



## **Sotrovimab (VIR-7831), an Investigational Antibody Utilizing Xencor's Xtend™ Technology, Receives U.S. FDA Emergency Use Authorization for the Treatment of COVID-19**

May 26, 2021

*-- Vir Biotechnology and GlaxoSmithKline's investigational SARS-CoV-2 antibody, engineered with the Xencor XmAb® Fc technology, Xtend™, is authorized for treatment of mild-to-moderate COVID-19 in high-risk adults and pediatric patients --*

*-- Treatment with sotrovimab resulted in an 85% reduction in the risk of hospitalization or death in high-risk adult outpatients compared to placebo, based on interim results from Phase 3 COMET-ICE trial --*

*-- Xencor to receive royalties on worldwide net sales --*

MONROVIA, Calif.--(BUSINESS WIRE)--May 26, 2021-- Xencor, Inc. (NASDAQ: XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies and cytokines for the treatment of cancer and autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted an emergency use authorization (EUA) for sotrovimab (previously VIR-7831), an XmAb®-engineered antibody developed by Vir Biotechnology, Inc. (Vir) and GlaxoSmithKline plc (GSK). Sotrovimab has not been approved, but has been authorized for emergency use by the FDA under an EUA, to treat mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Xencor has provided Vir non-exclusive licenses to XmAb Fc technologies, including Xtend™, designed to enhance the half-life of novel antibodies being investigated as potential treatments for patients with COVID-19.

"We are proud that Xtend technology was integrated into sotrovimab for the purpose of reducing the dose administered and potentially enhancing its lung tissue bioavailability and are grateful to Vir and GSK for advancing this important medicine. Xtend has demonstrated, in multiple antibodies and through numerous human clinical trials, the ability to extend antibody drug half-life and reduce dosing frequency in patients, an important feature in anti-viral therapy for pandemic use," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor. "Our partnership with Vir exemplifies our commitment to enabling the broad use of XmAb Fc technologies and to rapidly developing potential treatments for COVID-19 and other serious infectious diseases. Though the vaccine rollout is underway, antibody treatments remain an important therapeutic measure to reduce the number of hospitalizations and deaths due to COVID-19."

Vir and GSK are evaluating sotrovimab in an extensive ongoing clinical development program. In March 2021, the partners submitted an EUA application to the FDA based on 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 demonstrated an 85% reduction in hospitalization for more than 24 hours or death in high-risk adults receiving sotrovimab compared to placebo, the primary endpoint of the trial.

The emergency use of sotrovimab is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

### **License Agreement with Vir Biotechnology, Inc.**

Xencor previously entered into a technology license agreement with Vir Biotechnology, Inc., pursuant to which Vir has non-exclusive access to multiple Xencor Fc technologies, including Xtend™ Fc technology, designed to extend the half-life of novel antibodies that Vir is investigating as potential treatments for patients with COVID-19. Under the terms of the agreement, Vir is solely responsible for the activities and costs related to research, development, regulatory and commercial activities for their COVID-19 drug candidates, and Xencor is eligible to receive royalties on net sales in the mid-single digit percent range.

Vir is also developing and commercializing antibodies with Xencor's Fc technologies as potential treatments for patients with influenza and hepatitis B virus infection. Vir is solely responsible for the activities and costs related to research, development, regulatory and commercial activities for these additional candidates, and Xencor is eligible to receive development, regulatory and sales-based milestone payments, as well as royalties on net sales in the low- to mid-single digit percent range.

### **About Xtend™ XmAb® Fc Technology**

Xencor's Xtend™ XmAb® Fc domains have been shown to increase circulating half-life by increasing binding affinity to the receptor FcRn. FcRn is present inside lysosomes in endothelial cells lining the blood vessels and functions to rescue antibodies from the degradation that makes most proteins short-lived in circulation. Half-life extension can be exploited to potentially improve therapeutic antibody performance in several ways, such as increasing dosing interval or decreasing drug quantities at the same dosing interval compared to a parent antibody. Xtend technology is currently in

multiple clinical-stage programs and one approved therapy, Alexion's Ultomiris<sup>®</sup> (ravulizumab-cwvz).

### **About Cytotoxic XmAb<sup>®</sup> Fc Technology**

Xencor's Cytotoxic XmAb<sup>®</sup> Fc domain is designed to improve the immune system's elimination of tumor and other pathologic cells by antibody-dependent cellular cytotoxicity (ADCC). The Cytotoxic Fc domain is engineered to increase binding affinity to activating Fcγ receptors to enhance activation of natural killer (NK) cells and other immune cells such as macrophages, which play a role in immunity by engulfing and digesting foreign material. Xencor's cytotoxic Fc technology is currently in multiple clinical-stage programs and one approved therapy, MorphoSys' Monjuvi<sup>®</sup> (tafasitamab-cxix).

*Ultomiris<sup>®</sup> is a registered trademark of Alexion Pharmaceuticals, Inc. Monjuvi<sup>®</sup> is a registered trademark of MorphoSys AG.*

### **About Xencor, Inc.**

Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies and cytokines for the treatment of cancer and autoimmune diseases. Currently, 22 candidates engineered with Xencor's XmAb<sup>®</sup> technology are in clinical development internally and with partners. Xencor's XmAb antibody engineering technology enables small changes to the structure of proteins resulting in new mechanisms of therapeutic action. For more information, please visit [www.xencor.com](http://www.xencor.com).

### **Forward-Looking Statements**

Certain statements contained in this press release may constitute forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include statements that are not purely statements of historical fact, and can generally be identified by our use of words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "seek," "look forward," "believe," "committed," "investigational," and similar terms, or by express or implied discussions relating to the efficacy of sotrovimab (VIR-7831), Xtend's ability to enhance the immune function of novel antibodies, including by extending antibody drug half-life and reducing dosing frequency in patients, the ability of XmAb Fc technologies, generally, to enhance antibody effectiveness and facilitate the rapid development of potential treatments for COVID-19 and other serious infectious diseases, the importance of antibody treatments to reduce the number of hospitalizations and deaths due to COVID-19, Xencor's eligibility to receive royalties and sales-based milestone payments under its agreements with Vir, as well as the likelihood, timing and magnitude of such payments, and other statements that are not purely statements of historical fact. Such statements are made on the basis of the current beliefs, expectations, and assumptions of the management of Xencor and are subject to significant known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements and the timing of events to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. Such risks include, without limitation, the risks associated with the process of discovering, developing, manufacturing and commercializing drugs that are safe and effective for use as human therapeutics and other risks described in Xencor's public securities filings. For a discussion of these and other factors, please refer to Xencor's annual report on Form 10-K for the year ended December 31, 2020 as well as Xencor's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended to date. All forward-looking statements are qualified in their entirety by this cautionary statement and Xencor undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

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