ProBioGen
Intelligent Biopharmaceutical Solutions

GlymaxX®
Fucose Targeted Glyco-Engineering

PRESS RELEASE

ProBioGen Announces Successful Bispecific GlymaxX® Development Project for Zymeworks

Berlin, Germany, November 6th, 2018: ProBioGen AG, a premier service & technology provider for complex therapeutic antibodies and glycoproteins announced today that it has completed a cell line development project for one of Zymeworks Inc.'s bispecific antibody program which exceeded expectations. ProBioGen achieved the desired titers in classical fed-batch processes employing its industry-leading CHO.RiGHT® expression & manufacturing platform and its proprietary commercially available chemically defined medium platform. Further, ProBioGen's proprietary GlymaxX® ADCC enhancement technology was applied.

The project met the primary goals for the bispecific antibody cell line, which were achieving high titers and bispecific purity and maintaining stability during scale-up. Zymeworks is continuing further process development and large-scale production.

Dr. Wieland Wolf, ProBioGen's Chief Executive Officer, said, "We are very pleased to work with Zymeworks and their industry leading bispecific antibody technology. This project gave us the chance to fully exploit our skills, showcase the experience of our team and the quality of our CHO.RiGHT® expression & manufacturing platform, which we continuously improve and also to apply the unique GlymaxX® technology."

About ProBioGen AG – www.probiogen.de

ProBioGen is a premier, Berlin-based specialist for developing and manufacturing complex therapeutic glycoproteins. Combining both state-of-the-art development platforms, 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 was founded 1994, is privately owned and located in Berlin, Germany.

About GlymaxX® – www.glymaxx.com

ProBioGen developed the GlymaxX® technology to optimize antibody activity, notably the enhanced antibody-mediated cell killing or 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.

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