

PRESS RELEASE



For media

27th September, 2021
GlaxoSmithKline K.K.

GSK Received Approval for Monoclonal Antibody, “XEVDY for Intravenous Injection” (generic name: sotrovimab), for the treatment of COVID-19

- **Xevudy, developed in partnership with Vir Biotechnology, was approved as a Special Approval for Emergency (SAE) for the treatment of mild to moderate COVID-19**
- **For domestic supply of Xevudy, agreement has been made with the Government of Japan for purchase and distribution**

GlaxoSmithKline K.K. (Representative Director & President: Paul Lirette; Head Office: Minato-ku, Tokyo; hereinafter “GSK Japan”) today announced that it has received approval for “Xevudy (generic name sotrovimab), a single-dose monoclonal antibody, for the treatment of COVID-19, as a Special Approval for Emergency (SAE) under Article 14-3(1) of the Pharmaceutical Affairs Law by the Japanese Ministry of Health, Labour and Welfare (MHLW). With regard to the domestic supply of Xevudy, agreement has been reached with the Japanese government for their purchase and distribution of sotrovimab. GSK will continue to work together with the Japanese government to ensure a prompt and appropriate supply.

XEVDY 500mg for intravenous injection is approved for the treatment of mild to moderate COVID-19 patients who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19.

Paul Lirette, GSK Japan’s President, said, “With the prolonged pandemic caused by COVID-19, we are pleased that Xevudy can now contribute to patients in Japan as a new treatment option. Results from Phase II/III study (COMET-ICE study) showed that Xevudy (sotrovimab), a single dose monoclonal antibody, significantly reduced the risk of hospitalization or death in adult patients with mild to moderate COVID-19 who were at high risk of progressing to severe COVID-19¹. In addition, *in vitro* data show that sotrovimab has activity against circulating variants of concern and interest, including Delta and Lambda strains.³ We expect Xevudy may help many patients. We will continue to work with the Japanese government to ensure that Xevudy is delivered to those who need it in a timely and appropriate manner.”

Product Information about Xevudy

Brand name	XEVDY for Intravenous Injection 500mg
Active ingredients	Sotrovimab (genetical recombination)
Indication	Disease caused by SARS-CoV-2 infection
DOSAGE AND ADMINISTRATION	The usual dosage for adults and children aged ≥12 years and weighing ≥40 kg is single intravenous infusion of sotrovimab (genetical recombination) 500mg.



-End of release-

Related Releases

- GSK Japan Announces Submission of Monoclonal Antibody Sotrovimab to the Ministry of Health, Labour and Welfare (MHLW) for Approval; https://jp.gsk.com/media/7477/20210906_sotrovimab_e.pdf
- GSK and Vir Biotechnology announce continuing progress of the COMET clinical development programme for sotrovimab; <https://www.gsk.com/en-gb/media/press-releases/gsk-and-vir-biotechnology-announce-continuing-progress-of-the-comet-clinical-development-programme-for-sotrovimab/>

About Xevudy (sotrovimab)

Xevudy is a SARS-CoV-2 monoclonal antibody being developed globally by GSK and Vir Biotechnology Inc. The primary efficacy analysis of all 1,057 patients in Phase II/III clinical trial (COMET-ICE trial) demonstrated a 79% reduction (adjusted relative risk reduction) ($p < 0.001$) in hospitalisation for more than 24 hours or death due to any cause, by Day 29 compared to placebo, meeting the primary endpoint of the trial.¹ The most common adverse events observed in the sotrovimab treatment group in COMET-ICE were diarrhoea [sotrovimab group: 8(2%), placebo group: 4(<1%)], all 8 events were Grade 1 (mild) or Grade 2 (moderate).²

Xevudy binds to a highly conserved region of the spike protein, which may make it more difficult for resistance to develop. Data from *in vitro* studies published in [bioRxiv](#)³ shows that Xevudy as a single monoclonal antibody maintains activity against currently circulating variants of concern and interest, including Delta and Lambda strains. The clinical implications of the *in vitro* data on these variants are not yet known, and data collection and analysis are ongoing.

About the Special Approval for Emergency (SAE)

The Special Approval for Emergency system is used to approve medical products more quickly than the regular approval process can. These medical products must meet the following requirements: 1. they are needed in an emergency to prevent the spread of diseases, and no appropriate alternative means other than the use of the relevant medical product is available; and 2. they have been approved for sale overseas.*

*Article 14-3(1) of the Pharmaceutical Affairs Law

About the Vir and GSK Collaboration

In April 2020, Vir and GSK entered into a collaboration to research and develop solutions for coronaviruses, including SARS-CoV-2, the virus that causes COVID-19. The collaboration uses Vir's proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options to help address the current COVID-19 pandemic and future outbreaks. The companies will leverage GSK's expertise in functional genomics and combine their capabilities in CRISPR screening and artificial intelligence to identify anti-coronavirus compounds that target cellular host genes. They will also apply their combined expertise to research SARS-CoV-2 and other coronavirus vaccines.

GSK Commitment to Tackling COVID-19

GSK's response to COVID-19 has been one of the broadest in the industry, with multiple treatments in addition to our vaccine candidates in development with partner organisations. GSK is collaborating with several organisations on COVID-19 vaccines by providing access to our adjuvant technology. In addition to our work with Medicago, we recently announced positive Phase 2 data from our collaboration with Sanofi to develop an adjuvanted, protein-based vaccine candidate and started a Phase 3 trial in Q2. We are also working in collaboration with SK Bioscience. SK Bioscience receives funding from CEPI and the Bill and Melinda Gates Foundation to develop differentiated, affordable COVID-19 vaccines for supply globally through the COVAX facility. In August 2021 we began phase 3 testing following review of positive interim phase 1/2 data. The use of an adjuvant can be of particular importance in a pandemic since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and contributing to protecting more people.

GSK is also working with mRNA specialist, CureVac, to jointly develop next generation, multi-valent mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine. GSK will also support manufacturing of up to 100m doses of CureVac's first generation COVID-19 vaccine. GSK is also



providing manufacturing support for up to 60m doses of Novavax' COVID-19 vaccine in the UK. GSK is also exploring potential therapeutic or treatment options for COVID-19 patients. We are collaborating with Vir Biotechnology to develop existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options for COVID-19. We reported that an Independent Data Monitoring Committee recommended that the Phase 3 COMET-ICE trial evaluating Xevudy as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalisation be stopped for enrolment due to evidence of profound efficacy, based on an interim analysis of data from the trial. An analysis of data through Day 29 of the COMET-ICE trial was consistent with interim results. We have received Emergency Use Authorisation in the U.S. and have received temporary authorisations in other countries and a provisional marketing authorisation in Australia.

About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com/about-us.

References

- ¹ Review report: COMET-ICE study (overseas clinical trial) (Approved in 2021, CTD2.7.3.2.1)
- ² Review report: COMET-ICE study (overseas clinical trial) (Approved in 2021, CTD2.7.4.2.1.2)
- ³ Andrea L.C. et al. ,The dual function monoclonal antibodies VIR-7831 and VIR-7832 demonstrate potent in vitro and in vivo activity against SARS-CoV-2, bioRxiv, 2021.preprint: <https://doi.org/10.1101/2021.03.09.434607>