Biosimilars: affordable, high quality at capacity

- NeuClone and the Serum Institute of India (SIIPL) are developing 10 biosimilar Wave II and Wave III monoclonal antibodies for global commercialization
- High quality, affordable biosimilars are made possible through NeuClone's technology and the company's *Right from the Start*® approach to development
- NeuClone is responsible for upstream development of all biosimilars while SIIPL is responsible for FDA/EMA compliant manufacture at large scale
- NeuClone and SIIPL are jointly performing early clinical development
- Four biosimilars are curently in development, six more entering development
- HERCEPTIN and HUMIRA biosimilars enter clinical studies in 2017
- STELARA and SYNAGIS enter clinical studies in 2018
- NeuClone and SIIPL are pursuing a broad portfolio across cancer, autoimmune disease and infectious disease

Biosimilars, Right from the Start®

NeuClone is positioned early in the value chain and has developed a *Right from the Start*® approach to developing biosimilar candidates which consists of three core attributes:

Right Sequence - Early focus on primary structure (amino acid sequence) identification of originator through proprietary processes involving Peptide Mass Fingerprinting (PMF), intact mass and x-ray crystallography.
Right Approach - *Biosimilarity by Design*™ approach based on QbD principles to test and confirm biosimilarity from the earliest stages and throughout development to ensure biosimilarity is achieved downstream.
Right Price - NeuClone's NeuMAX® technology, incorporated at the start of development, allows for the low-cost manufacture of biosimilars and contributes to affordability and pricing flexibility.

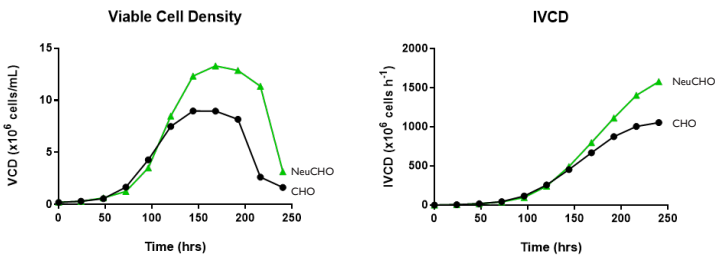
Why NeuClone

Quality, Capacity, Cost

- NeuClone is able to ensure biosimilar quality downstream by focussing on the earliest and most risk intensive stages of development – ensuring biosimilars are *Right from the Start*®
- SIIPL complements this with process experience and large manufacturing capacity for global supply
- The NeuClone/SIIPL partnership is aimed at becoming a cost leader in the global supply of FDA/EMA quality biosimilars
- Lowest drug supply price globally allows partners to enter the market, even late, grow these markets and maintain ROI despite competitors

Technology

- NeuClone's NeuMAX® platform allows for the low cost manufacture of biologics and includes a proprietary vector system, medium and parental cell line. The parental cell line, NeuCHO®, delivers increased viable cell density and extends culture life, allowing for increased yields on harvest compared to standard CHO cells.



NeuClone/SIIPL Responsibilities

NeuClone
- Upstream development and characterisation
- Intial process development and biosimilarity screening

Joint
- Pre-clinical analytics (top 5 CRO)
- Phase I clinical program (top 5 CRO)

SIIPL
- Process development and scale up
- Manufacture, fill and finish
- Marketing and distribution to ROW

Commercial opportunity created by NeuClone and SIIPL

The major opportunity is the Developed World Markets
- The current originator market is constrained in size by high price and limited product availability
- NeuClone and SIIPL can expand the current originator market by producing affordable high quality products for new patients

Emerging biosimilars market also an opportunity
- Emerging markets are constrained by price and availability of biologics and demand is estimated to be four times the current originator market in patient numbers