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ASIA EDITION

Samsung Biologics , TG Therapeutics address potential global demand for mAb ublituximab

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Expanding upon an existing contract manufacturing deal first entered into in 2018



South Korea based Samsung Biologics, the world's leading contract development and manufacturing organization and US based TG Therapeutics, have announced an expansion of a large-scale contract manufacturing deal for the supply of TG Therapeutics' ublituximab, an investigational anti-CD20 monoclonal antibody (mAb).

TG Therapeutics has completed a rolling submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) requesting approval of ublituximab, in combination with UKONIQTM (umbralisib), TG Therapeutics' oral once-daily inhibitor of PI3K-delta and CK1-epsilon, as a treatment for patients with CLL, based primarily on the positive results from the UNITY-CLL Phase 3 trial.

Ublituximab was also the subject of two successful Phase 3 trials in patients with relapsing forms of multiple sclerosis (RMS) and a BLA is currently being prepared for this indication.

"We are very glad to be able to flexibly accommodate our client's expanded needs through our facilities," John Rim, CEO of Samsung Biologics, commented. Rim added, "By supporting TG Therapeutics in this partnership, we are contributing to bringing needed treatments to patients around the world and getting a step closer to our vision of bringing about a better life for humanity."

In order to support all its current and potential clients around the world, Samsung Biologics is currently building its fourth and largest biomanufacturing facility in Incheon, Korea. Upon completion of the said plant in 2023, Samsung Biologics will hold 620,000 liters of biomanufacturing capacity, or approximately a quarter of the entire bio-CMO capacity globally. The company provides contract manufacturing, contract development, and testing services all from a single location, offering end-to-end services for its clients.