PRESS RELEASE

GSK Singapore Announces Additional Supply of Monoclonal Antibody Sotrovimab to the Government of Singapore

- GSK Singapore is contracted to supply the Government of Singapore with additional doses of sotrovimab, following the first purchase placed by the Ministry of Health (MOH) in June 2021
- Sotrovimab was approved by the Singapore Health Sciences Authority (HSA) under the Pandemic Special Access Route (PSAR) for interim authorization in June 2021

SINGAPORE, December 7, 2021 – GlaxoSmithKline Singapore announced an agreement with the Government of Singapore to supply additional doses of sotrovimab. Sotrovimab is an investigational single-dose monoclonal antibody developed in partnership with Vir Biotechnology, for the treatment of patients with COVID-19 who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19. This follows the initial purchase agreement signed between GSK Singapore and the government in June 2021.

Priya Kudva Menon, VP and General Manager, GSK Singapore, said: "As we move into the endemic stage of COVID-19 in Singapore, it is clear that multiple treatment options are needed to manage the impact of this virus on people and communities, in addition to vaccinations and other preventative measures. We are proud to continue partnering with the Singapore government to supply our monoclonal antibody and to support Singapore's healthcare system as the country continues to open up."

Dr Leong Hoe Nam, infectious disease specialist, Rophi Clinic, Mount Elizabeth Novena Hospital, said: "Early treatment of patients with COVID-19 has been shown consistently to reduce the risk of progressing to severe disease. As we transition to endemic COVID-19, we would experience individuals who remain unvaccinated or do not mount a sufficient immune response following vaccination. Treatments like sotrovimab is an extremely useful armament in our fight against COVID-19. I'm glad to learn of the Singapore government's successful procurement of yet another effective treatment option. It will further protect and save the lives of many Singaporeans."

In June 2021, GSK Singapore signed the first purchase agreement with the MOH for the supply of sotrovimab. Sotrovimab also received interim authorization approval from the Singapore HSA under the Pandemic Special Access Route (PSAR) in June.

GSK recently announced preclinical data that demonstrates sotrovimab retains activity against key mutations of the new Omicron SARS-CoV-2 variant (B.1.1.529), including those found in the binding site of sotrovimab. These data were generated through pseudo-virus testing of specific individual mutations found in Omicron. To date, sotrovimab has demonstrated ongoing activity against all tested variants of concern and interest defined by the World Health Organization (WHO). GSK and Vir are now completing in vitro pseudo-virus testing to confirm the neutralising activity of sotrovimab against the combination of all the Omicron mutations with the intent to provide an update by the end of 2021.

Sotrovimab was deliberately designed with a mutating virus in mind. By targeting a region of the spike protein that is shared between distantly related coronaviruses (including SARS, SARS-CoV-2 and animal sarbecoviruses), the sotrovimab binding site is less likely to mutate.

End of press release

Note to media: Below is additional background information.

About sotrovimab

Sotrovimab is an investigational SARS-CoV-2 neutralising monoclonal antibody. The antibody binds to an epitope on SARS-CoV-2 shared with SARS-CoV-1 (the virus that causes SARS), indicating that the epitope is highly conserved, which may make it more difficult for resistance to develop. Sotrovimab, which incorporates Xencor's Xtend™ technology, has also been designed to achieve high concentration in the lungs to ensure optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life.

Updated in vitro data, published in bioRxiv, demonstrate that sotrovimab retains activity against all current tested variants of concern and interest of the SARS-CoV-2 virus as defined by WHO, plus others, including but not limited to Delta (B.1.617.2), Delta Plus (AY.1 or AY.2), Mu (B.1.621) and key mutations of Omicron (B.1.1.529).

About the sotrovimab clinical development programme

- COMET-ICE: a Phase III, multi-centre, double-blind, placebo-controlled trial investigated intravenous (IV) infusion of sotrovimab in adults with mild-to-moderate COVID-19 at high-risk of progression to severe disease, who are not hospitalised and not requiring oxygen. The final COMET-ICE trial results in the full trial population of 1,057 participants 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. Interim data were published in *The New England Journal of Medicine* on October 27, 2021 and final data were pre-published on November 8, 2021 on *medRxiv*.
- COMET-TAIL: a Phase III randomised, multi-centre, open label, non-inferiority trial of intramuscular (IM) versus intravenous (IV) administration of sotrovimab for the early treatment of mild-to-moderate COVID-19 in high-risk non-hospitalised adult and paediatric patients (12 years of age and older). The trial's primary endpoint was met, and headline data demonstrated that intramuscularly administered sotrovimab was non-inferior and offered similar efficacy to intravenous administration for high-risk populations. The COMET-TAIL trial enrolled a total of 983 patients up to seven days after onset of symptoms. The companies plan to submit the full COMET-TAIL data set to a peer-reviewed journal for publication in the first quarter of 2022.

- COMET-PEAK: a Phase II randomised, multi-centre, parallel group trial evaluating IV and IM administration of sotrovimab in outpatients with mild-to-moderate COVID-19. Data available to date from open label Part B of the trial (500mg IV vs. 500mg IM) demonstrated equivalence on the virological response between the IM and IV arms, while also showing an acceptable tolerability profile for IM with only 10/82 participants (12%) reporting any injection site reaction, all of which were low grade (Grade 1). The companies plan to submit the full COMET-PEAK data set to a peer-reviewed journal for publication.
- GSK and Vir are also partnering to investigate the use of sotrovimab in uninfected immunocompromised adults to determine whether sotrovimab can prevent symptomatic COVID-19 infection. GSK and Vir are supporting investigator sponsored studies and fostering scientific collaborations with both experienced investigators and networks, who are involved in the continuum of care of immunocompromised patients, to understand the role sotrovimab for prophylaxis could play in this population. Discussions with regulatory authorities regarding the prophylaxis program will take place in due course.

About global access to sotrovimab

- Sotrovimab is authorised for emergency use in the United States and received a positive scientific opinion under Article 5(3) of Regulation 726/2004 from the Committee for Human Medicinal Products (CHMP) in the EU. Sotrovimab has been granted a provisional marketing authorisation in Australia and a conditional marketing authorisation in Saudi Arabia. In Japan it has been approved via the Special Approval for Emergency Pathway. Temporary authorisations have been granted in Bahrain, Brazil, Canada, Egypt, Italy, Kuwait, Oman, Qatar, Singapore, Switzerland, Thailand and the United Arab Emirates.
- Sotrovimab is supplied in several countries around the world, including through national agreements in the United States, Japan, Australia, Canada, Singapore and UAE. We have also signed a Joint Procurement Agreement with the European Commission to supply doses of sotrovimab. Other agreements are yet to be announced due to confidentiality or regulatory requirements.

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.

PRESS RELEASE

GSK Commitment to Tackling COVID-19

GSK's response to COVID-19 has been one of the broadest in the industry, with potential 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. We are working with Sanofi, Medicago and SK bioscience to develop adjuvanted, protein-based vaccine candidates, and all are now in Phase III clinical trials. 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 protect more people in need.

GSK is also working with mRNA specialist, CureVac, to jointly develop next generation, optimised mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine. GSK is also exploring treatments for COVID-19 patients, collaborating with Vir Biotechnology to investigate monoclonal antibodies that could be used as therapeutic or preventive options for COVID-19.

About GSK

GSK is a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

GSK cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020, GSK's Q3 Results and any impacts of the COVID-19 pandemic.

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