PRESS RELEASE

ProBioGen's GlymaxX® Technology reaches Phase III Clinical Development

Berlin, December 17, 2021:

ProBioGen, a leading technology developer and CDMO for cell line development through GMP manufacturing announces an important clinical milestone for its GlymaxX antibody-dependent cellular cytotoxicity (ADCC) enhancement technology. With Zymeworks' recently announced global Phase III clinical trial of zanidatamab in HER2-expressing gastroesophageal adenocarcinoma, the GlymaxX technology also reaches Phase III Clinical Development. ProBioGen completed cell line development for Zanidatamab in 2018 using its CHO.RiGHT® expression platform as well as applying its GlymaxX glyco-engineering technology to boost ADCC and cancer cell killing. GlymaxX is available under a non-exclusive license.

ProBioGen's CHO.RiGHT expression and analytical platform is perfectly suited for multispecific formats and complements Zymeworks' Azymetric™ technology platform for the development of bispecific and multispecific antibodies. The joint power of the two platforms resulted in a stable master cell bank, producing high purity of the zanidatamab heterodimer at high titers that exceeded expectations.

"Starting a Phase III clinical trial is an important milestone and we are proud to have successfully contributed to it. For ProBioGen, this is yet another cell line and GlymaxX-enhanced bispecific format demonstrating clinical validation", said Dr. Volker Sandig, Chief Scientific Officer at ProBioGen.

Mark Hollywood, Zymeworks' Senior Vice President, Technical and Manufacturing Operations added: "ProBioGen has been an important partner in the manufacturing of zanidatamab. Their cell line development platform and their innovative GlymaxX technology provided us with a high-quality cell line that contributed to the successful initiation of this Phase III trial."

About GlymaxX

ProBioGen developed the GlymaxX technology to optimize antibody activity, notably the enhanced antibody-mediated cell killing of cancerous or infected cells (known as "ADCC" activity). GlymaxX is based on the stable introduction into producer cells of a gene for an enzyme which blocks the cells' fucose biosynthesis pathway and hence the formation of the sugar "fucose". Consequently, no fucose is added to the antibody's N-linked carbohydrate part of the in-antibody producer cells. This absence of fucose in antibodies is known to greatly enhance ADCC.

As a unique feature, differentiating it from other approaches, GlymaxX can be applied to both novel or already existing antibody producer cell lines, and entire antibody expression and discovery platforms. GlymaxX does not negatively affect cellular productivity or other product characteristics. Furthermore, a GlymaxX cell line can be flexibly used to produce differently fucosylated products, depending on the upstream process: In fucose-free medium the antibody is literally afucosylated.

The same GlymaxX cell line grown in fucose-containing medium however, uses the provided fucose and produces fully fucosylated antibody. Thus, one GlymaxX cell line can be employed to produce several products: For instance ADCC-enhanced GlymaxX antibodies or wildtype-like, fully fucosylated mAbs, e.g. for a parallel Antibody-Drug-Conjugate (ADC) project. Moreover, GlymaxX has also been used to adjust the fucose level as wanted and by biosimilar-developing companies to match the originators glycoprofile. Overall, GlymaxX is simple, rapid, potent, and universally applicable to different CHO hosts and all other eukaryotic cell species. ProBioGen offers its GlymaxX technology royalty-free and non-exclusively as a service or as an individual license.

About ProBioGen

ProBioGen is a premier, Berlin-based specialist for developing and manufacturing complex therapeutic glycoproteins.

Combining both state-of-the-art development services, based on ProBioGen's CHO-RiGHT expression and manufacturing platform, together with intelligent product-specific technologies yields biologics with optimized properties.

Rapid and integrated cell line and process development, comprehensive analytical development and following reliable GMP manufacturing is performed by a highly skilled and experienced team. All services and technologies are embedded in a total quality management system to assure compliance with international ISO and GMP standards (EMA/FDA).

ProBioGen has been operational for more than 25 years. At two locations in Berlin, more than 200 employees contribute to the creation of new therapies in medicine and groundbreaking innovations worldwide through their creative and meticulous work.

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