



ExeVir Announces First Patient Enrolled in Phase 1b/2 Clinical Study evaluating XVR011 as antiviral treatment of patients hospitalised for COVID-19

Belgium, 1 September 2021: ExeVir, which is developing single domain antibody therapies providing broad protection against viral infections, today announces that the first patient has been treated in a Phase 1b/2 global clinical study of XVR011, its potent COVID-19 neutralizing antibody.

EXEVIR0101 is a two-part study, which will evaluate the safety and efficacy of XVR011 in neutralising the SARS-CoV-2 virus in patients hospitalized as a result of mild to moderate COVID-19, with the aim to allow a more rapid recovery. Phase 1b of the study in conjunction with the Phase 1a study in healthy volunteers, which was recently started, will inform and broaden the safety database for XVR011 as well as provide important antiviral and clinical activity data before the current study proceeds to Phase 2 which will evaluate both efficacy and safety.

The Phase 1b study will enrol up to 27 patients with mild to moderate symptoms caused by the SARS-CoV-2 coronavirus. The study will sequentially evaluate three different doses of intravenously administered XVR011 with the primary endpoint of proportion of patients with adverse events. Secondary endpoints include viral load, need for oxygen supplementation, clinical score (8-point ordinal scale) and other measures of clinical activity. Upon a positive recommendation from the independent data monitoring committee, the study will roll over into the Phase 2 part in 252 patients which will evaluate the efficacy at the dose selected from Phase 1b. Further details of the study can be found on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04884295) under the identifier [NCT04884295](https://clinicaltrials.gov/ct2/show/study/NCT04884295)

Dominique Tersago, Chief Medical Officer of ExeVir Bio, said: “Treatments for patients admitted to hospital for mild to moderate COVID-19 are still urgently needed and we are very pleased that our lead compound XVR011 is now being evaluated in this setting. XVR011 was recently demonstrated to neutralise the Delta variant *in vitro*, as well as all current COVID-19 variants of concern and we look forward to confirming the activity in the clinic. Our study is designed to rapidly treat eligible patients upon admission to hospital with the aim to curtail the infection and allow a faster recovery and avoid progression to more severe disease. We remain committed to bringing a next generation, single-dose treatment to patients with COVID-19.”

The XVR011 molecule was developed by VIB-Ghent University (Belgium) scientists led by Professors Xavier Saelens and Nico Callewaert. They also showed that based on epitope sequencing, the potency is not expected to be impacted by any currently circulating variant of concern or variant of interest. This has been confirmed recently in the laboratory of Professor Johan Neyts at the Rega institute (KU Leuven, Belgium) with data that show XVR011 has strong *in vitro* neutralization potency against the variants of concern Delta, Alpha, Beta and Gamma.

The Belgian-based global biopharmaceutical company UCB helped design and optimize the therapeutic properties of XVR011 and manufactured the antibody at large scale for the clinical trial. The development work is presently undergoing peer review and was recently pre-printed



in [BioRxiv](#), demonstrating highly potent and broad neutralizing activity and infection protection in both hamster and mouse models against SARS-CoV-2.

-ENDS-

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About XVR011 (VHH72-Fc)

ExeVir's lead asset XVR011 is a single domain-based anti-SARS-CoV-2 antibody (VHH-Fc) optimized for stability, safety, broad neutralizing capability and excellent manufacturability. It demonstrates best-in-class potential offering breadth and potency against a range of Coronaviruses and is significantly differentiated from other antibody treatments.

- The single domain antibody (VHH) anti-coronavirus platform was developed by VIB- Ghent University scientists, Professor Xavier Saelens and Professor Nico Callewaert.
- The llama-derived single-domain antibodies are smaller than human antibodies and can attach to parts of a virus that are difficult to access for the human immune system.
- XVR011 inactivates SARS-CoV-2 spike proteins and sterically blocks spike binding to ACE2, preventing virus from entering a human cell, stopping viral replication; this is expected to support the patient's own immune response in a critical time window during which many patients' immune system reacts too slowly or inadequately.
- Epitope of XVR011 is much less susceptible to human antibody immune pressure that can lead to "viral escape", resulting in retained potency against such escape variants – No impact of any variants of concern on potency as of today.
- XVR011: Targets unique epitope in conserved region, leading to broad spectrum of binding to spike RBDs across numerous sarbecoviruses.

About ExeVir Bio

ExeVir Bio is a clinical stage company harnessing its VHH technology platform to generate robust antiviral therapies providing broad protection against viral infections, including coronaviruses. It is a spin out from VIB, the world class Belgium-based life sciences research institute. ExeVir's platform is based on the work of and collaboration with Professor Dr. Xavier Saelens and Professor Dr. Nico Callewaert from VIB. ExeVir Bio is led by a team of experts that combines international biotech and pharma experience with a successful track record of developing and bringing products to market. It has raised over €42M from blue chip investors led by Fund+, VIB, UCB Ventures, SFPI-FPIM, V-Bio Ventures, SRIW, Noshag, Vives IUF, SambrInvest and several Belgian Family Offices. ExeVir has also been awarded funding from the Flanders Agency for Innovation & Entrepreneurship (VLAIO). www.exevir.com.

About UCB



UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8000 people operating in approximately 40 countries, the company generated revenue of € 5.3 billion in 2020. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news