

# GlycoExpress

Expression system for  
new generations of  
highly active & fully human  
biologics

# Why **Glyco**Express ?

- Expression system to generate **fully human glycosylated** and **optimized sialylated** glycoproteins
- For optimization of:
  - activity
  - serum half life
  - stability
  - antigenicity and immunogenicity
- Integrated expression platform for identification and production of **higher active biologics & new generations of biopharmaceuticals**

# GlycoExpress Characteristics

- Glycoengineered human cell line NM-F9 of myeloid leukemia origin
- Human posttranslational modifications including N- and O-glycosylation
- Allows controlled regulation of sialylation from 0% to 100%
- Use of special expression vectors for high secretory expression
- Biotechnologically favourable  
(e.g. virus free, serum free, safe, origin and transformation events known, full documentation, easy single cell cloning, suspension culture, 15 h doubling time)

# GlycoExpress - An Integrated System

GlycoExpress serves for fast identification AND production of higher active glycoproteins

## IDENTIFICATION

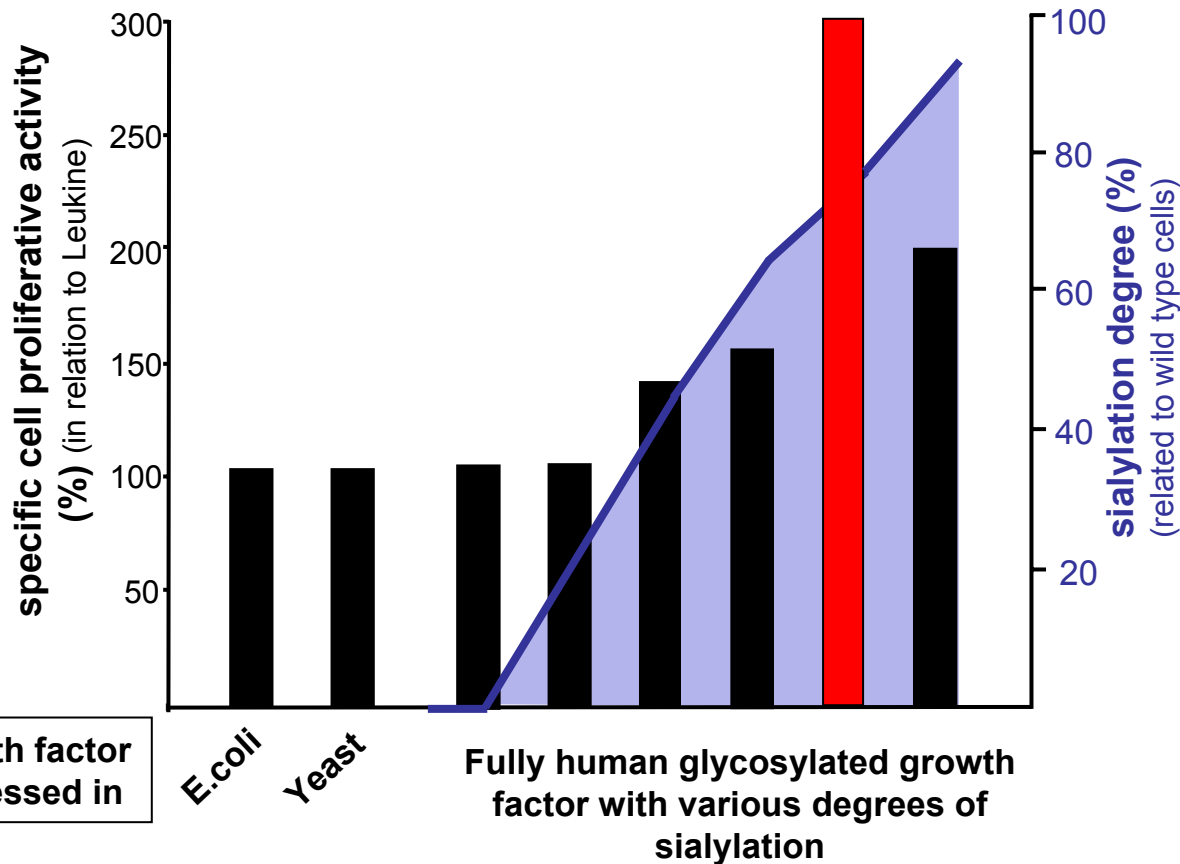
- Cloning of target protein into own expression vectors
- Expression of various fully human glycosylated forms of the target protein with different sialylation degrees
- **Functional Screening** of the sialylation forms
- Selection and characterization of sialylation form with highest biological activity

## PRODUCTION

- Generation of **stable high expression** clones
- Generation & purification of desired sialylation form of target protein
- Up-scaling
- Production

# Screening for the optimal sialylation

Differentially sialylated proteins express different activities



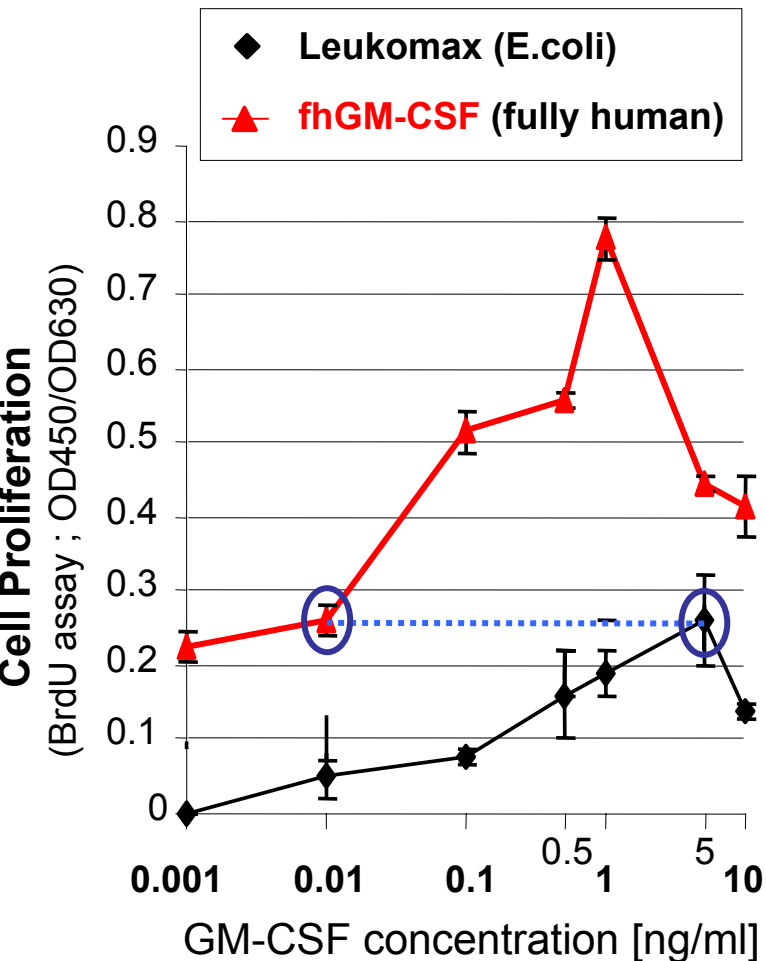
- Target protein is expressed in GlycoExpress.
- A series of differentially **sialylated variants** are analysed for **specific activity**.
- The **optimized sialylation** is identified in bioassays.

Growth factor expressed in

E.coli  
Yeast

Fully human glycosylated growth factor with various degrees of sialylation

# Fully human **GM-CSF** is much higher active than GM-CSF expressed in E.coli or yeast



*In vitro* activity of **fhGM-CSF** is **~500 times** higher than hGM-CSF expressed in E.coli (Leukomax) or yeast (Leukine)

Fully human glycosylation with a high sialylation degree expects:

- largely increased serum half life
- largely decreased antigenicity and immunogenicity
- lower doses, less administrations
- less side effects

# Intellectual Property

## Patent protection of GlycoExpress

- The glycoengineered cell lines
- The method for identification of higher active glycoproteins
- The method for production of higher active glycoproteins
- Fully human GM-CSF

⇒ Allows the protection of new generations of biologics and biopharmaceuticals with a new patent situation