

GSK Singapore and Vir Biotechnology Announce Advance Purchase Agreement with the Government of Singapore for Monoclonal Antibody Sotrovimab (VIR-7831)

- GSK Singapore has signed an Advance Purchase Agreement with the Government of Singapore for sotrovimab
- Sotrovimab is currently undergoing review by the Singapore Health Sciences Authority (HSA) under the Pandemic Special Access Route (PSAR) for interim authorization
- Announcement follows the emergency use authorization (EUA) granted to sotrovimab by the US Food and Drug Administration (FDA) and a positive scientific opinion by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP)

SINGAPORE, June 30, 2021 – GlaxoSmithKline Singapore and Vir Biotechnology announced an agreement with the Government of Singapore for the supply of sotrovimab, an investigational single-dose monoclonal antibody, 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.

“We are proud to have entered into this agreement with Singapore to supply sotrovimab. This is another example of Singapore’s role in the global innovation ecosystem and their commitment to invest in innovation,” said Mike Crichton, SVP Specialty and Primary Care Therapy Area, GSK. “As variants continue to arise, vaccines together with the availability of safe and effective monoclonal antibody treatments have the potential to increase the chance of ending the pandemic. We’re committed to partnering with the government of Singapore to make this important treatment option available to its citizens and to be part of its long-term solution to manage COVID-19.”

“We are very pleased to be working with the Singapore government to ensure that patients who are ill with COVID-19 have access to the most recent therapeutic options,” said Phil Pang, chief medical officer of Vir Biotechnology. “Sotrovimab was designed from the beginning to combat COVID-19 as it evolved, and, based on our most recent in vitro data, we are heartened to see that it appears to retain activity against all circulating variants of concern.”

GSK Singapore has submitted an application under the Pandemic Special Access Route (PSAR) for sotrovimab to the Health Sciences Authority of Singapore (HSA). Sotrovimab is currently undergoing regulatory review for interim authorization under the PSAR.

The PSAR application includes submission of data from an interim analysis of efficacy and safety data from the Phase 3 COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early) trial, which was stopped early by an independent data monitoring committee in March due to evidence of profound clinical efficacy. Results of the interim analysis, based on data from 583 randomised patients, demonstrated an 85% ($p=0.002$) reduction in hospitalisation or death in those receiving sotrovimab compared to placebo, the primary endpoint of the trial. The PSAR review will also consider the medicine’s quality and safety data. COMET-ICE final results will be available later this year.

Preclinical data suggest sotrovimab targets a conserved epitope of the SARS-CoV-2 spike protein which is less likely to mutate over time. Data from several in vitro studies demonstrated that sotrovimab maintains activity against multiple circulating variants of concern, including the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), and Delta (B.1.617.2) variants, based on in vitro data from live virus and pseudotyped virus assays. The clinical impact of these variants is not yet known. Data collection and analysis is still ongoing.

On 26 May, the US Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) to sotrovimab. The European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive scientific opinion following the referral of sotrovimab to the CHMP under

Article 5(3) of Regulation 726/2004. The CHMP opinion under Article 5(3) can now be considered by the national authorities in EU member states when taking evidence-based decisions on the early use of the medicine prior to marketing authorisation.

GSK and Vir are in discussions with other governments to explore similar supply agreements, as countries accelerate their vaccine and therapeutics programmes against COVID-19.

End of press release

Note to media: Below is additional background information.

About the COMET-ICE Study Design

The multi-center, double-blind, placebo-controlled, Phase 3 COMET-ICE trial investigated intravenous (IV) infusion of sotrovimab in adults with mild or moderate COVID-19 at high risk of progression to severe disease.

This ongoing trial evaluated the safety and efficacy of a single IV infusion of sotrovimab (500 mg) or placebo in non-hospitalized participants globally. The safety of sotrovimab is primarily based on an interim analysis from 868 patients (430 patients in the treatment arm and 438 in the placebo arm) through Day 29. Among those studied, 63% were Hispanic or Latino and 7% were Black or African American. According to the US Centers for Disease Control and Prevention, these populations are approximately three times more likely to be hospitalized and approximately two times more likely to die of COVID-19. The primary efficacy endpoint was the proportion of patients who have progression of COVID-19 as defined by the need for hospitalisation for at least 24 hours or death within 29 days of randomisation.

The only event to occur with a frequency of greater than 1% in the sotrovimab arm was diarrhoea (less than 1% in placebo group). All other adverse events with a frequency of greater than 1% occurred in the placebo arm. No other treatment-emergent adverse events were reported at a higher rate with sotrovimab compared to placebo. The EUA includes a warning for hypersensitivity including anaphylaxis and infusion-related reactions. Sotrovimab's safety and efficacy is continuing to be studied in ongoing clinical trials with analysis of safety and efficacy data at Day 29 for the full population from COMET-ICE expected as early as the first half of 2021.

About the Sotrovimab Clinical Development Program

In addition to the COMET-ICE trial, the full COMET clinical development program for sotrovimab includes:

- COMET-PEAK: An ongoing Phase 2 trial with two parts: to compare the safety and viral kinetics of 500 mg intramuscularly (IM) administered sotrovimab to 500 mg intravenously administered sotrovimab among low-risk adults with mild to moderate COVID-19 and to evaluate the similarity in pharmacokinetics between sotrovimab manufactured by different processes
- COMET-TAIL: A Phase 3 trial expected to begin in the second quarter of 2021 as an early treatment for COVID-19 in high-risk adults to assess whether IM-administered sotrovimab can reduce hospitalisation or death due to COVID-19
- COMET-STAR: A Phase 3 trial expected to begin in the third quarter of 2021 in uninfected adults at high risk to determine whether IM-administered sotrovimab can prevent symptomatic infection.

Sotrovimab was also evaluated in the outpatient setting in BLAZE-4, a Phase 2 trial sponsored by Eli Lilly and Company, designed to assess the safety and efficacy of bamlanivimab (LY-CoV555) alone and bamlanivimab with other neutralizing antibodies, including sotrovimab, versus placebo in low-risk adults

with mild to moderate COVID-19. An interim analysis found that bamlanivimab (700 mg) co-administered with sotrovimab (500 mg) demonstrated a 70% relative reduction of patients with persistently high viral load at day 7 compared to placebo, meeting the primary endpoint.

Additionally, sotrovimab, along with VIR-7832 is being evaluated in the Phase 1b/2a National Health Service-supported AGILE trial in adults with mild to moderate COVID-19. VIR-7832 (GSK4182137) is the second monoclonal antibody from the Vir-GSK collaboration to be investigated as a potential COVID-19 treatment.

About Sotrovimab (previously VIR-7831)

Sotrovimab is an investigational SARS-CoV-2 monoclonal antibody. Preclinical data suggest it has the potential to both block viral entry into healthy cells and clear infected cells. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (the virus that causes SARS), indicating that the epitope is conserved, which may make it more difficult for resistance to develop. Sotrovimab, which incorporates Xencor's Xtend™ technology, also has 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.

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 three potential treatments in addition to our vaccine candidates in development.

GSK is collaborating with several organisations on COVID-19 vaccines by providing access to our adjuvant technology. In addition to our work with Medicago, a collaboration with Sanofi on an adjuvanted, protein-based vaccine candidate is now in Phase 2. 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 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 recently 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. We

have received Emergency Use Authorisation in the US and are seeking authorisations in other countries. We are also assessing whether an investigational monoclonal antibody, otilimab, can help severely ill COVID-19 patients aged over 70 who experience an overreaction of their immune system.

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.

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 and any impacts of the COVID-19 pandemic.

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