

PRESS RELEASE

ProBioGen Launches Unique Portfolio of Engineered High-Performance Cell Lines for Biopharmaceutical Manufacturing

Berlin, Germany, November 12th, 2012 - ProBioGen announces the launch of a comprehensive set of engineered, royalty-free biopharmaceutical CHO production cell lines, individually optimized for enhanced ADCC activity, adjusted galactosylation levels or increased production of the target antibodies or proteins. This elaborate cellular toolbox allows the rapid and targeted creation of antibody and protein molecules with specific pre-defined properties.

The cells fitness for purpose can either be proven via fee-for-service-based demonstration studies at ProBioGen or by providing the cell lines under research licenses to interested parties. The engineered cell lines are royalty-free and are suitable for clinical and commercial production. All engineered cells are based on ProBioGen's biopharmaceutical CHO platform of DG44 and K1 cell lines and can be freely combined with ProBioGen's stable expression vector system and chemically defined media platform.

Besides applying the described permanent cell modifications to newly created cells lines and molecules, all technologies can also be rapidly introduced into existing protein producer cell lines and even into any clients' own expression platforms.

CHO cells with the following modifications are available:

The *GlymaxX[®] technology* boosts antibody ADCC activity by preventing the addition of the sugar "fucose" to the N-linked antibody carbohydrate part in antibody-producing cells. The GlymaxX[®] technology is based on the introduction of a gene for an enzyme which deflects the cellular pathway of fucose biosynthesis. GlymaxX[®] is universally applicable to different CHO hosts and to any other eukaryotic cell line; it is also simple and potent. It can be applied in a few weeks to any existing antibody producer cell line, or can be included into newly developed cell lines. ProBioGen offers this technology royalty-free to third parties.

The *Galactosylation Adjustment Technology* is a genetically controlled way to adjust protein galactosylation levels through the additional presence of an enzyme in the producer cells (as opposed to media supplementation to influence galactosylation levels). CHO cells predominantly produce G0 structures (no Galactose molecules). Galactosylation adjustment can increase protein drug galactosylation to almost maximal extent (G2).

The gradual activity of this stably transfected enzyme allows a carefully adjusted or maximized galactosylation of antibodies or proteins. This is desirable e.g. for matching originators galactosylation levels when developing biosimilars, for half-life extension or other reasons.

The *Pathway Modulator Technology* is highly versatile and readily applicable to any animal cell line and, notably, even to existing producer cell lines, optimizing their productivity. It works through the additional expression of an engineered non-human enzyme in the producer cells. Upon stable transfection, the modulator enzymes' concerted action on several cellular pathways results in substantially enhanced volumetric productivities of protein drugs. For various monoclonal antibodies and fusion proteins tested in CHO, the stable modification increased yields between 1.3 and 2.6-fold.

About ProBioGen - www.probiogen.de

ProBioGen is an internationally operating technology provider and Contract Development and Manufacturing Organization (CDMO) with almost 20 years of experience in cell culture, process development, and GMP-manufacturing. ProBioGen is a competent and reliable CDMO partner, offering customized solutions for even the most challenging development and manufacturing requirements. This is backed by the company's established, fee-for-service-based CHO cell and media platform, and its innovative platform technologies, as well as the comprehensive portfolio of cell-based activity assays. 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 and is located in Berlin, Germany.

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