PRESS RELEASE

For media

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GlaxoSmithKline K.K.

GSK Japan Announces Submission of Monoclonal Antibody Sotrovimab to the Ministry of Health, Labour and Welfare (MHLW) for Approval

- **Sotrovimab is a single dose monoclonal antibody for the treatment of COVID-19**
- **Application submitted for Special Approval for Emergency (SAE)**

GlaxoSmithKline K.K. (Representative Director & President: Paul Lirette; Head Office: Minato-ku, Tokyo; hereinafter "GSK Japan") today announced that it has submitted an application for approval to the Japanese Ministry of Health, Labour and Welfare (MHLW) for sotrovimab, a single-dose, monoclonal antibody, for the treatment of COVID-19. GSK Japan seeks to obtain Special Approval for Emergency (SAE) for this application.

The application of sotrovimab in intravenous infusion formulation was submitted 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.

Sotrovimab 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]

Sotrovimab binds to a highly conserved region of the spike protein, which provides a high barrier against variants. Data from *in vitro* studies published in bioRxiv[2] shows that sotrovimab 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.

Paul Lirette, GSK Japan's President, said, "As the pandemic is being prolonged with the emergence of new variants and the increasing number of infected people, we are doing our best to bring sotrovimab as a new treatment option to Japanese patients as soon as possible. "

Sotrovimab is authorized for emergency use in the U.S., has a positive scientific opinion from the Committee for Human Medicinal Products (CHMP) in the European Union (EU), and has also been granted temporary authorisation in Canada, Italy, Singapore, the United Arab Emirates and other countries. It has also received marketing authorization in Australia.

-End of release-

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, by allowing the post-approval submission of documents for approval (excluding clinical studies results). These medical products must meet the following requirements: 1. they are needed in an emergency to prevent the spread of diseases; 2. no appropriate alternative means other than the use of the relevant medical product is available; and 3. they have been approved for sale overseas.*article 14-3(1) of the Pharmaceutical and Medical Device Act

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. An earlier stage collaboration with SK Bioscience is also ongoing. 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. 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 sotrovimab 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 authorisations in other countries.

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.

[1] 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/
[2] 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