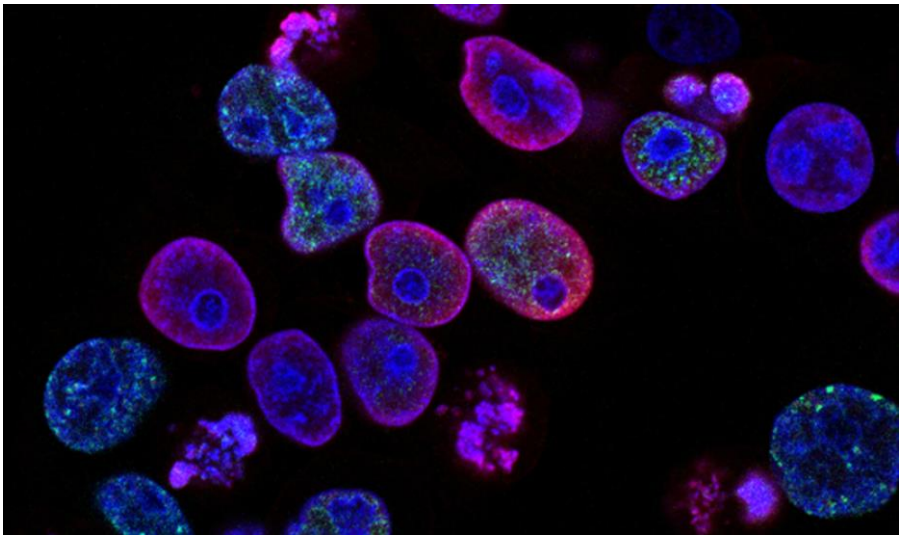
NovaUCD

Technology Licensing Opportunity

Cellular glycoengineering to maximise therapeutic protein galactosylation “GalMAX”



Opportunity

GalMAX is a simple, rapid, and robust cell engineering strategy that maximises product N-linked β-1,4 galactosylation by simultaneously eliminating metabolic and cellular machinery bottlenecks.

Glycosylation is considered a critical quality attribute of many high-grossing biopharmaceuticals, including most mAbs. mAb N-glycan variability arises from the glycosylation process where $\beta(1,4)$-galactosylation, in particular, is the major source of product variability. Maximising galactosylation reduces product heterogeneity and increases the clinical efficacy of biopharmaceuticals.

Background

A team led by Dr. Ioscani Jimenez del Val at University College Dublin (UCD) has produced a mammalian cell engineering strategy (GalMAX) which maximises the galactoylation capacity of monoclonal antibody (mAb) production cell lines.

Around 60% of biopharmaceuticals are produced through mammalian cell culture, including many of the top-selling biopharmaceuticals. There is a need for a method of producing glycosylated pharmaceuticals that exhibit less inherent variability, thus passing regulatory inspection faster and more easily, and producing drugs that are safer and more efficacious due to their increased homogeneity.

FUNDERS: CONACYT, IRISH RESEARCH COUNCIL An Chomhairle um Thaighde in Eirinn

Value Proposition:
Maximises of monoclonal antibody (mAb) galactoyslation

Markets:
Biomanufacturing and development of new glycosylated biopharmaceuticals, including mAbs, biosimilars, biobetters and viral vectors for gene therapy;
CDMOs supporting biopharma process development and seeking manufacturing platform cell lines’
Clinical-stage biopharma companies seeking product development platform cell lines

Lead Inventor:
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University College Dublin.

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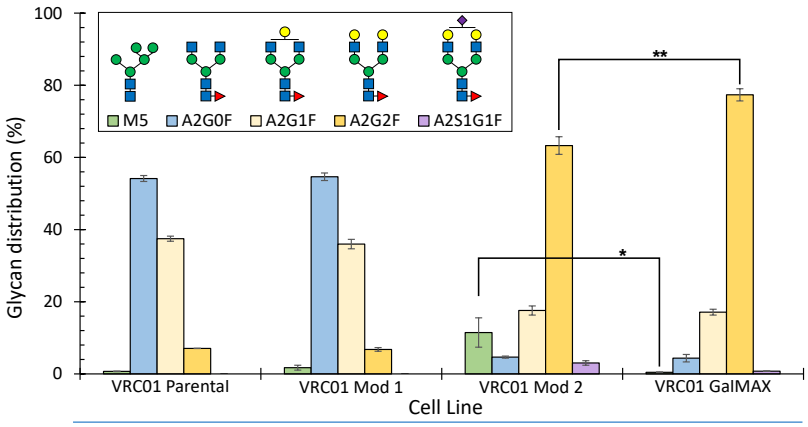

	G0F	G1F	G2F
Parental	**54.2 ± 0.8**	37.5 ± 0.7	**7 ± 0.0**
Mod. 1	54.6 ± 1.0	36 ± 1.3	6.8 ± 0.5
Mod. 2	4.6 ± 0.3	17.6 ± 1.3	63.3 ± 2.5
GalMAX	**4.4 ± 1.0**	17.1 ± 0.8	**77.4 ± 1.7**

12-fold reduction! **11-fold increase!**

Example of CHO VRC01 Cell Line results (fed-batch culture)

Key Features/Advantages:

- Greatly reduces the glycosylation heterogeneity of mAbs.
- GalMAX also has the potential of enhancing mAb:
  - Pharmacodynamics: ↑ADCC, ↑CDC & ↑immune modulation via enhanced sialylation
  - Pharmacokinetics:↑serum half-life via enhanced sialylation
  - It can also be deployed to produce non-mAb glycoprotein therapeutics
- GalMAX can also be used as a platform technology to control mAb β-1,4 galactosylation at target setpoints
- Not specific to one cell-engineering strategy

Application:

This technology has applications in biomanufacturing by reducing heterogeneity of biopharmaceutical products, thus facilitating their quality assurance and safety. GalMAX may also enhance the pharmacodynamics of mAb products by increasing their Antibody Dependent Cell mediated Cytotoxicity (ADCC) and Complement Dependent Cytotoxicity (CDC) and can also enhance pharmacokinetics through enhanced product sialylation.

The strategy has been demonstrated in two independent CHO cell lines cultured in batch and fed-batch mode. GalMAX is also applicable to other mammalian cell lines (NS0, Sp2/0) and cell lines used for producing gene therapy viral vectors (Sf9, HEK).
In both CHO DP12 (ATCC ATCC® CRL-12445™) and CHO VRC01, GalMAX drives a significant improvement in mAb Fc glycosylation by reducing the G0F glycan (non-galactosylated) and increasing the G1F and G2F glycans (galactosylated), over the parental line and other cellular glycoengineering technologies.

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