰⁰ <https://seekingalpha.com/news/3634385-atossas-covidminus-19-nasal-spray-safe-in-early-stage-study>

¹⁰¹ [AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19 \(astrazeneca.com\)](https://www.astrazeneca.com/press-releases/2020/11/16/azd1222-vaccine-meets-primary-efficacy-endpoint-in-preventing-covid-19)

¹⁰² <https://www.biopharmadive.com/news/astrazeneca-oxford-coronavirus-vaccine-efficacy-results/589542/> and <https://www.fiercebiotech.com/biotech/astrazeneca-s-covid-19-vaccine-70-effective-phase-3> and <https://www.abc.net.au/news/2020-11-23/astrazeneca-oxford-covid-19-vaccine-can-be-up-to-90pc-effective> and <https://www.medscape.com/viewarticle/941422> and [Do vaccines prevent disease or infection? And how long does immunity last? Your COVID-19 vaccine questions answered - ABC News](https://www.abc.net.au/news/2020-11-23/astrazeneca-oxford-covid-19-vaccine-can-be-up-to-90pc-effective)

¹⁰³ <https://www.fiercebiotech.com/biotech/astrazeneca-probes-mistake-behind-90-covid-vaccine-efficacy> and [AstraZeneca vaccine: Experts raise questions about data for University of Oxford collaboration | 7NEWS.com.au](https://www.7news.com.au/health/astrazeneca-vaccine-experts-raise-questions-about-data-for-university-of-oxford-collaboration)

¹⁰⁴ <https://www.fiercepharma.com/manufacturing/astrazeneca-hopes-warmer-storage-needs-for-covid-19-vaccine-will-be-advantage-against> and <https://www.reuters.com/article/health-coronavirus-astrazeneca-gavi/hundreds-of-millions-of-astrazeneca-vaccine-doses-secured-gavi-alliance-idUSKBN2841L9>

¹⁰⁵ [Coronavirus: AstraZeneca COVID-19 vaccine 70 per cent effective, to start rolling out by Christmas \(smh.com.au\)](https://www.smh.com.au/health/2020/11/16/coronavirus-astrazeneca-covid-19-vaccine-70-per-cent-effective-to-start-rolling-out-by-christmas-20201116)

- Australia's Health Minister Greg Hunt said Astra Zeneca's interim results meant the first doses would probably be available to healthcare workers and the elderly by March 2021.¹⁰⁶
- Both the Pfizer/ BioNTech¹⁰⁷ partnership and Moderna¹⁰⁸ announced efficacy of their COVID-19 vaccines in Phase III studies.
- Pfizer announced that early data from its vaccine trial suggested it may be 90 per cent effective at preventing COVID-19¹⁰⁹, and that the company expected to file an emergency use application with US regulators in November.¹¹⁰ The company later said further data had raised the efficacy level.¹¹¹ It submitted its application to the USFDA on 20 November. The US FDA said reviews of COVID-19 vaccines will take weeks, not days.¹¹²
- In the US, Pfizer's vaccine will be considered by an expert panel on 10 December, with Moderna's on 17 December.¹¹³ There are reports that the US will begin administering COVID-19 vaccines by mid- December.¹¹⁴ An advisory panel of the US CDC says the population must be warned about the vaccines' side effects.¹¹⁵
- BioNTech and Fosun Pharma have initiated a Phase II trial of their vaccine in China.¹¹⁶

¹⁰⁶ [Oxford-AstraZeneca COVID-19 vaccine result gives Australia pathway to 'normal', Government says - ABC News](#) and [AstraZeneca Vaccine Can Be 90% Effective, On Track For Australia By March | HuffPost Australia \(huffingtonpost.com.au\)](#)

¹⁰⁷ <https://pipelinereview.com/index.php/2020110976436/Vaccines/Pfizer-and-BioNTech-Announce-Vaccine-Candidate-Against-COVID-19-Achieved-Success-in-First-Interim-Analysis-from-Phase-3-Study.html> and <https://www.fiercepharma.com/pharma/five-important-questions-about-pfizer-s-covid-19-vaccine>

¹⁰⁸ <https://www.nih.gov/news-events/news-releases/promising-interim-results-clinical-trial-nih-moderna-covid-19-vaccine> and <https://www.independent.co.uk/news/world/americas/covid-coronavirus-vaccine-moderna-pfizer-b1719770.html> and <https://www.fiercebiotech.com/biotech/moderna-s-covid-19-vaccine-aces-phase-3-no-severe-cases> and <https://www.healio.com/news/infectious-disease/20201116/covid19-vaccine-developed-by-moderna-nih-is-945-effective-early-data-show> and https://www.huffpost.com/entry/moderna-coronavirus-vaccine-effective_n_5fb26a3ac5b6f79d6019118f and <https://pipelinereview.com/index.php/2020111276510/Vaccines/Moderna-Has-Completed-Case-Accrual-for-First-Planned-Interim-Analysis-of-its-mRNA-Vaccine-Against-COVID-19-mRNA-1273.html> and <https://www.biopharmadive.com/news/moderna-coronavirus-vaccine-near-readout/588906/>

¹⁰⁹ [Pfizer, BioNTech see stock, hope soar as they say COVID-19 vax 90% effective, plot November EUA |](#)

¹¹⁰ <https://www.abc.net.au/news/2020-11-10/pfizer-says-vaccine-data-suggests-may-be-90-per-cent-effective/12865626> and <https://www.biopharmadive.com/news/pfizer-biontech-coronavirus-vaccine-details-safety/588733/> and

<https://www.reuters.com/article/health-coronavirus-vaccines-pfizer/potential-approval-of-pfizer-vaccine-still-several-weeks-away-u-s-official-idUSW1N2HI043>

¹¹¹ <https://www.fiercebiotech.com/biotech/pfizer-biontech-to-seek-emergency-covid-19-nod-friday>

¹¹² <https://www.fiercepharma.com/pharma/as-covid-vaccine-developers-post-impressive-data-fda-official-says-reviews-will-take-weeks>

¹¹³ <https://www.fiercepharma.com/vaccines/moderna-to-file-covid-shot-for-emergency-nod-november-as-pfizer-rollout-pegged-for-early>

¹¹⁴ <https://www.reuters.com/article/us-health-coronavirus-usa/covid-19-shots-could-reach-first-americans-by-mid-december-top-health-official-says-idUSKBN2820JZ> and [Pfizer vaccine distribution could kick off within weeks pending FDA approval, Azar says | TheHill](#)

¹¹⁵ <https://thehill.com/policy/healthcare/527372-cdc-advisory-panel-says-people-must-be-warned-about-vaccine-side-effects>

¹¹⁶ [BioNTech and Fosun Pharma Announce the Start of a Phase 2 Clinical Trial of Lead mRNA COVID-19 Vaccine BNT162b2 in China | BioNTech](#) and <https://www.fiercebiotech.com/biotech/biontech-fosun-start-covid-19-vaccine-trial-to-support-chinese-approval>

- Johnson & Johnson's vaccine uses a single-dose regimen. A Phase III study in 60,000 participants is proceeding.¹¹⁷
- INOVIO launched the second segment of its Phase II/ III clinical trial for its DNA vaccine candidate INO-4800.¹¹⁸
- Tonix Pharmaceuticals reported immune response in non-human primates to its vaccine.¹¹⁹
- German company CureVac says its mRNA-based vaccine candidate induced strong binding and neutralising antibody responses in a Phase I trial.¹²⁰ CureVac has released Phase I/II data on its candidate CVnCoV. The company said the mRNA vaccine dose selected for further development triggered "increases in virus-neutralizing antibodies and early indications of T-cell activation".¹²¹
- Sinovac had a Phase III trial of its vaccine in Brazil paused because of a safety concern.¹²² Sinovac said there had been a serious adverse event but it was not related to the vaccine. China has five potential COVID-19 vaccines yet to complete final clinical trials. Over 60,000 Chinese citizens have so far received trial vaccines¹²³. An experimental Sinopharm vaccine is being administered in the UAE.

Regulatory approval, sales and distribution

- Moderna finalized a deal to supply 160 million doses of its vaccine to the EU.¹²⁴ The European Medicines Agency began a rolling review of Moderna's vaccine, mRNA-1273.¹²⁵
- Moderna announced that an independent data monitoring committee would conduct an interim review during November of its continuing 30,000-person trial of its vaccine candidate mRNA-1273.¹²⁶
- The UK's Medicines and Healthcare products Regulatory Agency began the rolling review of Moderna's mRNA-1273.¹²⁷ The UK has signed a deal to acquire five million doses of Moderna's COVID-19 vaccine now it is claimed to be 94.5 per cent effective.¹²⁸

¹¹⁷ <https://pipelinereview.com/index.php/2020111776560/Vaccines/Johnson-Johnson-Initiates-Second-Global-Phase-3-Clinical-Trial-of-its-Janssen-COVID-19-Vaccine-Candidate.html>

¹¹⁸ <https://pipelinereview.com/index.php/2020111776561/Vaccines/INOVIIO-announces-initiation-of-Phase-2-segment-of-Phase-2/3-clinical-trial-for-COVID-19-DNA-vaccine-candidate-INO-4800.html>

¹¹⁹ <https://pipelinereview.com/index.php/2020111776573/Vaccines/Tonix-Pharmaceuticals-Reports-Positive-Immune-Response-Results-from-COVID-19-Vaccine-Candidate-TNX-1800-Following-Vaccination-of-Non-Human-Primates.html>

¹²⁰ http://www.pmlive.com/pharma_news/curevac_reveals_early_data_for_mrna-based_covid-19_vaccine_candidate_1355839

¹²¹ <https://www.fiercebiotech.com/biotech/curevac-links-covid-19-vaccine-to-immune-response-setting-it-up-to-enter-pivotal-trial> and <https://www.fiercebiotech.com/biotech/curevac-climbs-vaccine-data-despite-tolerability-questions>

¹²² <https://www.fiercebiotech.com/biotech/china-s-sinovac-hit-by-late-stage-covid-vaccine-halt-after-reports-a-death-brazilian-trial>

¹²³ <https://www.abc.net.au/news/2020-11-07/chinese-coronavirus-trial-vaccine-phase-3-covid-19/12851880>

¹²⁴ <https://www.fiercepharma.com/manufacturing/moderna-eu-clinch-supply-deal-for-160m-doses-mrna-based-coronavirus-vaccine>

¹²⁵ <https://pipelinereview.com/index.php/2020111776576/Vaccines/European-Medicines-Agency-Begins-Rolling-Review-of-Modernas-mRNA-Vaccine-Candidate-Against-COVID-19-mRNA-1273.html>

¹²⁶ <https://www.reuters.com/article/idUSKBN27E1VA>

¹²⁷ http://www.pharmatimes.com/news/uks_mhra_starts_rolling_review_of_modernas_covid-19_vaccine_1355243

¹²⁸ http://www.pharmatimes.com/news/uk_strikes_deal_for_five_million_doses_of_modernas_covid-19_vaccine_1357026

- Pfizer's mRNA vaccine candidate in its current form has stringent (frozen) storage requirements.¹²⁹ Moderna says its mRNA-1273, can be stored at refrigerator temperatures (36 degrees to 46 degrees Fahrenheit) for up to 30 days, and is stable for 12 hours at "room temperature"¹³⁰. CureVac says its mRNA vaccine is stable for up to three months at refrigerator temperatures and can also be kept for up to 24 hours at room temperature¹³¹.
- Pfizer's chief scientist has said: "I think we'll roll out next year a vaccine in powder format".¹³² If Pfizer's mRNA vaccine is authorized by the US FDA, it will use its own distribution system, not the government's system, to deliver the vaccine to healthcare providers to ensure it remains at minus 94 degrees Fahrenheit.¹³³
- Astra Zeneca said it was behind schedule with vaccine delivery in the UK, as clinical trial delays caused it to delay manufacturing.¹³⁴ One estimate suggested final data should be ready before the end of 2020, and from then it would be the approval process that determined how soon distribution occurred.¹³⁵ The company said that its Oxford University vaccine AZD1222 produces an immune response in both young and elderly adults¹³⁶, showing similar immune responses in people aged over and under 70 years.¹³⁷ The UK's Medicines and Healthcare products Regulatory Agency (MHRA) had begun an accelerated (rolling) review of the vaccine.¹³⁸
- Astra Zeneca will present its vaccine trial data from Britain, Brazil and South Africa to the US FDA in seeking emergency use approval.¹³⁹

¹²⁹ <https://www.fiercepharma.com/vaccines/amid-cold-chain-blues-pfizer-looks-to-powder-vaccine-formula-2021-report> and <https://in.reuters.com/article/health-coronavirus-vaccines-distribution/cold-storage-challenges-could-hamper-distribution-of-pfizer-moderna-covid-19-vaccines-fauci-idINKBN27R2DX> and <https://www.fiercepharma.com/pharma/despite-pfizer-s-high-efficacy-expectations-other-covid-vaccines-may-have-a-logistics-edge> and [Planes, trucks and ultracold boxes: Pfizer preps massive COVID-19 vaccine distribution effort](#) and <https://www.fiercepharma.com/manufacturing/airlines-rally-cold-chain-supplies-to-ship-pfizer-moderna-s-frigid-covid-19-shots>

¹³⁰ <https://www.fiercepharma.com/pharma/along-promising-data-moderna-says-its-vaccine-stable-refrigerators-for-30-days>

¹³¹ <https://www.fiercepharma.com/pharma/curevac-s-mrna-coronavirus-shot-holds-edge-over-pfizer-and-moderna-counterparts-refrigerated> and <https://www.curevac.com/en/2020/11/12/curevacs-covid-19-vaccine-candidate-cvncov-suitable-for-standard-fridge-temperature-logistics/> and <https://pipelinereview.com/index.php/2020/11/176490/Vaccines/CureVac-Publishes-Detailed-Interim-Phase-1-Data-of-its-COVID-19-Vaccine-Candidate-CVnCoV.html>

and <https://www.fiercepharma.com/pharma/curevac-s-mrna-coronavirus-shot-holds-edge-over-pfizer-and-moderna-counterparts-refrigerated>

¹³² <https://www.fiercepharma.com/vaccines/amid-cold-chain-blues-pfizer-looks-to-powder-vaccine-formula-2021-report> and <https://www.businessinsider.com/pfizer-is-developing-powder-version-of-its-covid-19-vaccine-2020-11>

¹³³ <https://www.fiercepharma.com/pharma/pfizer-sidelines-us-government-covid-19-vaccine-distribution-plan-favor-its-own-reports>

¹³⁴ <https://www.fiercepharma.com/manufacturing/astrazeneca-ceo-stresses-covid-19-vaccine-manufacturing-maneuvering-as-it-misses>

¹³⁵ <https://www.fiercebiotech.com/biotech/trial-chief-tips-astrazeneca-covid-19-vaccine-for-2020-data-drop>

¹³⁶ <https://www.medscape.com/viewarticle/939749>

¹³⁷ <https://www.fiercebiotech.com/biotech/astrazeneca-s-covid-19-vaccine-shows-midphase-promise-seniors> and [Oxford-AstraZeneca covid vaccine shows promising signs in elderly \(news.com.au\)](https://www.news.com.au/technology/science/oxford-astrazeneca-vaccine-produces-fewer-side-effects-for-older-adults-phase-two-trials-find/news-story/68071506b508c02fd5f88ac2d4901d32) and <https://www.news.com.au/technology/science/oxford-astrazeneca-vaccine-produces-fewer-side-effects-for-older-adults-phase-two-trials-find/news-story/68071506b508c02fd5f88ac2d4901d32>

¹³⁸ http://www.pharmatimes.com/news/uks_mhra_starts_rolling_review_of_azs_coronavirus_vaccine_1355933

¹³⁹ <https://www.reuters.com/article/us-astrazeneca-results-vaccine-trials/astrazeneca-aims-to-bring-non-u-s-vaccine-data-before-the-fda-idUSKBN27L1F8>

- Johnson & Johnson says it is “well on its way to producing 1 billion doses of its COVID-19 vaccine in 2021 and is looking ahead to 2022”.¹⁴⁰ The company has recruited data experts at UnitedHealth Group Inc. to accelerate the enrolment of 60,000 participants for its COVID-19 vaccine trial.¹⁴¹
- Novavax has been expanding in Maryland as its vaccine candidate NVX-CoV2373, underwent late-stage testing in the UK and was prepared for a large Phase III trial in the US and Mexico.¹⁴² Novavax has set specific minority targets for the latter trial.¹⁴³ The US FDA has granted fast track status to this Novavax candidate.¹⁴⁴ Novavax has had delays in scaling up manufacturing of its vaccine.
- Three Russian doctors have reportedly been infected with COVID-19 despite having received the Sputnik V vaccine.¹⁴⁵ A report suggests Russia will not meet its own timeline for mass vaccination to be well in hand by the end of 2020, with developers having problems with scaling up manufacturing and achieving quality control.¹⁴⁶ A poll in October found almost sixty per cent of Russians were unwilling to have the Sputnik V vaccine.¹⁴⁷
- Takeda will distribute 50 million doses of Moderna’s mRNA vaccine in Japan.¹⁴⁸
- The Australian Government concluded agreements for 50 million more potential vaccine doses, if they are proved to be safe and effective. Companies concerned are Novavax and Pfizer/BioNtech.¹⁴⁹ There are already agreements for the Astra Zeneca/Oxford vaccine, and the University of Queensland vaccine. Australia’s Health Minister says the University of Queensland vaccine could be widely available by late 2021.¹⁵⁰
- CureVac has agreed to supply the EU with 225 million doses initially, with an option for another 180 million doses¹⁵¹. Pfizer/ BioNTech has a deal with the EU to supply

¹⁴⁰ <https://www.fiercepharma.com/manufacturing/j-j-touts-covid-vaccine-supply-chain-stability-eyes-plans-for-2022>

¹⁴¹ <https://www.bloomberg.com/news/articles/2020-11-13/j-j-taps-unitedhealth-to-accelerate-covid-19-vaccine-trial>

¹⁴² <https://www.fiercepharma.com/manufacturing/novavax-expands-maryland-as-it-gears-up-for-late-stage-covid-vaccine-trial-u-s> and <https://ir.novavax.com/news-releases/news-release-details/novavax-provides-phase-3-covid-19-vaccine-clinical-development> and <https://www.fiercebiotech.com/biotech/manufacturing-delays-push-novavax-s-covid-19-vax-trial-to-end-november> and <https://pipelinereview.com/index.php/2020102776324/Vaccines/Novavax-Provides-Phase-3-COVID-19-Vaccine-Clinical-Development-Update.html>

¹⁴³ <https://www.reuters.com/article/health-coronavirus-vaccine-novavax/novavax-lays-out-specific-minority-targets-for-u-s-covid-19-vaccine-trial-idUSL1N2HL1VP>

¹⁴⁴ <https://seekingalpha.com/news/3633652-novavaxs-covid-19-vaccine-secures-fast-track-tag-in-u-s>

¹⁴⁵ <https://bgr.com/2020/11/12/coronavirus-vaccine-covid-19-infection-after-sputnik-v-shot/>

¹⁴⁶ <https://www.themoscowtimes.com/2020/11/04/russia-not-on-track-for-mass-coronavirus-vaccination-by-year-end-the-bell-a71951>

¹⁴⁷ <https://www.themoscowtimes.com/2020/11/02/mistrust-grows-for-russias-coronavirus-vaccine-poll-a71929>

¹⁴⁸ <https://www.fiercepharma.com/manufacturing/takeda-moderna-partner-up-to-bring-50m-coronavirus-shots-to-japan>

¹⁴⁹ <https://www.abc.net.au/news/2020-11-04/two-new-coronavirus-vaccine-deals-50-million-doses-government/12849572>

¹⁵⁰ <https://www.abc.net.au/news/2020-11-13/coronavirus-queensland-vaccine-covid-19-greg-hunt-available-2021/12863950>

¹⁵¹ <https://www.fiercepharma.com/pharma/curevac-eu-ink-supply-deal-for-up-to-405m-doses-mrna-coronavirus-shot-reuters> and <https://www.reuters.com/article/us-health-coronavirus-eu-curevac/curevac-deal-takes-eus-covid-vaccine-supplies-close-to-2-billion-idUSKBN27W1YV>

up to 300 million doses.¹⁵²The European Union says only a proportion of its population will be vaccinated before 2022, even if effective vaccines become available. The bloc has a population of 450 million. It has secured more than 1 billion doses of potential vaccines from three suppliers and is negotiating for a further one billion vials with other suppliers.¹⁵³

- NHS England said it was preparing to deliver a COVID-19 vaccine as early as December 2020.¹⁵⁴

Early stage of development

- The Nanovaccine Institute at Iowa State University is developing a nasal spray nanovaccine against SARS-CoV-2.¹⁵⁵
- Covaxx, whose vaccine should enter Phase II/ III testing before the end of 2020, has signed deals with Brazil, Ecuador and Peru.¹⁵⁶
- Other developers announcing progress on a variety of vaccines at an earlier stage include ImmunityBio¹⁵⁷, Arcturus Therapeutics¹⁵⁸, Capricor Therapeutics¹⁵⁹, Medicago¹⁶⁰, Medigen/ BlueWillow Biologics¹⁶¹, PDA Biotech/ Farmacore¹⁶², and BioVaxys¹⁶³.
- OncoSec Medical Incorporated announced that the US FDA had approved its investigational new drug application for a first-in-human Phase I trial for CORVax12, a DNA-encodable vaccine against SARS-CoV-2.¹⁶⁴
- The Coalition for Epidemic Preparedness Innovations (CEPI) allocated \$US 3.5 million in April to help China's Clover Biopharma mount a Phase I trial for its vaccine. CEPI added \$US 66 million in July to assist with scaling up manufacturing, and is

¹⁵² <https://www.fiercepharma.com/manufacturing/pfizer-biontech-ink-deal-eu-for-up-to-300m-doses-covid-19-vaccine>

¹⁵³ <https://www.medscape.com/viewarticle/939841>

¹⁵⁴ <https://www.bmj.com/content/371/bmj.m4291>

¹⁵⁵ <https://www.fiercepharma.com/drug-delivery/iowa-state-taps-device-maker-zeteo-for-early-work-nasal-spray-covid-19-vaccine>

¹⁵⁶ <https://www.fiercepharma.com/manufacturing/covaxx-inks-supply-deals-worth-2-8b-lead-up-to-coronavirus-vaccine-mid-stage-trials>

¹⁵⁷ <https://pipelinereview.com/index.php/2020110976449/Vaccines/ImmunityBios-hAd5-COVID-19-Vaccine-Candidate-Stimulates-Memory-T-Cell-Recall-in-Patients-Infected-with-SARS-CoV-2.html>

¹⁵⁸ [https://pipelinereview.com/index.php/2020110976459/Vaccines/Arcturus-Therapeutics-Announces-Positive-Interim-ARCT-021-LUNAR-COV19-Phase-1/2-Study-Results-for-Both-Single-Shot-and-Prime-boost-Regimens-and-Up-to-\\$220-Million-in-Additional.html](https://pipelinereview.com/index.php/2020110976459/Vaccines/Arcturus-Therapeutics-Announces-Positive-Interim-ARCT-021-LUNAR-COV19-Phase-1/2-Study-Results-for-Both-Single-Shot-and-Prime-boost-Regimens-and-Up-to-$220-Million-in-Additional.html)

¹⁵⁹ <https://pipelinereview.com/index.php/2020110976462/Vaccines/Capricor-Therapeutics-Announces-Positive-Preclinical-Data-for-Multivalent-Exosome-mRNA-Vaccine-For-COVID-19.html>

¹⁶⁰ <https://pipelinereview.com/index.php/2020111076471/Vaccines/Medicago-announces-positive-Phase-1-results-for-its-COVID-19-vaccine-candidate.html> and

<https://pipelinereview.com/index.php/2020111376516/Vaccines/Medicago-and-GSK-announce-start-of-Phase-2/3-clinical-trials-of-adjuvanted-COVID-19-vaccine-candidate.html> and <https://www.fiercebiotech.com/biotech/tapping-gsk-tech-medicago-kickstarts-later-stage-covid-vax-tests>

¹⁶¹ <https://pipelinereview.com/index.php/2020111076476/Vaccines/Medigen-and-BlueWillow-Biologics-Partner-to-Develop-Intranasal-Vaccine-for-SARS-CoV-2.html>

¹⁶² <https://pipelinereview.com/index.php/2020111176489/Vaccines/PDS-Biotech-and-Farmacore-Announce-Updates-to-Co-Development-of-Versamune-Based-COVID-19-Vaccine.html>

¹⁶³ <https://pipelinereview.com/index.php/2020111176492/Vaccines/BioVaxys-Announces-96.4-Percent-Positive-Antibody-Immune-Response-Results-from-an-In-Vivo-Murine-Model-Study-of-Its-SARS-CoV-2-Vaccine.html>

¹⁶⁴ <https://pipelinereview.com/index.php/2020103076357/Vaccines/OncoSec-Announces-FDA-Clearance-of-IND-Application-for-Initiation-of-Phase-1-Clinical-Trial-of-its-CORVax12-Vaccine-Candidate-for-COVID-19.html>

now adding \$US 258.5 million to see Clover through a Phase II/III study and licensure in China and elsewhere.¹⁶⁵

9. Managing the pandemic

Individual country experience

- In the US, on 30 October over 99,000 new cases were recorded.¹⁶⁶ Then three million new COVID-19 cases were notified by 22 November.¹⁶⁷ With Thanksgiving gatherings and holiday travel that week, experts were particularly anxious about where the numbers might be in three weeks' time.¹⁶⁸ On 27 November the daily new cases passed 200,000¹⁶⁹
- By 30 November, 65 Americans were dying from COVID-19 every hour and the US CDC was predicting the national death toll could reach 300,000 by mid-December.¹⁷⁰
- The US CDC wants a centralized cloud-based platform where COVID-19 testing labs can report results to public health departments.¹⁷¹
- In both Belgium and North Dakota, healthcare workers with COVID-19 have been allowed back to work because of staff shortages.¹⁷²
- Data released by the Australian Bureau of Statistics suggested that 53 per cent of Australians "would definitely get a COVID-19 test if they woke up with mild symptoms of a respiratory infection".¹⁷³
- Sweden's Chief Epidemiologist said Sweden's immunity to COVID-19 is less than previously estimated and the country is experiencing a second wave.¹⁷⁴ Stockholm

¹⁶⁵ <https://www.businesswire.com/news/home/20201102005858/en/> and <https://www.fiercebiotech.com/biotech/clover-biopharma-nabs-250m-for-covid-19-vaccine-expanded-cepi-deal>

¹⁶⁶ <https://edition.cnn.com/2020/11/03/health/us-coronavirus-tuesday/index.html> and <https://www.reuters.com/article/us-health-coronavirus-usa-trends/as-u-s-covid-19-cases-break-records-weekly-deaths-rise-3-idUSKBN27I2OF>

¹⁶⁷ <https://edition.cnn.com/2020/11/22/health/us-coronavirus-sunday/index.html> and <https://www.nbcnews.com/health/health-news/more-61-000-children-got-covid-19-last-week-record-n1245851> and <https://edition.cnn.com/2020/11/05/health/us-coronavirus-thursday/index.html> and <https://edition.cnn.com/2020/11/06/health/us-coronavirus-friday/index.html> and <https://edition.cnn.com/2020/11/11/health/us-coronavirus-wednesday/index.html> and <https://edition.cnn.com/2020/11/15/health/us-coronavirus-sunday/index.html> and <https://www.reuters.com/article/us-health-coronavirus-usa-death-toll/u-s-covid-19-deaths-surpass-250000-mark-as-infections-surge-idUSKBN27Z00X> and https://www.washingtonpost.com/health/covid-3-million-plus-infected/2020/11/18/d9f079a8-2849-11eb-8fa2-06e7cbb145c0_story.html

¹⁶⁸ <https://edition.cnn.com/2020/11/25/health/us-coronavirus-wednesday/index.html>

¹⁶⁹ [Coronavirus live news: Fauci warns of 'surge upon surge' in US cases after Thanksgiving | World news | The Guardian](https://www.theguardian.com/world/2020/nov/26/coronavirus-live-news-fauci-warns-of-surge-upon-surge-in-us-cases-after-thanksgiving)

¹⁷⁰ [US tops 13 MILLION coronavirus cases and 264,000 deaths 65 Americans dying from disease every hour | Daily Mail Online](https://www.dailymail.co.uk/health/article-6881111/US-tops-13-MILLION-coronavirus-cases-and-264000-deaths-65-Americans-dying-from-disease-every-hour.html)

¹⁷¹ <https://www.aha.org/news/headline/2020-11-04-cdc-seeks-input-proposal-centralize-covid-19-laboratory-test-reporting> and <https://www.beckershospitalreview.com/supply-chain/cdc-seeks-to-create-centralized-reporting-system-for-covid-19-test-results.html>

¹⁷² <https://www.bmj.com/content/371/bmj.m4455> and <https://www.medpagetoday.com/infectiousdisease/covid19/89637>

¹⁷³ <https://www.abs.gov.au/media-centre/media-releases/one-two-would-test-if-they-had-mild-covid-19-symptoms>

¹⁷⁴ <https://www.medscape.com/viewarticle/940856>

paused home COVID-19 testing after increasing demand left 16,000 people waiting for tests for active infections.¹⁷⁵

- Scientists in Italy reported that “about 1-in-6 people who recovered from COVID-19 subsequently retested positive at least 2 weeks later”. The lead author said: "Patients who continued to have respiratory symptoms, especially, were more likely to have a new positive test result."¹⁷⁶
- Microsoft announced that hackers working for the Russian and North Korean governments have targeted a number of organisations round the world which are involved in researching COVID-19 treatment and vaccines.¹⁷⁷

Transmission

- A UK study in healthcare workers found that people who have had a COVID-19 infection are unlikely to contract it again for at least six months.¹⁷⁸
- Australian scientists say people infected with SARS-CoV-2 retain immunity for at least eight months.¹⁷⁹
- Antiviral mouthwash has been suggested as a means of limiting coronavirus transmission.¹⁸⁰
- Some scientists think SARS-CoV-2 infections may be to some extent seasonal.¹⁸¹
- A randomised controlled study¹⁸² demonstrated that wearing a mask is somewhat more effective in preventing COVID-19 than not wearing a mask in situations where physical distancing is in place and other preventive measures are suggested.¹⁸³
- A study in Tennessee found that COVID-19 hospitalisations rose at a far lower rate in areas that had mask-wearing mandates than those that did not.¹⁸⁴
- Data suggests that mandatory use of face shields by health care workers at a Texas hospital significantly reduced their risk of acquiring SARS-CoV-2 infections.¹⁸⁵
- A study has shown that minks can transmit SARS-CoV-2 to humans.¹⁸⁶ Denmark announced it was culling the nation's entire mink herd (17 million) to prevent transmission in the species of the SARS-CoV-2 virus with mutations which might undermine the effectiveness of the COVID-19 vaccines currently being developed.¹⁸⁷

¹⁷⁵ <https://www.medscape.com/viewarticle/940145>

¹⁷⁶ <https://www.medscape.com/viewarticle/940114>

¹⁷⁷ <https://www.medscape.com/viewarticle/940956>

¹⁷⁸ <https://www.medscape.com/viewarticle/941345>

¹⁷⁹ [COVID-19 immunity could last for eight months, according to Monash University researchers | 7NEWS.com.au](https://www.7NEWS.com.au)

¹⁸⁰ <https://www.medscape.com/viewarticle/940421>

¹⁸¹ [Is coronavirus seasonal after all? - Coronacast - ABC Radio](https://www.abc.com.au/radio/2020/10/28/is-coronavirus-seasonal-after-all/)

¹⁸² [Bundgaard H, et al. *Ann Intern Med.* 2020;doi:10.7326/M20-6817.](https://doi.org/10.7326/M20-6817) See also [Laine C, et al. *Ann Intern Med.* 2020;doi:10.7326/M20-7448;](https://doi.org/10.7326/M20-7448) [Frieden TR, et al. *Ann Intern Med.* 2020;doi:10.7326/M20-7499;](https://doi.org/10.7326/M20-7499) and <https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html>.

¹⁸³ <https://www.healio.com/news/primary-care/20201118/study-covid19-risk-slightly-lower-for-mask-wearers>

¹⁸⁴ https://www.vumc.org/health-policy/sites/default/files/public_files/Vanderbilt%20COVID19%20Report-Oct%2027.pdf and <https://www.forbes.com/sites/alisondurkee/2020/10/28/areas-with-mask-mandates-have-lower-covid-19-hospitalization-rate-study-finds-tennessee-vanderbilt/?sh=6681ded623ef>

¹⁸⁵ <https://www.healio.com/news/primary-care/20201028/universal-face-shield-ussignificantly-reduces-sarscov2-infections-among-hcps>

¹⁸⁶ <https://www.the-scientist.com/news-opinion/qa-minks-can-transmit-sars-cov-2-to-humans-study-shows-68156>

¹⁸⁷ <https://www.statnews.com/2020/11/05/spread-of-mutated-coronavirus-in-danish-mink-hits-all-the-scary-buttons-but-fears-may-be-overblown/>

Then Greek mink farms were found to be affected.¹⁸⁸ The French agriculture ministry announced that mink infected with coronavirus had been found at a farm in the Eure-et-Loire region of western France, and 1000 mink would be culled.¹⁸⁹

- Researchers say that the SARS-CoV-2 virus can survive over nine hours on human skin.¹⁹⁰
- Increasing airflow inside enclosed spaces has perhaps received less attention than other COVID-19 prevention strategies, but now the WHO, the US CDC, and the European Commission have all acknowledged airborne aerosol transmission is significant in spreading the SARS-CoV-2 virus.¹⁹¹
- Researchers found that droplets from a cough may spread further than 6 feet away and carry sufficient SARS-CoV-2 virus to infect someone else, either through direct inhalation or later from touching their skin or clothes and then their face.¹⁹²
- During the current pandemic, researchers have discussed whether the primary method of transmission of the SARS-CoV-2 virus is via relatively large respiratory droplets, which drop quickly to the floor/ ground or tiny aerosolised droplets which continue circulating in the air for a long time. A study¹⁹³ (not yet peer reviewed) reinforces the role of aerosolised droplets. Researchers report that the virus spreads via aerosolised particles between ferrets more than a meter apart.¹⁹⁴
- A study¹⁹⁵ (not yet peer reviewed) found that mortality from COVID-19 in selected countries without universal Bacille Calmette-Guérin (BCG) vaccination for tuberculosis (including Italy and the US) was higher than in selected countries with universal BCG vaccination. This found correlation but did not determine a causal relationship.¹⁹⁶ However, trials are in progress of the BCG vaccine in groups at high risk of exposure to SARS-CoV-2 to determine if it can provide at least partial, temporary protection.¹⁹⁷
- Scientists at the US National Institutes of Health have identified a pathway apparently used by SARS-CoV-2 to hijack and exit cells as it spreads through the body. They hope their discovery may lead to a means of stopping the transmission of the virus.¹⁹⁸
- A study found that children with asymptomatic COVID-19 have lower viral load than symptomatic children.¹⁹⁹

Testing

- Scientists at Northwestern University report they have trained an artificial intelligence algorithm to detect the signs of COVID-19 on a basic X-ray of the lungs. It can

¹⁸⁸ [Coronavirus found at two Greek mink farms | News | The Times](#) and

<https://www.aljazeera.com/news/2020/11/13/greece-find-covid-19-among-mink-at-two-farms>

¹⁸⁹ <https://www.reuters.com/article/us-health-coronavirus-france-mink-idUSKBN2820GC>>

¹⁹⁰ <https://www.healio.com/news/infectious-disease/20201106/sarscov2-survives-for-9-hours-on-human-skin>

¹⁹¹ <https://www.abc.net.au/news/2020-11-16/ventilation-indoor-airflow-could-be-important-against-covid-19/12881444>

¹⁹² <https://www.medscape.com/viewarticle/940473>

¹⁹³ <https://www.biorxiv.org/content/10.1101/2020.10.19.345363v1.full>

¹⁹⁴ <https://www.the-scientist.com/news-opinion/ferret-study-reinforces-role-of-aerosols-in-sars-cov-2-spread-68094>

¹⁹⁵ <https://www.medrxiv.org/content/10.1101/2020.03.24.20042937v2>

¹⁹⁶ <https://www.the-scientist.com/news-opinion/an-old-tb-vaccine-finds-new-life-in-coronavirus-trials-67504>

¹⁹⁷ <https://www.the-scientist.com/features/how-some-vaccines-protect-against-more-than-their-targets-68059>

¹⁹⁸ <https://www.nih.gov/news-events/news-releases/nih-scientists-discover-key-pathway-lysosomes-coronaviruses-use-exit-cells>

¹⁹⁹ <https://consumer.healthday.com/asymptomatic-children-with-sars-cov-2-have-lower-viral-load-2648534537.html>

quickly screen patients on admission to hospital for any reason and triage patients whose healthcare workers will need personal protective equipment (PPE).²⁰⁰

- A CRISPR-based, paper-strip test developed as an assay for sickle cell anaemia has been repurposed to diagnose COVID-19 and returns results within an hour.²⁰¹
- A rapid coronavirus test developed at the University of Oxford is being used to screen passengers at international airports in London and Hong Kong.²⁰²
- Singapore's Breathonix has said a clinical trial of its COVID-19 breathalyser test achieved at least 90 per cent accuracy after screening participants for 60 seconds.²⁰³
- A US study in Marine recruits found that temperature and COVID-19 symptom checks "again proved inadequate for spotting coronavirus infections and preventing outbreaks".²⁰⁴
- A pilot program with a rapid COVID-19 test in Greater Manchester was reported to have missed over half of the positive cases.²⁰⁵
- Stanford University scientists have developed a CRISPR-based "lab on a chip" to detect COVID-19. They are collaborating with Ford to develop a market-ready product.²⁰⁶
- A study (not yet peer reviewed) has supported the use of pooled testing for COVID-19 as efficient and effective where substantial numbers are involved. For each pool, several samples are combined. The pooled sample is tested, and if the result is positive, people in the group are tested individually.²⁰⁷

10. Miscellaneous news

Infectious diseases other than COVID-19

- Remdesivir failed in a trial for Ebola virus infection but a Phase II trial has found it reduces virus levels in the semen of recovered patients, reducing the risk of transmission of Ebola to sexual partners.²⁰⁸
- The US National Institutes of Health has found that the antibiotic methacycline could prevent brain infections and reduce neurological problems associated with the Zika virus in mice. Scientists also found that drugs originally developed to combat Alzheimer's disease and inflammation may help fight Zika infection.²⁰⁹
- The European Medicines Agency's Committee for Medicinal Products for Human Use recommended the approval of Roche's Xofluza® (baloxavir marboxil) for the treatment of uncomplicated influenza in patients aged 12 years and above. It also recommended Xofluza for approval as a preventive treatment (post-exposure

²⁰⁰ <https://www.fiercebiotech.com/medtech/northwestern-univ-publishes-open-ai-spots-covid-19-chest-x-rays>

²⁰¹ <https://www.the-scientist.com/news-opinion/assay-for-sickle-cell-anemia-is-repurposed-to-diagnose-covid-19-68163>

²⁰² <https://www.fiercebiotech.com/medtech/oxford-s-rapid-covid-19-test-acquired-by-prenetics-to-screen-airport-passengers-london-hong>

²⁰³ <https://www.fiercebiotech.com/medtech/singapore-startup-develops-60-second-covid-19-breathalyzer-test>

²⁰⁴ <https://www.medscape.com/viewarticle/940850>

²⁰⁵ <https://www.bmj.com/content/371/bmj.m4323>

²⁰⁶ <https://www.fiercebiotech.com/medtech/stanford-develops-crispr-lab-a-chip-for-detecting-covid-19> and <https://www.pnas.org/content/early/2020/11/03/2010254117>

²⁰⁷ <https://www.bmj.com/content/371/bmj.m4267>

²⁰⁸ <https://www.medpagetoday.com/meetingcoverage/astmh/89790>

²⁰⁹ <https://www.nih.gov/news-events/news-releases/commonly-used-antibiotic-shows-promise-combating-zika-infections> and Abrams, R.P.M., Yasgar, A. et al., Therapeutic Candidates for the Zika Virus Identified by a High Throughput Screen for Zika Protease Inhibitors. PNAS, November 23, 2020 DOI: [10.1073/pnas.2005463117](https://doi.org/10.1073/pnas.2005463117)

prophylaxis) of individuals aged 12 years and above.²¹⁰ The US FDA has approved Roche's Xofluza to prevent influenza in people ages 12 years and older following contact with an infected person.²¹¹

- With the apparent success in clinical trials of two mRNA vaccines against the SARS-CoV-2 virus, hopes have strengthened that this technology will be able to be employed against other viruses including influenza.²¹²
- 7 Hills Pharma announced the first healthy volunteers have been dosed in a Phase 1 trial of 7HP349, the company's first-in-concept immunostimulant. The drug is designed to improve the effectiveness of vaccines for COVID-19 and influenza, and immuno-oncology drugs.²¹³
- The largest flu vaccine manufacturing plant in the southern hemisphere will be built in Melbourne's Airport business park and is expected to be operational by 2026. The Australian Government is contributing \$A1 billion. Seqirus - a subsidiary of CSL - will contribute \$A 800 million. Flu vaccines made at the plant will be cell-based rather than egg-based. The facility will make a range of products including antivenoms.²¹⁴
- In South Korea 101 people died after receiving their seasonal flu vaccine, but health authorities said 97 of the deaths had "very limited relation with the flu shots", while four were still under investigation.²¹⁵
- South Korea found highly pathogenic avian influenza H5N8 in wild birds.²¹⁶
- Alberta officials are investigating after a human case in Canada of a rare swine flu variant was detected during October.²¹⁷
- TFF Pharmaceuticals, which has patented its Thin Film Freezing technology platform, announced that, in collaboration with the University of Georgia's Center for Vaccines and Immunology, it had obtained positive preclinical immunogenicity and efficacy data from TFF formulated University of Georgia universal influenza hemagglutinin recombinant vaccines.²¹⁸
- Data from six African countries indicates that anti-retroviral therapy reduces the risk that children with HIV will get or die from tuberculosis.²¹⁹
- Researchers in the US report that patients newly infected with HIV are being diagnosed in greater numbers, attending hospitals with COVID-like symptoms.²²⁰
- Worldwide, deaths from measles increased by 50 per cent from 2016 to 2019, with 200,000 deaths in 2019.²²¹

²¹⁰ <https://pipelinereview.com/index.php/2020111376538/Small-Molecules/CHMP-recommends-EU-approval-of-Roches-Xofluza-baloxavir-marboxil-for-the-treatment-of-influenza.html>

²¹¹ [Genentech Announces FDA Approval of Xofluza for the Prevention of Influenza Following Contact With an Infected Person | Business Wire](https://www.businesswire.com/news/home/20201113005271/en/Genentech-Announces-FDA-Approval-of-Xofluza-for-the-Prevention-of-Influenza-Following-Contact-With-an-Infected-Person) and <https://www.fiercepharma.com/marketing/roche-s-xofluza-wins-fda-nod-to-prevent-flu-but-hits-a-snag-bid-to-reach-younger-patients>

²¹² [How mRNA vaccines work, and how they might protect us from the flu and other diseases - ABC News](https://www.abc.net.au/news/2020-11-16/new-vaccine-facility-melbourne-coronavirus-anti-venom/12886346)

²¹³ <https://pipelinereview.com/index.php/2020110976465/Small-Molecules/7-Hills-Pharma-Announces-First-Healthy-Volunteers-Dosed-in-Landmark-Phase-1-Trial-of-Immunostimulant-to-Improve-Immuno-Oncology-Drugs-COVID-19-and-Influenza-Vaccines.html>

²¹⁴ <https://www.abc.net.au/news/2020-11-16/new-vaccine-facility-melbourne-coronavirus-anti-venom/12886346>

²¹⁵ <https://www.aa.com.tr/en/asia-pacific/south-korea-flu-deaths-rise-amid-spike-in-virus-cases/2038292>

²¹⁶ https://www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review

²¹⁷ <https://www.cbc.ca/news/canada/edmonton/canada-s-first-case-of-rare-swine-flu-variant-found-in-central-alberta-patient-1.5789440>

²¹⁸ <https://pipelinereview.com/index.php/2020102776312/Vaccines/TFF-Pharmaceuticals-Announces-Positive-Preclinical-Results-with-University-of-Georgia-Universal-Influenza-Vaccines.html>

²¹⁹ <https://www.healio.com/news/primary-care/20201113/art-reduces-risk-that-children-with-hiv-will-die-from-tb>

²²⁰ <https://www.medpagetoday.com/meetingcoverage/idweekvideoppearls/89627>

²²¹ <https://www.medscape.com/viewarticle/940872>

- A newborn baby died of meningococcal disease in Adelaide.²²²
- Ology Bioservices announced that the US Department of Defense, through the Joint Science and Technology Office of the Defense Threat Reduction Agency, had awarded the company a contract worth \$US 6.3 million to manufacture a live attenuated tularemia vaccine.²²³
- Engineers at Rice University have designed a microneedle device that can detect key markers of malaria without drawing any blood.²²⁴

Other

- Emergex Vaccines Holding Limited, which is developing synthetic 'set point' vaccines which prime the T-cell immune response, has raised \$US 11 million in a funding round supported by new and existing investors. This round follows a successful \$US 11 million Series A completed in January 2020.²²⁵
- Canadian researchers detected high rates of hidden atrial fibrillation after heart surgery.²²⁶
- A Canadian study found that children who survived Kawasaki disease remained at risk for cardiovascular events for more than a decade.²²⁷

²²² <<https://au.news.yahoo.com/newborn-dies-in-hospital-after-contacting-meningococcal-disease-070733864.html>>

²²³ <https://pipelinereview.com/index.php/2020102776313/Vaccines/Department-of-Defense-Awards-Ology-Bioservices-Contract-to-Manufacture-and-Test-Novel-Live-Attenuated-Tularemia-Vaccine-Candidate.html>

²²⁴ <https://newatlas.com/medical/microneedle-patch-malaria-draw-blood/>

²²⁵ [https://pipelinereview.com/index.php/2020111876583/Vaccines/Emergex-Vaccines-Raises-US\\$11-million-to-Advance-Pipeline-of-Synthetic-T-Cell-Vaccines-for-Infectious-Diseases.html](https://pipelinereview.com/index.php/2020111876583/Vaccines/Emergex-Vaccines-Raises-US$11-million-to-Advance-Pipeline-of-Synthetic-T-Cell-Vaccines-for-Infectious-Diseases.html)

²²⁶ <https://www.fiercebiotech.com/medtech/aha-digital-monitoring-study-finds-high-rates-hidden-atrial-fibrillation-after-heart>

²²⁷ <https://www.medpagetoday.com/meetingcoverage/acr/89549>