

Monitoring International Trends

June 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.

In the period covered by this report, the emphasis within the health sector worldwide has been on the COVID-19 pandemic. Clinical trials for non-related treatments have in many cases been paused, launches of recently approved drugs have been postponed, and the emphasis of research and product development in both the public and private.

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1. Treatments for haemophilia and sickle cell disease

- The World Federation of Haemophilia Virtual Summit¹ was told that fitusiran leads to sustained reductions in bleed frequency in people with moderate-to-severe haemophilia A or B regardless of inhibitor status.²
- Pfizer and Sangamo reported at the Summit their updated Phase I/II results demonstrating that their gene therapy candidate for severe haemophilia A, giroctocogene fitelparvovec (SB-525 or PF-07055480), offered sustained factor VIII activity levels, no bleeding events, and no necessary FVIII infusions in all five patients within one of the trial's four dose cohorts.³
- Catalyst Biosciences presented data from preclinical studies of its haemophilia B gene therapy CB 2679d-GT at the Summit. The therapy combines engineered AAV capsids with Catalyst's novel high potency FIX transgene. Nassim Usman, president and chief executive officer of Catalyst, said: "The preclinical data from our constructs demonstrated a strong dose response and improved reduction in bleeding relative to the Padua variant. The enhanced FIX activity and reduced viral dose may offer advantages over current AAV-based gene therapies in clinical development."⁴
- The Summit was also told that subcutaneous preventive treatment with Dalcinonacog alfa (DalcA) led to sustained and protective levels of factor IX in patients with severe haemophilia B.⁵
- CSL Behring has agreed to acquire from uniQure its late-stage gene therapy candidate for haemophilia B.⁶
- Data is emerging for BioMarin's gene therapy for haemophilia A that show the effect on factor VIII activity levels waning over time, suggesting that patients might need to be re-dosed to keep up protection against bleeds.⁷
- Regeneron Pharmaceuticals and Intellia Therapeutics are expanding a gene editing collaboration signed four years ago, now adding projects to treat hemophilia.⁸
- At the Virtual Edition of the 25th European Hematology Association Annual Congress CRISPR Therapeutics and Vertex Pharmaceuticals Incorporated announced new clinical data for CTX001, an investigational CRISPR/Cas9 gene-editing therapy, from the CLIMB-111 and CLIMB-121 Phase I/II trials in transfusion-dependent beta

¹ <https://www.wfh.org/virtual-summit/home>

² <https://hemophilianewstoday.com/2020/06/22/fitusiran-prevents-bleeds-in-moderate-severe-hemophilia-a-or-b-extension-study-shows/> and [press release](#).

³ <https://www.genengnews.com/news/pfizer-sangamo-report-positive-phase-i-ii-data-for-severe-hemophilia-a-gene-therapy/> and <https://pipelinereview.com/index.php/2020061875042/DNA-RNA-and-Cells/Pfizer-and-Sangamo-Announce-Updated-Phase-1/2-Results-Showing-Sustained-Factor-VIII-Activity-Levels-and-No-Bleeding-Events-or-Factor-Usage-in-3e13-vg/kg-Cohort-Followin.html>

⁴ <https://pipelinereview.com/index.php/2020062075061/DNA-RNA-and-Cells/Catalyst-Biosciences-Presents-Preclinical-FIX-Gene-Therapy-Data-in-an-Oral-Presentation-at-the-World-Federation-of-Hemophilia-Virtual-Summit-2020.html>

⁵ [Phase 2b Trial to Evaluate the Safety and Factor IX Levels of a Daily Subcutaneous Prophylaxis Treatment Regimen of Dalcinonacog alfa in Hemophilia B](#) and <https://hemophilianewstoday.com/2020/06/17/dalca-shows-sustained-efficacy-for-patients-severe-hemophilia-b-in-phase-2b-trial/>

⁶ <https://www.cslbehring.com/newsroom/2020/csl-behring-acquires-uniqure-amt-061> and [http://www.pmlive.com/pharma_news/csl_licenses_uniqure_haemophila_b_gene_therapy_in_\\$2bn-plus_deal_1342897](http://www.pmlive.com/pharma_news/csl_licenses_uniqure_haemophila_b_gene_therapy_in_$2bn-plus_deal_1342897)

⁷ <https://www.fiercebitech.com/biotech/biomarin-s-hemophilia-gene-therapy-roc-solid-after-4-years>

⁸ <https://www.biopharmadive.com/news/regeneron-intellia-crispr-gene-therapy-deal-hemophilia/578969/>

thalassemia and severe sickle cell disease. They outlined recent progress in the CTX001 development program.⁹

- Also at the Virtual Edition of the 25th European Hematology Association Annual Congress Forma Therapeutics, Inc. announced positive Phase 1 results from the sickle cell disease patient arm of a continuing study of FT-4202.¹⁰
- Agios Pharmaceuticals announced clinical proof-of-concept based on a preliminary analysis in the Phase I study of mitapivat (AG-348) in patients with sickle cell disease.¹¹ The US Food and Drug Administration (FDA) has granted orphan drug designation to mitapivat for treatment of thalassemia¹².
- Global Blood Therapeutics is asking the FDA to approve the use of Oxbryta in children aged 4 to 11 with sickle cell disease. It is already approved for patients 12 and over.¹³

2. Clinical experience with COVID-19

Respiratory and cardiovascular concerns

- A study has shown that in patients with COVID-19 who underwent surgery, 30-day mortality was high and around half of the patients had postoperative pulmonary complications¹⁴.
- A study found that patients with asthma were no more likely to be hospitalized due to COVID-19 than patients without asthma.¹⁵
- Dyspnoea (difficult or laboured breathing) is said to be the most significant end-of-life symptom in COVID-19, with respiratory or heart failure the most frequent causes of death.¹⁶
- A study showed that although COVID-19 patients with hypertension had an increased risk of mortality, those who were treated for hypertension had a lower mortality risk than those who were not.¹⁷
- COVID-19 is thought to be causing collateral damage in patients with COPD (chronic obstructive pulmonary disease).¹⁸

⁹ <https://pipelinereview.com/index.php/2020061374984/More-News/CRISPR-Therapeutics-and-Vertex-Announce-New-Clinical-Data-for-Investigational-Gene-Editing-Therapy-CTX001-in-Severe-Hemoglobinopathies-at-the-25th-Annual-European-Hematology-As.html> and <https://www.biopharmadive.com/news/crispr-vertex-bluebird-sickle-cell-thalassemia-study-update/579692/>

¹⁰ <https://pipelinereview.com/index.php/2020061374974/Small-Molecules/Forma-Therapeutics-Presents-Safety-Pharmacokinetic-and-Pharmacodynamic-Data-from-Phase-1-Clinical-Trial-for-Investigational-Agent-FT-4202-in-Patients-with-Sickle-Cell-Dis.html>

¹¹ <https://pipelinereview.com/index.php/2020061374981/Small-Molecules/Agios-Announces-Clinical-Proof-of-Concept-Has-Been-Established-in-Phase-1-Study-of-Mitapivat-First-in-Class-PKR-Activator-in-Sickle-Cell-Disease.html>

¹² <https://www.pharmacytimes.com/>

¹³ <https://www.reuters.com/article/us-global-blood-therapeutics-fda/global-blood-therapeutics-to-seek-to-expand-label-for-sickle-cell-treatment-idUSKBN23F2QP>

¹⁴ <https://www.healio.com/news/pulmonology/20200602/postoperative-pulmonary-complications-common-in-covid19> and Myles PS, et al. *Lancet*. 2020;doi:10.1016/S0140-6736(20)31256-3.

¹⁵ <https://www.healio.com/news/pulmonology/20200622/asthma-not-associated-with-increased-hospitalization-in-patients-with-covid19>

¹⁶ <https://www.medscape.com/viewarticle/932660>

¹⁷ https://www.healio.com/news/cardiology/20200622/antihypertensive-treatment-may-reduce-mortality-risk-in-covid19?utm_source

¹⁸ <https://www.medscape.com/viewarticle/932810>

- A study found that cardiac arrest and heart rhythm disorders are 10 times more common among COVID-19 patients requiring intensive care than among other hospitalized COVID-19 patients.¹⁹
- A single-centre study found that hypercoagulability on thromboelastography had predictive value for thrombotic events among COVID-19 patients admitted to the ICU.²⁰
- A study of 34 children hospitalised with COVID-19 in China found that fever and cough were common, but the type of lung lesions seen in adults were rare.²¹

Suggested disease modifying factors

- A single-centre study found that obese COVID-19 patients had a higher risk of pulmonary embolism, even if they were not in the ICU. Statin therapy before admission was found to reduce likelihood of pulmonary embolism in the multivariate model.²²
- French researchers reported that more than one in 10 diabetics hospitalized with COVID-19 die within a week, while nearly a third require mechanical ventilation.²³
- Autopsies of African Americans who died from COVID-19 in New Orleans have identified the pulmonary and cardiac pathology which probably contributed to mortality in this patient population.²⁴
- Scientists say that variants in both the ABO blood group locus and a cluster of genes on chromosome 3 appear more frequently in COVID-19 patients who suffer respiratory failure than in the population as a whole.²⁵

Other issues in clinical management

- The American College of Rheumatology announced the “Clinical Guidance for Pediatric Patients with Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with SARS-CoV-2 and Hyperinflammation in COVID-19” on June 18, alongside another set of [COVID-19 guidance for pediatric patients with rheumatic disease](#).²⁶
- A study of children critically ill with COVID-19 confirmed that the recently identified multi-inflammatory syndrome has different blood and infection markers from other conditions, like Kawasaki disease and staphylococcal toxic shock syndrome, with which it shares several symptoms.²⁷

¹⁹ <https://consumer.healthday.com/infectious-disease-information-21/coronavirus-1008/severe-covid-19-raises-odds-for-dangerous-heart-conditions-10-fold-758838.html>

²⁰ <https://www.medpagetoday.com/infectiousdisease/covid19/86930>

²¹ https://www.the-scientist.com/news-opinion/covid-19-is-very-different-in-young-kids-versus-adults-67637?utm_campaign

²² <https://www.medpagetoday.org/infectiousdisease/covid19/86798>

²³ <https://www.medscape.com/viewarticle/931470>

²⁴ <https://www.healio.com/news/pulmonology/20200529/study-identifies-cardiopulmonary-contributors-to-death-in-covid19>

²⁵ <https://www.the-scientist.com/news-opinion/two-genetic-regions-linked-with-severe-covid-19-67619> and <https://www.medscape.com/viewarticle/932333> and <https://www.ft.com/content/587de199-add0-41d9-992e-8f329f8db047>

²⁶ <https://www.healio.com/news/rheumatology/20200622/acr-unveils-guidance-for-multisystem-inflammatory-syndrome-in-children-with-covid19>

²⁷ <https://www.nbcnews.com/health/kids-health/blood-markers-discovered-covid-linked-syndrome-children-n1215546>

- Researchers say headache may be the first and most significant symptom of COVID-19 in individual patients.²⁸
- UK researchers found that COVID-19 patients who have high levels of the steroid hormone cortisol on admission to hospital have a significantly increased risk of dying.²⁹
- Researchers funded by the US National Heart, Lung and Blood Institute are researching the long-term effects of COVID-19.³⁰

3. Developing vaccines for COVID-19

- By late June, there were almost 150 COVID-19 vaccines in development globally, but only 13 had reached clinical trials.
- In mid-June The University of Queensland, the [Coalition for Epidemic Preparedness Innovations](#) and CSL signed a new agreement for the development, production and distribution of a molecular clamp-enabled vaccine for COVID-19, formalising the support provided by CSL since the beginning of the pandemic.³¹ Recruitment began of healthy volunteers to participate in human trials of the vaccine.³²
- A researcher at Griffith University is using convalescent plasma to “pinpoint what parts of the virus are being recognised by the antibodies in those people who have recovered” and “identify what the actual vaccine components will be.”³³
- Carol Kao³⁴ from Emory University School of Medicine and her colleagues have said that the real incidence of COVID-19 in children [may be underrepresented](#) as they are less likely than adults to be tested. They said vaccine trials should include children if herd immunity is to be achieved.³⁵
- Inovio, testing its COVID-19 vaccine in humans, signed a \$US71 million supply deal with the US Department of Defense to manufacture devices that use electrical pulses to deliver vaccines into the skin.³⁶
- In late June, Sanofi and Translate Bio expanded their collaboration to develop mRNA vaccines across a range of infectious diseases, including COVID-19.³⁷ Sanofi has also partnered with GlaxoSmithKline to use its adjuvant on a protein subunit vaccine program.³⁸

²⁸ <https://www.medscape.com/viewarticle/932637>

²⁹ <https://www.medscape.com/viewarticle/932705>

³⁰ <https://www.nhlbi.nih.gov/news/2020/looking-forward-understanding-long-term-effects-covid-19>

³¹ <https://www.labonline.com.au/content/life-scientist/news/uq-csl-and-cepi-partner-on-covid-19-vaccine-development-198787954> and <https://pipelinereview.com/index.php/2020060874903/Vaccines/The-University-of-Queensland-CEPI-and-CSL-partner-to-advance-development-and-manufacture-of-COVID-19-vaccine-candidate.html>

³² <https://nam11.safelinks.protection.outlook.com/>

³³ <https://www.abc.net.au/news/2020-06-24/covid19-plasma-vaccine-gold-coast-university-hospital/12384212>

³⁴ assistant professor of paediatric infectious diseases at Emory University School of Medicine

³⁵ <https://www.healio.com/news/pediatrics/20200617/qa-should-children-be-included-in-covid19-vaccine-trials>

³⁶ <https://www.fiercepharma.com/pharma/inovio-scores-71m-department-defense-deal-to-scale-up-vaccine-delivery-devices>

³⁷ <https://www.fiercebiotech.com/biotech/sanofi-spends-425m-to-double-down-translate-bio-mrna-pact-eyes-q4-covid-vax-start> and <https://www.sanofi.com/en/media-room/press-releases/2020/2020-06-23-06-59-00>

³⁸ <https://www.fiercepharma.com/pharma/sanofi-chose-a-proven-program-over-speed-its-covid-19-vaccine-hunt-ceo-says>

- AstraZeneca signed a tenth supply deal for its candidate vaccine, AZD1222, this time with Symbiosis Pharmaceutical, based in Scotland.³⁹
- AstraZeneca's CEO said the company's COVID-19 candidate vaccine would protect against infection for about a year.⁴⁰
- Astra Zeneca made a deal with Europe's Inclusive Vaccines Alliance (IVA) to supply up to 400 million doses of its University of Oxford-partnered COVID vaccine, AZD1222.⁴¹ Meanwhile, Catalent Biologics committed a production facility in Italy to provide vial filling and packaging.⁴²
- Astra Zeneca made a \$US750 million deal with the Coalition of Epidemic Preparedness Innovations (CEPI) and the vaccine alliance Gavi to produce 300 million doses of Oxford University's COVID vaccine by the end of 2020. AstraZeneca also signed a licensing agreement with the Serum Institute of India to distribute a billion vaccine doses to low-income countries.⁴³
- The US National Institutes of Health (NIH) said in early June that it would run large phase III trials of COVID vaccines from Moderna, AstraZeneca and Johnson & Johnson, with Moderna in July, AstraZeneca in August, and J & J in September.⁴⁴
- Novavax signed a \$US 60 million contract with the US Department of Defense to help produce components for its vaccine candidate, NVX-CoV2373. Under the contract, Novavax will deliver 10 million doses by the end of the year.⁴⁵
- Novavax has recruited Japan's AGC Biologics to supply immune-boosting adjuvant for its coronavirus vaccine candidate.⁴⁶
- In mid-June, the EU was negotiating with Johnson and Johnson to secure access to its COVID-19 vaccine.⁴⁷
- China's Clover Biopharmaceuticals dosed patients in a Phase I trial for its COVID-19 vaccine candidate, SCB-2019.⁴⁸ Clover has partnered with both GSK and Dynavax to test whether adding the companies' adjuvants could improve the vaccine's effectiveness.⁴⁹

³⁹ <https://uk.reuters.com/article/uk-health-coronavirus-astrazeneca-symbio/astrazeneca-scotlands-symbiosis-sign-deal-for-covid-19-vaccine-supply-idUKKBN23V1U7>

⁴⁰ <https://www.fiercepharma.com/vaccines/astrazeneca-s-covid-19-to-protect-for-about-one-year-ceo-says>

⁴¹ <https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2020/astrazeneca-to-supply-europe-with-up-to-400-million-doses-of-oxford-universitys-vaccine-at-no-profit.html>

⁴² <https://www.fiercepharma.com/manufacturing/astrazeneca-taps-catalent-for-covid-19-vaccine-finishing-packaging-at-italian-plant> and

<https://pipelinereview.com/index.php/2020061575001/Vaccines/Catalent-Signs-Agreement-with-AstraZeneca-to-Manufacture-COVID-19-Vaccine-Candidate.html>

⁴³ <https://www.fiercepharma.com/manufacturing/astrazeneca-unveils-massive-750m-deal-effort-to-produce-billions-covid-19-shots>

⁴⁴ <https://www.fiercepharma.com/vaccines/nih-preps-late-stage-studies-moderna-az-and-j-j-coronavirus-vaccines-wsj>

⁴⁵ <https://www.fiercepharma.com/manufacturing/novavax-scores-60m-department-defense-contract-for-u-s-covid-19-vaccine-manufacturing>

⁴⁶ <https://www.fiercepharma.com/manufacturing/novavax-enlists-agc-biologics-to-manufacture-adjuvant-for-covid-19-shot>

⁴⁷ <https://www.reuters.com/article/health-coronavirus-eu-vaccine/exclusive-eu-in-advanced-talks-with-johnson-johnson-on-covid-19-vaccine-deal-sources-idUSL8N2DV32T> and

<https://www.fiercepharma.com/pharma/johnson-johnson-talks-to-supply-covid-19-vaccine-europe-reports>

⁴⁸ <https://www.fiercebitech.com/biotech/using-gsk-dynavax-tech-clover-kickstarts-covid-vax-trial-data-drop-august>

⁴⁹ <https://www.biopharmadive.com/news/clover-gsk-dynavax-coronavirus-vaccine-study/580180/>

- The British government contributed \$US 56 million to Imperial College London's COVID-19 vaccine research, which uses self-amplifying RNA technology to trigger an immune response.⁵⁰
- China's state-owned Sinopharm described Phase I/II results for its inactivated COVID-19 vaccine, which it said hit a seroconversion rate of 100 per cent after two doses a month apart.⁵¹ The company will conduct Phase III trials in Brazil.⁵²
- Singapore's Duke-NUS Medical School announced plans to start safety trials of its messenger RNA (mRNA)-based coronavirus vaccine.⁵³
- In Germany, the state-owned bank, Kreditanstalt für Wiederaufbau, has invested in CureVac, which is testing its mRNA COVID-19 vaccine, and will hold around a 23 per cent stake in the company.⁵⁴ CureVac announced that the German Health Authority Paul-Ehrlich-Institute and the Belgian Federal Agency for Medicines and Health Products had approved the Phase 1 clinical trial to be conducted in Germany and Belgium.⁵⁵
- Swiss company Saiba AG has selected AGC Biologics to manufacture its recombinant subunit virus-like particle vaccine against COVID-19.⁵⁶
- Panacea Biotech (India) and Refana (Ireland) have agreed to work towards an inactivated coronavirus vaccine.⁵⁷
- Codagenix announced the synthesis of a readily-scalable live-attenuated vaccine candidate against COVID-19, CDX-005.⁵⁸
- PDS Biotechnology Corporation announced a co-development agreement with Farmacore Biotechnology for a vaccine to prevent COVID-19.⁵⁹
- PepTC Vaccines' says its PolyPEPI-SCoV-2 investigative vaccine should give long-term T cell immunity. It includes 10 different, 30-amino acid long synthetic peptides.⁶⁰

⁵⁰ <https://www.fiercebiotech.com/biotech/hard-cash-from-u-k-govt-imperial-to-kickstart-next-gen-covid-vaccine-trials-month> and <https://pipelinereview.com/index.php/2020061675007/Vaccines/Government-funded-Imperial-College-COVID-19-vaccine-moves-into-first-human-trials.html>

⁵¹ <https://www.fiercepharma.com/pharma-asia/china-s-sinopharm-touts-100-antibody-response-for-covid-19-vaccine-it-s-already-giving>

⁵² <https://www.fiercepharma.com/vaccines/china-s-sinovac-says-covid-19-vaccine-shows-early-positive-results-phase-2>

⁵³ <https://uk.reuters.com/article/us-health-coronavirus-singapore-vaccine/singapore-scientists-to-start-human-trials-of-covid-19-vaccine-in-august-idUKKBN23N16V>

⁵⁴ <https://www.fiercebiotech.com/biotech/after-a-turbulent-few-months-germany-takes-a-stake-covid-vaccine-drugmaker-curevac>

⁵⁵ <https://pipelinereview.com/index.php/2020061875038/Vaccines/CureVac-Receives-Regulatory-Approval-from-German-and-Belgian-Authorities-to-Initiate-Phase-1-Clinical-Trial-of-its-SARS-CoV-2-Vaccine-Candidate.html> and <https://www.fiercebiotech.com/biotech/curevac-gets-ok-to-start-testing-mrna-covid-19-vaccine-humans>

⁵⁶ <https://pipelinereview.com/index.php/2020061675017/Vaccines/Saiba-AG-Selects-AGC-Biologics-to-Develop-and-Produce-COVID-19-Vaccine.html>

⁵⁷ <https://www.moneycontrol.com/news/business/companies/panacea-joins-hands-with-irelands-refana-to-develop-covid-19-vaccine-by-early-next-year-5384951.html>

⁵⁸ <https://pipelinereview.com/index.php/2020061875047/Vaccines/Codagenix-Announces-the-Synthesis-and-Preliminary-Safety-of-Scalable-Live-attenuated-Vaccine-Candidate-Against-COVID-19.html>

⁵⁹ <https://pipelinereview.com/index.php/2020061775033/Vaccines/PDS-Biotechnology-and-Farmacore-Biotechnology-Announce-Co-Development-of-PDS0204-COVID-19-Vaccine.html>

⁶⁰ <https://pipelinereview.com/index.php/2020061574997/Vaccines/Treos-Bio-Forms-New-Subsidiary-to-Develop-a-Preventive-COVID-19-Peptide-Vaccine.html>

- ATUM and Phylex BioSciences are collaborating to develop a universal SARS vaccine.⁶¹ Researchers have developed a technique for preparing vaccines which exhibit temperature stability and can be administered orally.⁶²

4. Antibodies and COVID-19

- Antibodies are developed by COVID-19 patients; and antibodies, human or recombinant, may be used to treat the disease.⁶³
- A Chinese study found that people infected with COVID-19 may not retain antibodies for more than a few months.⁶⁴ Researchers said that such people may have no defence against a mutation such as D614G which presented in 70 per cent of samples sequenced in Europe and North America.⁶⁵
- Regeneron in mid-June said REGN-COV2, its antibody cocktail binds to more than one region of the virus, preventing it from mutating and becoming drug-resistant. It was in placebo- controlled trials in hospitalised and non-hospitalised patients.⁶⁶
- Regeneron also sees its cocktail as a stop-gap for the elderly and immunocompromised until a vaccine is available.⁶⁷
- Humanigen reported positive trial results for its antibody treatment lenzilumab.⁶⁸
- Eli Lilly on 11 June said it might have at least one of its antibody therapies ready by September.⁶⁹
- Other companies working to develop antibodies to prevent or treat COVID-19 are
 - Amgen⁷⁰
 - Abbie Vie with Harbour BioMed, Utrecht University and Erasmus Medical Centre⁷¹
 - I-MAB Biopharma⁷²

⁶¹ <https://pipelinereview.com/index.php/2020061574995/Vaccines/ATUM-and-Phylex-BioSciences-Collaborate-to-Accelerate-the-Development-of-a-Universal-SARS-Coronavirus-Vaccine.html>

⁶² <https://www.the-scientist.com/modus-operandi/vaccines-without-vials-fridges-or-needles-67583>

⁶³ <https://www.medscape.com/viewarticle/932527> and

<https://www.the-scientist.com/news-opinion/first-antibody-trial-launched-in-covid-19-patients--67604>

⁶⁴ <https://www.medscape.com/viewarticle/932671> and <https://www.reuters.com/article/us-health-coronavirus-antibody/antibody-levels-in-recovered-covid-19-patients-decline-quickly-research-idUSKBN23T1CJ>

⁶⁵ <https://amp-scmp.com.cdn.ampproject.org/c/s/amp.scmp.com/coronavirus/greater-china/article/3089983/coronavirus-recovered-chinese-patients-may-be-defenceless> and

<https://www.reuters.com/article/us-health-coronavirus-infectivity/mutation-in-new-coronavirus-increases-chance-of-infection-study-idUSKBN23M1M9>

⁶⁶ <https://www.fiercebiotech.com/research/how-regeneron-s-covid-19-antibody-cocktail-cuts-risk-resistance>

⁶⁷ <https://www.fiercebiotech.com/biotech/regeneron-starts-testing-covid-19-antibody-cocktail-humans>

⁶⁸ <https://www.fiercebiotech.com/research/drug-by-martin-shkreli-s-former-company-humanigen-shows-early-promise-covid-19> and

<https://pipelinereview.com/index.php/2020061574994/Antibodies/Mayo-Clinic-Study-of-Humanigens-Lenzilumab-Shows-Rapid-Recovery-and-Discharge-in-Severe-and-Critical-COVID-19-Patients.html>

⁶⁹ <https://theprint.in/health/us-drug-company-eli-lilly-says-its-covid-treatment-could-be-ready-as-early-as-september/439468/> and <https://www.biopharmadive.com/news/eli-lilly-abcellera-coronavirus-antibody-drug-first-trial/578980/>

⁷⁰ <https://grapevine.is/news/2020/06/08/icelanders-white-blood-cells-flown-to-canada-for-covid-19-treatment-research/>

⁷¹ <https://www.fiercebiotech.com/biotech/after-kaletra-setback-abbvie-joins-forces-biotech-academia-for-experimental-covid-hopeful>

⁷² <https://www.fiercebiotech.com/research/i-mab-advances-repositioned-ra-drug-early-trial-to-treat-covid-19-cytokine-storm>

- CORAT Therapeutics GmbH⁷³
- SAB Therapeutics⁷⁴
- GlaxoSmithKline⁷⁵
- Astra Zeneca⁷⁶
- Convalescent plasma is also being used directly in treatment.⁷⁷ It was found to be safe and effective in the first peer-reviewed study of the treatment in the US.⁷⁸
- The American Association for Clinical Chemistry issued guidance on serology and antibody testing for SARS-CoV-2⁷⁹.

5. Other potential treatments for COVID-19

- Gilead said its antiviral drug remdesivir was of modest benefit in patients with moderate COVID-19 given a five-day course. They did better than those who took the drug for 10 days.⁸⁰ Gilead is conducting a trial of remdesivir in paediatric patients.⁸¹ It is also developing versions of the drug which do not require intravenous administration. This includes an inhaled version.⁸²
- In the UK, the arthritis and asthma drug dexamethasone was found to reduce mortality in patients on ventilators and on oxygen.⁸³

⁷³ <https://pipelinereview.com/index.php/2020061775031/Antibodies/CORAT-Therapeutics-Takes-Over-the-Fast-Track-Development-of-a-Novel-COVID-19-Antibody-Drug-Program.html>

⁷⁴ <https://www.npr.org/sections/health-shots/2020/06/17/877844458/cows-help-with-covid-19-treatment-no-bull>

⁷⁵ <https://www.fiercebiotech.com/biotech/gsk-taps-experimental-arthritis-antibody-to-calm-cytokine-storm-hitting-covid-19-patients>

⁷⁶ <https://www.astrazeneca.com/media-centre/articles/2020/advancing-our-discovery-of-novel-coronavirus-neutralising-antibodies-against-covid-19.html>

⁷⁷ <https://endpts.com/johns-hopkins-researchers-publish-a-how-to-guidebook-on-covid-19-plasma-transfusions/>

⁷⁸ [https://ajp.amjpathol.org/article/S0002-9440\(20\)30257-1/fulltext](https://ajp.amjpathol.org/article/S0002-9440(20)30257-1/fulltext) and <https://www.medscape.com/viewarticle/931740> and https://www.eurekalert.org/pub_releases/2020-06/hm-sfc_1060120.php

⁷⁹ <https://www.healio.com/news/primary-care/20200601/guidelines-shed-light-on-serology-antibody-testing-for-covid19> and <https://www.aacc.org/media/press-release-archive/2020/05-may/aacc-issues-recommendations-on-the-use-of-covid19-antibody-tests> and https://www.aacc.org/-/media/Files/Science-and-Practice/Statements/AACC-Statement_Serology-Testing_20200515.pdf

⁸⁰ <https://www.reuters.com/article/us-health-coronavirus-gilead-sciences/gileads-remdesivir-shows-modest-improvement-in-moderate-covid-19-patients-idUSKBN2382IU> and <https://www.biopharmadive.com/news/gilead-remdesivir-nejm-nih-results/578545/> Earlier data can be found at <https://www.fiercepharma.com/pharma/gilead-s-remdesivir-helps-moderate-covid-19-patients-but-just-how-much>

⁸¹ <https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-clinical-trial-of-remdesivir-in-pediatric-patients>

⁸² <https://www.reuters.com/article/us-health-coronavirus-gilead-sciences/gileads-next-step-on-coronavirus-inhaled-remdesivir-other-easier-to-use-versions-idUSKBN2391FP> and <https://www.fiercepharma.com/pharma/gilead-to-start-testing-inhaled-remdesivir-eyeing-earlier-covid-19-use> and <https://www.biopharmadive.com/news/gilead-coronavirus-remdesivir-inhaled/580285/>

⁸³ <https://www.bbc.com/news/health-53061281> and <https://www.gov.uk/government/news/world-first-coronavirus-treatment-approved-for-nhs-use-by-government> and <https://www.rfi.fr/en/science-and-technology/20200617-who-welcomes-great-news-as-cheap-steroid-shown-to-be-effective-against-covid-19> and <https://metro.co.uk/2020/06/17/dr-hilary-jones-issues-stark-warning-breakthrough-coronavirus-drug-12862838/> and <https://uk.reuters.com/article/us-health-coronavirus-steroid-data/show-me-the-data-u-s-doctors-skeptical-of-reported-covid-breakthrough-idUKKBN23N3ER> and <https://www.medrxiv.org/content/10.1101/2020.06.22.20137273v1> and <https://www.fiercepharma.com/pharma/preprint-dexamethasone-data-suggest-life-saving-potential->

- Eli Lilly announced on 15 June that the first patient had been enrolled in a Phase III randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of baricitinib, an oral JAK1/JAK2 inhibitor licensed from Incyte, in hospitalized adults with COVID-19. The rheumatoid arthritis drug is marketed as OLUMIANT®.⁸⁴
- Monash University researchers have tested the way a molecule called α -ketoamide blocks one of the proteins needed to replicate the SARS-CoV-2 virus.⁸⁵
- University of Melbourne researchers have demonstrated that a natural antibiotic, teixobactin, can treat bacterial lung conditions and those commonly linked with COVID-19. The drug deals with *Staphylococcus aureus* (MRSA)⁸⁶.
- The US FDA approved an investigational new drug application for AgenT-797 for the treatment of patients with COVID-19 infection. The drug is an allogeneic, unmodified [invariant natural killer T](#) (iNKT) cell therapy in Phase I clinical trials cancer.⁸⁷
- Other treatments being investigated include
 - Ridgeback's antiviral EIDD-2801⁸⁸
 - Colchicine⁸⁹
 - Favipiravir, sold by Fujifilm as Avigan⁹⁰
 - Tocilizumab, sold by Roche as Actemra⁹¹
 - Roche's Tecentriq and Avastin in combination⁹²
 - The combination HIV drug lopinavir/ritonavir⁹³
 - PTC Therapeutics' early stage cancer drug PTC29⁹⁴
 - TRVO27, targeting blood clots in hospitalised COVID-19 patients⁹⁵
 - Celltrion Healthcare's Remsima⁹⁶
 - An inhalation therapy approved in Japan for other indications, being studied for COVID-19 by Daiichi Sankyo and various partners⁹⁷

[for-severe-covid-19-patients](#) and <https://thehill.com/policy/healthcare/503161-who-new-treatment-only-meant-for-severe-covid-19-cases>

⁸⁴ <https://pipelinereview.com/index.php/2020061574996/Small-Molecules/Lilly-Begins-a-Phase-3-Clinical-Trial-with-Baricitinib-for-Hospitalized-COVID-19-Patients.html> and <https://www.fiercepharma.com/pharma/lilly-starts-testing-arthritis-med-olumiant-covid-19-alongside-antibody-works> and <https://www.prnewswire.com/news-releases/lilly-begins-a-phase-3-clinical-trial-with-baricitinib-for-hospitalized-covid-19-patients-301076569.html>

⁸⁵ <https://www.9news.com.au/national/coronavirus-treatment-australian-research-team-may-have-found-covid19-blocker/ab539577-b472-40d0-8d8e-1d1e9d0bcdd9?app=applenews>

⁸⁶ <https://www.news.com.au/national/breaking-news/natural-antibiotic-outsmarts-superbugs/news-story/8ed343cc27b89769b2e6431b4c744abb>

⁸⁷ <https://www.healio.com/news/hematology-oncology/20200602/fda-clears-ind-for-natural-killer-t-cell-therapy-to-treat-covid19>

⁸⁸ <https://www.fiercebiotech.com/biotech/ridgeback-tests-covid-19-antiviral-for-patients-hospital-and-at-home>

⁸⁹ <https://medicalxpress.com/news/2020-06-early-trial-ancient-drug-severe.html>

⁹⁰ <https://www.timesnownews.com/health/article/research-on-avigan-as-potential-treatment-for-covid19-may-drag-on-until-july-fujifilm/602978>

⁹¹ <https://www.fiercepharma.com/pharma/roche-s-actemra-fails-italian-study-early-stage-covid-19-pneumonia>

⁹² <https://www.japantimes.co.jp/news/2020/06/08/business/financial-markets/chugai-stock-surge-virus-treatment/#.XwOXHBPIuFu>

⁹³ <https://uk.reuters.com/article/uk-health-coronavirus-who-lopinavir/who-testing-interim-data-from-covid-19-trial-on-hiv-drugs-idUKKBN23P1ID>

⁹⁴ <https://www.fiercebiotech.com/biotech/ptc-therapeutics-taps-experimental-cancer-drug-for-new-covid-trial>

⁹⁵ <https://www.independent.co.uk/news/health/coronavirus-uk-treatment-vaccine-drug-trial-blood-clots-trv027-a9565966.html>

⁹⁶ <http://www.koreaherald.com/view.php?ud=20200611000802>

⁹⁷ <https://www.pharmaceutical-technology.com/news/daiichi-sankyo-nafamostat-covid-19/>

- AQCH, a plant-based drug originally developed against dengue⁹⁸
- Ibuprofen⁹⁹
- Apabetalone from Resverlogix¹⁰⁰
- Sars-CoV-2 main proteases inhibitors¹⁰¹
- BerGenBio's bemcentinib¹⁰²

6. The pandemic – its spread and management

- Researchers say that one of the things making SARS-CoV-2 spread so easily is that the spike on the virus is so sticky, up to 20 times as sticky as the spike on the original SARS virus.¹⁰³
- US researchers say that a mutation (D614G) in SARS-CoV-2 can increase its ability to infect cells.¹⁰⁴
- A study found that COVID-19 spreads easily among people who live together and other family members, even before an infected person shows any symptoms; and that it spreads among household members more easily than severe acute respiratory syndrome (SARS) or Middle East respiratory syndrome (MERS).¹⁰⁵
- Researchers from the National Library of Medicine, part of the US National Institutes of Health, identified genomic features of SARS-CoV-2, and other high-fatality coronaviruses that are not shared with other coronaviruses. This may allow prediction of the severity of future coronavirus disease outbreaks and the detection of animal coronaviruses that have the potential to devastate human populations.¹⁰⁶
- The US government and the Bill and Melinda Gates Foundation are funding the development of digital means to detect early symptoms of COVID-19, with healthcare workers in mind.¹⁰⁷
- A study reported that greater physical distancing reduces risk of COVID-19 transmission and that N95 masks, particularly for health care workers, are more effective than other masks.¹⁰⁸

⁹⁸ <https://www.bnnbloomberg.ca/india-s-largest-drugmaker-starts-trials-for-plant-based-covid-19-drug-1.1446091>

⁹⁹ <http://www.pharmafile.com/news/550329/kings-college-london-launches-trial-investigating-effectiveness-ibuprofen-covid-19-patie> and <https://www.medscape.com/viewarticle/931741>

¹⁰⁰ <https://www.resverlogix.com/investors/news?article=665>

¹⁰¹ <https://pipelinereview.com/index.php/2020060974922/Small-Molecules/A2A-Pharmaceuticals-Collaborates-With-LAXAI-Life-Sciences-to-Co-develop-SARS-CoV-2-Main-Proteases-Inhibitors-for-the-Treatment-of-COVID-19.html>

¹⁰² http://www.pharmatimes.com/news/first_patient_dosed_in_bemcentinib_covid-19_trial_1341390

¹⁰³ <https://theconversation.com/revealed-the-protein-spike-that-lets-the-2019-ncov-coronavirus-pierce-and-invade-human-cells-132183> and <https://www.abc.net.au/news/2020-06-18/coronavirus-covid-vaccine-race-how-the-candidates-work/12310814>

¹⁰⁴ <https://www.reuters.com/article/us-health-coronavirus-infectivity/mutation-in-new-coronavirus-increases-chance-of-infection-study-idUSKBN23M1M9>

¹⁰⁵ <https://consumer.healthday.com/infectious-disease-information-21/coronavirus-1008/how-easily-does-coronavirus-spread-at-home-758702.html>

¹⁰⁶ <https://www.nih.gov/news-events/news-releases/nih-researchers-identify-key-genomic-features-could-differentiate-sars-cov-2-other-coronaviruses-cause-less-severe-disease> and

<https://www.medscape.com/viewarticle/931898>

<https://www.pnas.org/content/117/26/15193>

¹⁰⁷ <https://www.fiercebitech.com/medtech/barda-taps-evidation-health-to-digitally-monitor-healthcare-workers-for-early-covid-19>

¹⁰⁸ <https://www.medscape.com/viewarticle/931551> and Chu DK et al. *Lancet*. 2020 2

June [doi.org/10.1016/S0140-6736\(20\)31142-9](https://doi.org/10.1016/S0140-6736(20)31142-9).

- UK researchers suggested that lockdowns would not prevent resurgence of COVID-19, but that even homemade masks worn in public could significantly reduce transmission.¹⁰⁹
- Analysis has found that COVID-19 may spread through patient faeces.¹¹⁰
- A Swedish study showed fewer people had developed antibodies to COVID-19 than expected.¹¹¹
- Italian scientists found traces of the coronavirus in wastewater from Milan and Turin collected in December 2019.¹¹²
- There is continuing speculation amongst researchers globally about how many cases of COVID-19 there were in Wuhan in January 2020.¹¹³
- Harvard Medical School researchers say that satellite images of hospital travel patterns and search engine data suggest that the coronavirus might have been spreading in China as early as August 2019.¹¹⁴
- Scientists reported that breastmilk samples from a nursing mother infected with SARS-CoV-2 has tested positive.¹¹⁵
- In Mexico newborn triplets tested for COVID-19 four hours after birth had a positive result though both parents tested negative.¹¹⁶
- Italian clinicians reported two cases of possible transmission of Sars-CoV-2 *in utero*.¹¹⁷
- Saudi Arabia is limiting the number of Hajj pilgrims to around 1000 because of the pandemic.¹¹⁸
- In their annual dialogue, officials from the European Commission (EC), the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) agreed on priorities for collaboration in the context of the pandemic.¹¹⁹

7. Other news

- Scientists from Texas A&M University have developed a microfluidic device to study blood clot therapies. It mimics the vasculature architecture.¹²⁰
- A Canadian study found that co-administration of clarithromycin and a direct oral anticoagulant (DOAC) increases the risk of a major haemorrhage in elderly patients.¹²¹

¹⁰⁹ <https://www.medscape.com/viewarticle/932077> see also

¹¹⁰ https://www.upi.com/Health_News/2020/06/11/COVID-19-may-spread-through-feces-of-those-infected-analysis-finds/5681591885913/?sl=3

¹¹¹ <https://www.medscape.com/viewarticle/932550>

¹¹² <https://www.9news.com.au/world/coronavirus-italy-sewage-study-december/5be2e423-7eb8-4a59-97e1-855b4c2359d7>

¹¹³ <https://www.the-scientist.com/news-opinion/estimates-vary-widely-for-number-of-wuhan-covid-19-cases-in-january-67642>

¹¹⁴ <https://7news.com.au/lifestyle/health-wellbeing/coronavirus-in-china-may-have-been-circulating-in-august-2019-satellite-images-and-search-engine-data-shows-c-1089098>

¹¹⁵ <https://www.medscape.com/viewarticle/931378>

¹¹⁶ <https://7news.com.au/travel/coronavirus/unheard-of-doctors-baffled-after-new-twist-in-newborn-covid-triplets-c-1123757>

¹¹⁷ <https://www.medscape.com/viewarticle/931269>

¹¹⁸ <https://www.arabnews.com/node/1694346/saudi-arabia>

¹¹⁹ <https://www.raps.org/news-and-articles/news-articles/2020/6/new-priorities-set-for-trans-atlantic-collaboratio>

¹²⁰ <https://www.medgadget.com/2020/06/microfluidic-device-mimics-blood-vessels-to-test-clotting.html>

¹²¹ <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2766918> and <https://thelimbic.com/haematology/antibiotic-interaction-warning-on-doacs-bleeding-risk/>

- Japanese researchers created a portable analyser for rapid onsite testing and have been able to detect anti-avian influenza virus antibody in blood serum within 20 minutes.¹²²
- Researchers Scientists say that high levels of a neurotoxin in north -eastern Brazil's drinking water exacerbated the incidence of microcephaly in babies born to women who had Zika virus at a critical stage of their pregnancy.¹²³
- The New South Wales Department of Primary Industries confirmed the first case of Hendra virus in Australia for 2020 was found in a horse on a property near Murwillumbah, in the north of the state.¹²⁴
- Researchers are working on a one-time gene therapy for Parkinson's disease.¹²⁵
- Merck and Pfizer are both working on next-generation pneumococcal vaccines.¹²⁶
- MIT engineers created a strong, double-sided adhesive that can be stuck and unstuck when required, wet or dry.¹²⁷
- The American College of Chest Physicians, the American Association for Bronchology and Interventional Pulmonology, and the Association of Interventional Pulmonology Program Directors released guidance on the use of tracheostomy during the current pandemic, while minimizing the risk of infection for healthcare professionals.¹²⁸
- Batavia Biosciences and Valneva Sweden AB have agreed to accelerate market-access of a low-cost inactivated polio vaccine.¹²⁹
- Researchers have developed a more sensitive blood test for cancer.¹³⁰
- Roxadustat demonstrated non-inferiority to Darbepoetin in Phase III DOLOMITES study of anaemia in non-dialysis-dependent adults with chronic kidney disease.¹³¹
- CSL Behring agreed to acquire Vitaeris Inc., a company focussed on the Phase III development of clazakizumab, an anti-interleukin-6 (IL-6) monoclonal antibody for treating chronic active antibody-mediated rejection the main cause of long-term rejection in kidney transplant recipients.¹³²
- The US FDA awarded Chembio Diagnostics 510(k) clearance to market its DPP Zika IgM System, for the presumptive detection of Zika virus IgM antibodies in whole blood, serum or plasma.¹³³

¹²² <https://www.labonline.com.au/content/consumables/news/antibody-for-bird-flu-detected-in-20-min-1062524777>

¹²³ <https://www.the-scientist.com/notebook/did-contaminated-water-exacerbate-brazilian-babies-zika-symptoms--67572>

¹²⁴ <https://www.abc.net.au/news/2020-06-03/first-case-of-hendra-virus-confirmed-for-2020/12312690>

¹²⁵ <https://www.fiercebiotech.com/research/one-and-done-gene-therapy-wipes-out-parkinson-s-symptoms-mouse-models>

¹²⁶ <https://www.fiercepharma.com/vaccines/merck-posts-phase-3-trial-wins-amid-next-gen-pneumococcal-vaccine-race-pfizer>

¹²⁷ <https://www.fiercebiotech.com/medtech/mit-researchers-develop-strong-yet-detachable-surgical-tape>

¹²⁸ <https://www.healio.com/news/pulmonology/20200622/guidance-for-tracheostomy-use-during-covid19-pandemic> and [Press Release](#).

¹²⁹ <https://pipelinereview.com/index.php/2020061574988/Vaccines/Batavia-Biosciences-and-Valneva-Collaborate-to-Accelerate-Development-of-Low-cost-Inactivated-Polio-Vaccine.html>

¹³⁰ http://www.pharmatimes.com/news/researchers_develop_highly_sensitive_blood_test_for_cancer_1342471

¹³¹ <https://pipelinereview.com/index.php/2020060874901/Small-Molecules/Roxadustat-Demonstrates-Non-Inferiority-to-Darbepoetin-in-Phase-3-DOLOMITES-Study-of-Anemia-in-Non-Dialysis-Dependent-Adult-Patients-with-Chronic-Kidney-Disease.html>

¹³² <https://pipelinereview.com/index.php/2020060974921/More-News/CSL-Behring-to-Acquire-Biotech-Company-Vitaeris.html>

¹³³ <https://seekingalpha.com/pr/17893352-chembio-diagnostics-receives-fda-510-k-clearance-for-dpp-zika-igm-system>

- A small study of a vaccine designed to provide broad protection against mosquito-borne diseases found it to be safe, and that it elicited a strong immune response in healthy volunteers. Further studies are needed to determine its effectiveness against specific diseases.¹³⁴

¹³⁴ <https://www.nih.gov/news-events/nih-research-matters/universal-mosquito-vaccine-tested>