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Demonstrating a powerful scale-up strategy for Biosimilar mAb in single use systems via physicochemical and functional characterization

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Demonstrating a Powerful Scale-Up Strategy for TUR01 Biosimilar mAb in Single Use Systems via Physicochemical and Functional Characterization

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Turgut BioPharmaceuticals

R&D Center



GMP Production Plant



Biosimilar Development Strategy & Collaborations

Turgut BioPharmaceuticals

Product and Process Development

- Cell Line Development
- Process Development
- Analytical Method Development
- Clinical Development
- Regulatory Development



GMP Production

- Drug Substance
- Drug Product
- R & D Laboratory
- Quality Control Laboratory
- Quality Assurance



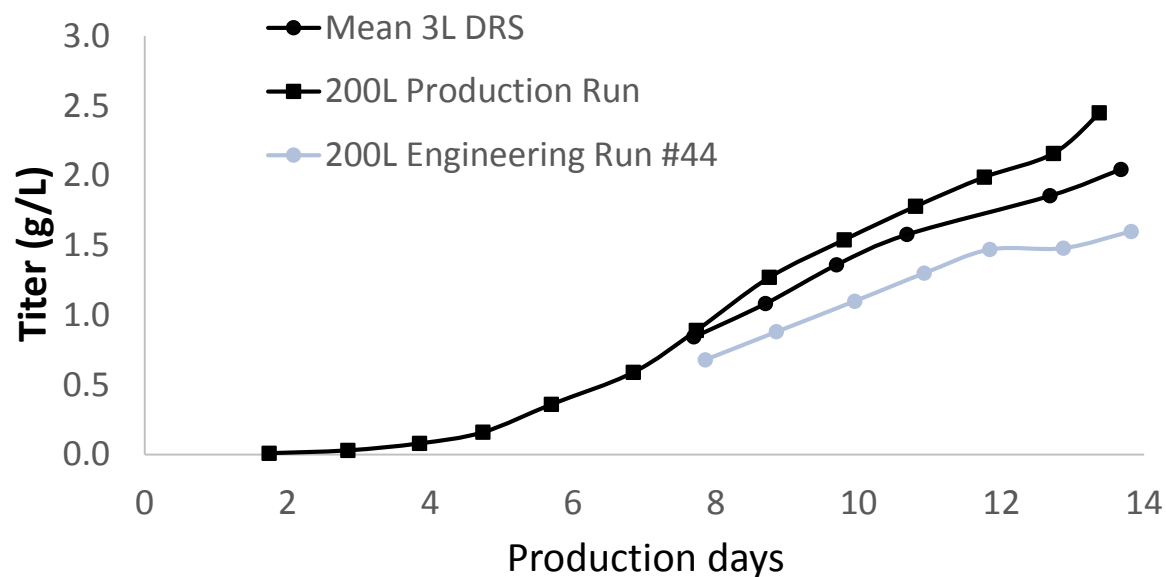
Global Partnerships

- CDMOs
 - Product Development
 - Technology Transfers
 - Contract Development & Manufacturing
 - Portfolio Development
 - Co-development Projects

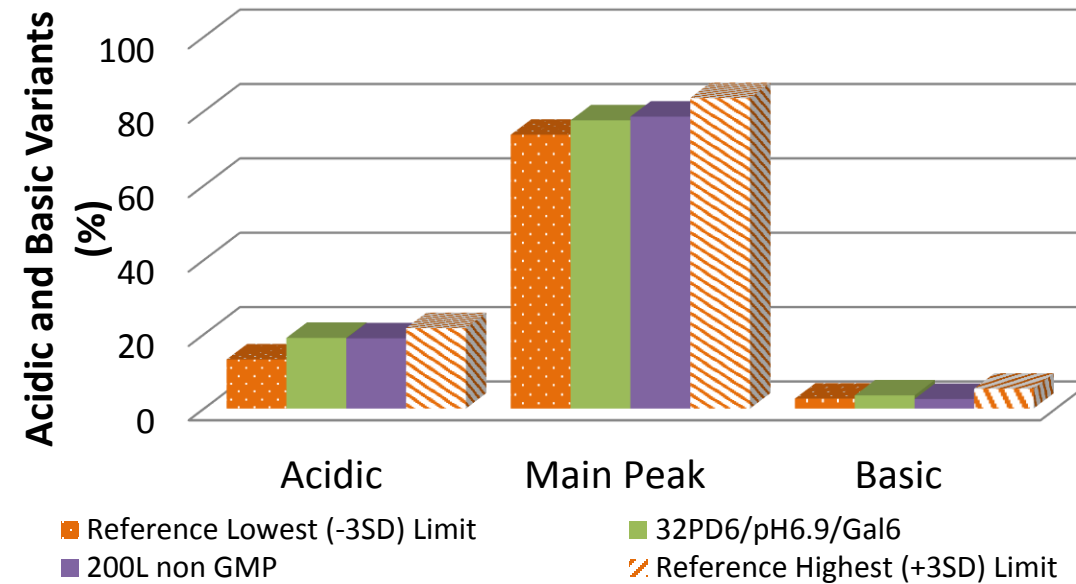


3 L and 200 L Scale TUR01 Biosimilar mAb

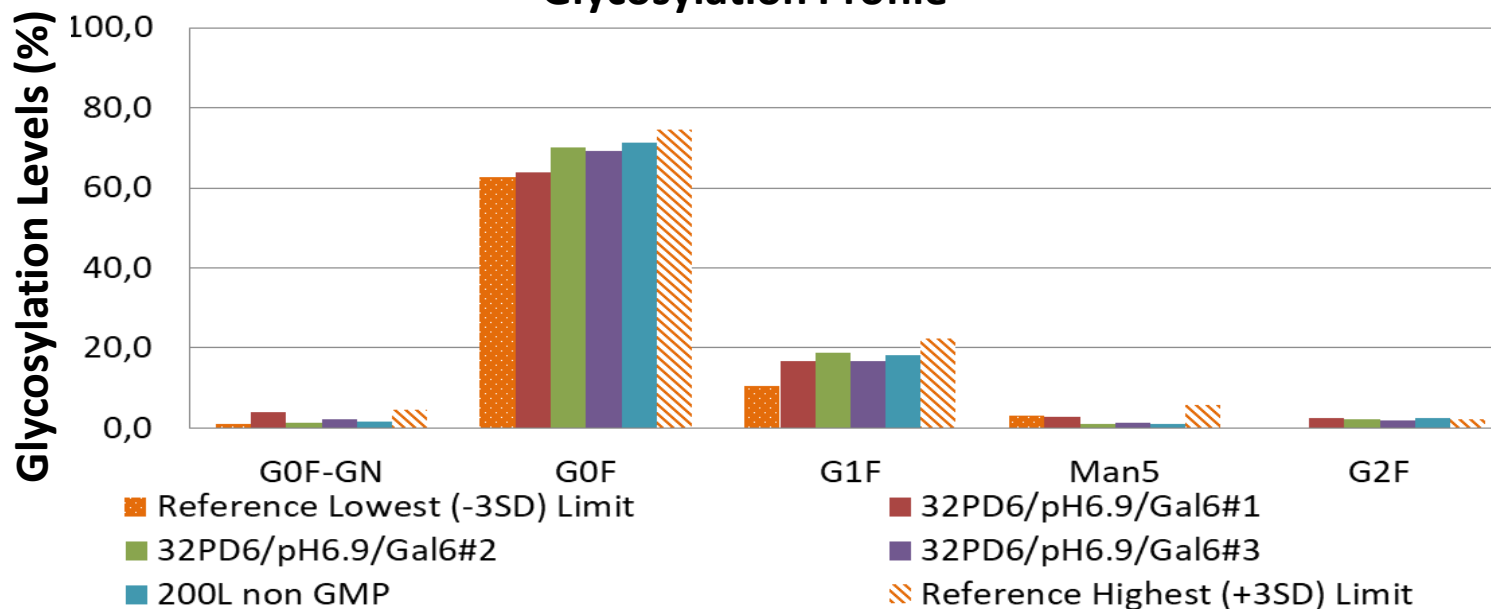
Productivity



Acidic & Basic Variants

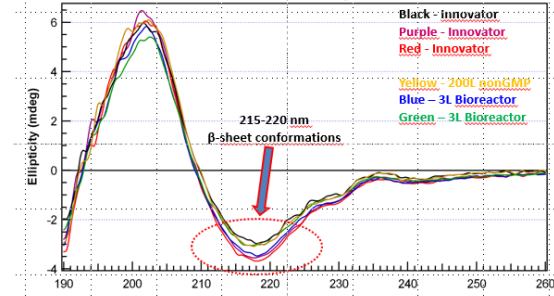


Glycosylation Profile

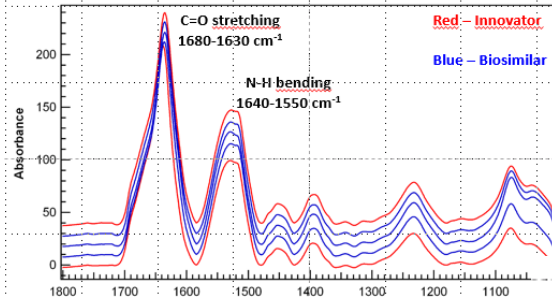


Demonstration of Biosimilarity via State of Art Analytical Techniques

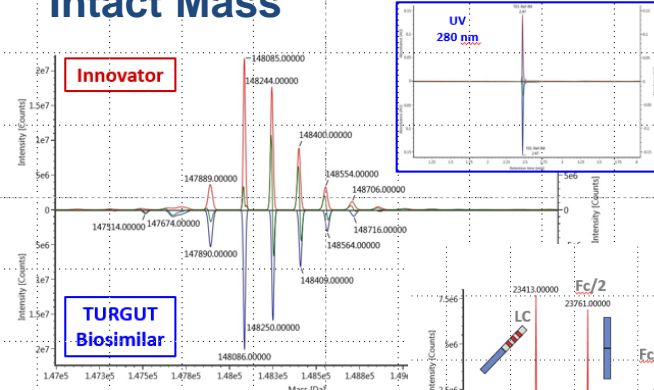
CD Analysis



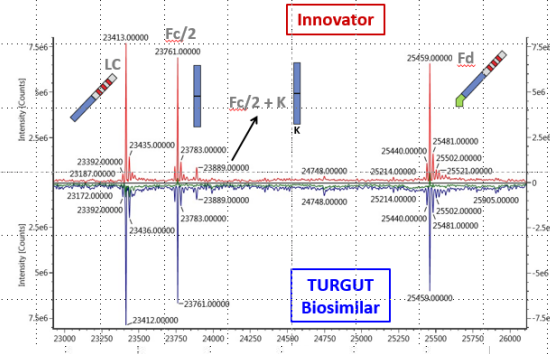
FTIR Analysis



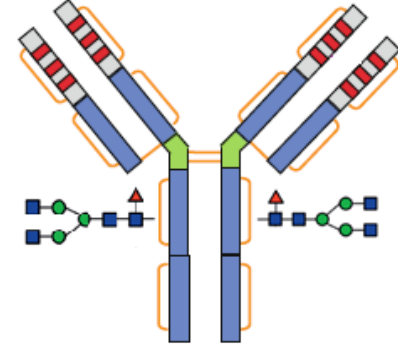
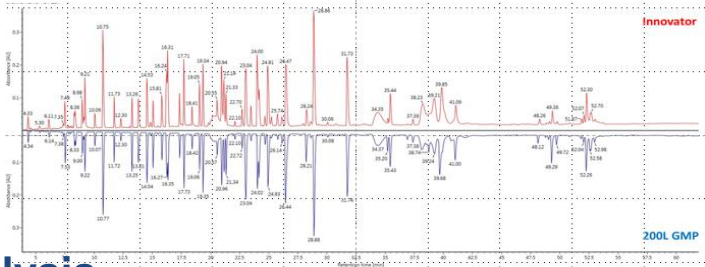
Intact Mass



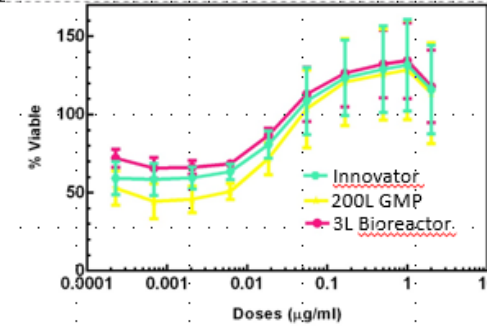
Subunit Mass



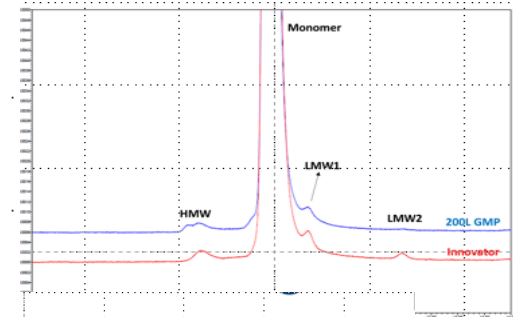
Peptide Mapping



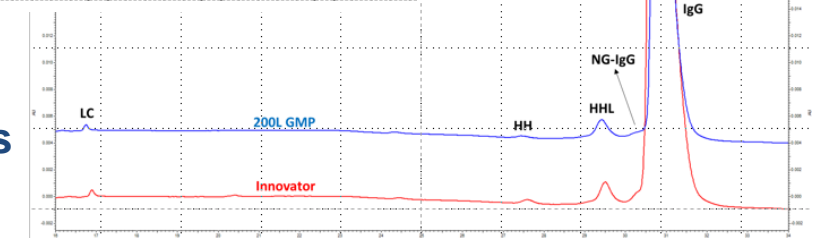
Cell Based Assays



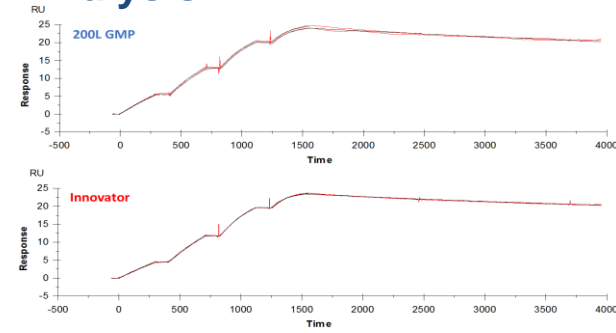
SEC-UPLC



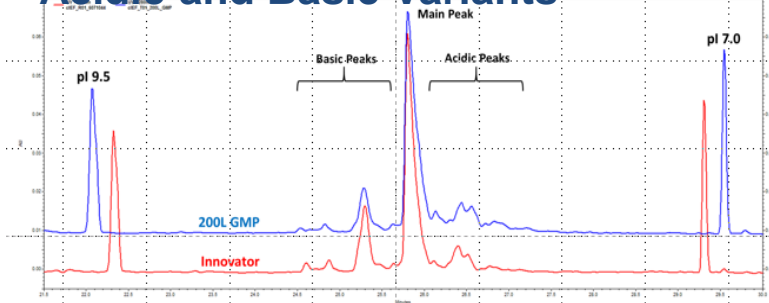
CE-SDS Analysis



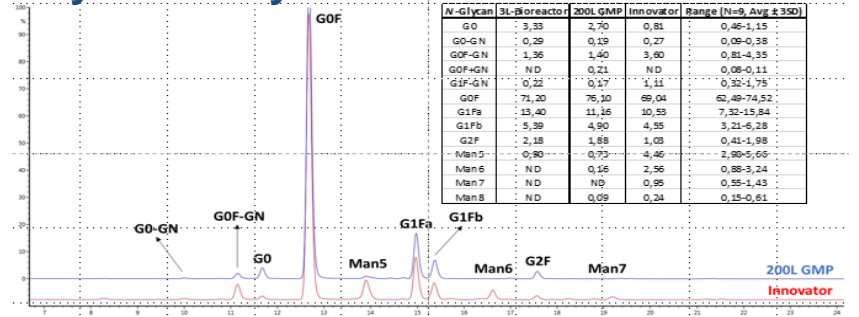
SPR Analysis



Acidic and Basic Variants



Glycan Analysis



- A platform technology based on state of art analytical techniques is established for biosimilar development
- Cell line development for three different biosimilar mAbs are successfully completed
- Upstream & Downstream development of two biosimilar products are completed at small scale (3L)
- 200L GMP batch of one biosimilar mAb is currently in progress for Phase I study
- State-of-the-art analytical instruments are now routinely used for:
 - ❖ biopharmaceutical characterization
 - ❖ comparability assessment
 - ❖ stability studies
 - ❖ batch-to-batch consistency

Thanks for Your Attention



Kaya Turgut
(President&Founder)



Turgut Biotechnology Group