PRESS RELEASE

ProBioGen's GlymaxX® Technology made it again into Clinical Phase I

Berlin, November 17, 2021:

ProBioGen, a premier CDMO for cell line development through GMP manufacturing which has also developed innovative technologies, announced that another product candidate applying its antibody-dependent cellular cytotoxicity (ADCC) enhancement technology GlymaxX has entered clinical development. Abcuro, a clinical-stage biotechnology company developing therapies for autoimmune diseases and cancer through precise targeting of cytotoxic T cells, recently announced initial data on ABC008, for which ProBioGen generated the production clone applying its proprietary GlymaxX technology and produced the GMP drug substance using its CHO.RiGHT® expression and manufacturing platform.

The CHO.RiGHT platform is perfectly suited for different kinds of complex biopharmaceuticals. ProBioGen´s sophisticated approach resulted in the generation of a stable, high titer producer clone and the manufacturing of high quality GMP drug substance with strongly enhanced ADCC.

"This phase I clinical trial is an important milestone for Abcuro, and we are proud to have successfully contributed to production of drug substance. We are currently observing a strong increase of ADCC-enhanced product candidates, a high number of which use our GlymaxX technology. Clinical applicability of this approach continues to be demonstrated by our clients.", said Dr. Lutz Hilbrich, Chief Executive Officer at ProBioGen.

David de Graaf, Ph.D., Abcuro's Chief Executive Officer added: "ProBioGen is an important partner in the generation of ABC008. Their expertise, passion and dedicated team, along with their innovative GlymaxX technology, provided high-quality drug substance material for our Phase 1 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 by 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 recombinant glycoproteins.

The combination of state-of-the-art development services based on ProBioGen's CHO.RiGHT expression and manufacturing platform and smart 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 sophisticated 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 230 employees contribute to the creation of new therapies in medicine and groundbreaking innovations worldwide through their creative and meticulous work.

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