ExeVir's CRO hunt for Phase II/III COVID-19 subQ antibody trial to start midyear, also USD 50–100m Series B raise, CEO says

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- Parexel is CRO for Phase Ib/II IV XVR011 trial
- Dose-ranging Phase Ib IV data likely available by June

ExeVir Bio will open its doors to CRO pitches mid-year for a Phase II/III trial investigating its subcutaneously administered neutralizing antibody XVR011 in outpatient COVID-19 patients, CEO Torsten Mummenbrauer said. Decisions will be made in 2H21 for a 2Q22 trial start, he added. **Parexel** (NASDAQ:PRXL) is the CRO for the Phase Ib/II trial studying an intravenous version of XVR011 in hospitalized COVID-19 patients, with the trial slated to begin in the coming weeks and Phase Ib data likely to be available by June, he noted.

Ghent, Belgium-based ExeVir will also likely initiate a USD 50–100m Series B raise starting mid-year, which would close by the end of the year, Mummenbrauer added. The raise will fund subcutaneous (subQ) XVR011 development, commercial manufacturing, and infectious diseases pipeline development beyond COVID-19, he said.

The successful Phase II/III subQ XVR011 CRO would provide a full service and be equipped in running global clinical trials during the pandemic, Mummenbrauer said. CRO experience in staging outpatient trials is important as the Phase II/III will recruit such patients, he added. The Phase I subQ XVR011 trial in healthy volunteers will start in 1Q22, but will not need a CRO, he said.

Parexel is managing the Phase Ib/II intravenous (IV) XVR011 trial because it has a record of staging clinical trials effectively during the pandemic, and operates quickly at a high standard, Mummenbrauer said. It has the capacity and expertise to provide a close and tailored service to ExeVir, he said, adding that the CRO is providing a full service. Parexel will be considered in the Phase II/III subQ trial should it apply, he said.

The Phase Ib portion of the IV XVR011 study will determine the dosing of XVR011, Mummenbrauer said. It will dose patients with either 250mg, 500mg, or 1g of XVR011, he added. The Phase II portion is designed as a registrational trial, and so will be randomized, blinded and placebo-controlled, he said. The Phase Ib/II will recruit in six European countries, Brazil, South Africa, the US, and potentially Mexico, he added.

XVR011 is a neutralizing antibody that binds to the spike protein of the SARS-CoV-2 virus, preventing it from entering human cells. There is preclinical data showing it can neutralize the virus and prevent SARS-CoV-2 infection, even variants of concern, Mummenbrauer said.

Series B to help catapult ExeVir into manufacturing

As for the Series B, the raise will also help ExeVir explore commercial manufacturing for it to become a product-generating company by next year, Mummenbrauer said. ExeVir is looking for large international investors in the US and Europe, he said. Mummenbrauer declined to put a figure on the stake ExeVir would be willing to sell in the Series B.

The company will be including previous Series A investors in the Series B, and is open to discussions with banks, Mummenbrauer said. On 16 March, ExeVir announced it completed a USD 50m Series A with participation from Belgium-based firms Fund+, Noshaq, SRIW, SambrInves, SFPI-FPIM, UCB Ventures, research institute VIB, V-Bio Ventures, and Vives IUF.

An initial public offering in the US or Europe is an option moving forward, and so ExeVir would be interested in speaking with crossover investors, Mummenbrauer said. If the listing were to happen in the US, it would be on the NASDAQ, he added.

ExeVir is also on the lookout for partners who can support XVR011's manufacturing and commercialization, Mummenbrauer said. The company is already in early-stage discussions with two potential partners in low- and middle-income countries, he said.

In developed countries, ExeVir would be looking at engaging with large pharmaceutical companies, Mummenbrauer said. The partnership hunt would likely start after Phase I intravenous trial data is revealed, he added. In the COVID-19 space, he pointed to **Roche's** (SIX:ROG) partnership with **Regeneron Pharmaceuticals** (NASDAQ:REGN) or **Pfizer's** (NYSE:PFE) partnership with **BioNTech** (NASDAQ:BNTX) as examples of strong manufacturing and commercialization partnerships.

by Sean Rai-Roche in London

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