

# GLOBAL RIGHTS TO RISK MANAGED BIOSIMILARS AT SCALE

- NeuClone and Serum Institute of India (SIPL) are developing 10 biosimilar Wave II and Wave III antibody products for global commercialization.
- High quality, affordable biosimilars are made possible through NeuClone's technology and our Right from the Start<sup>®</sup> approach to development, as well as SIPL's large scale biomanufacturing expertise.
- NeuClone is responsible for upstream development of all biosimilars while SIPL is responsible for process development and FDA/EMA compliant manufacture of finished product.

## PROGRESS AND OUTLOOK

- Four biosimilars transferred by NeuClone to SIPL with six more to follow
- HERCEPTIN biosimilar to enter Phase I in Australia in 2018
- STELARA biosimilar to enter Phase I in Australia in 2019
- PROLIA and SYNAGIS biosimilars to enter clinical studies from 2019
- We seek commercialisation partners to contribute to the development and global registration of our products.

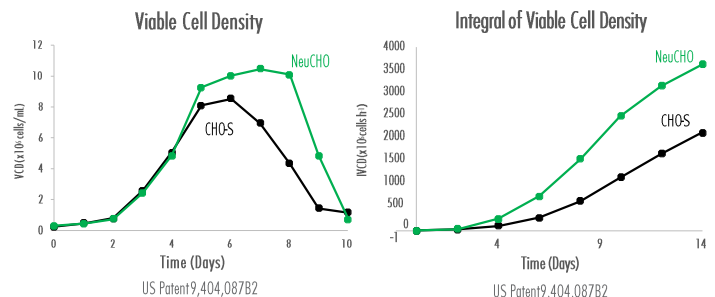
## BIOSIMILARS, RIGHT FROM THE START<sup>®</sup>

NeuClone implements a Right from the Start<sup>®</sup> approach to biosimilar development consisting of three attributes:

1. **RIGHT SEQUENCE:** Early focus on primary structure identification of originator through proprietary processes involving Peptide Mass Fingerprinting (PMF), intact mass and X-ray crystallography.
2. **RIGHT APPROACH:** Biosimilarity by Design<sup>™</sup> approach based on QbD principles confirms biosimilarity from the earliest stages and throughout development to ensure quality is maintained downstream.
3. **RIGHT PRICE:** NeuClone's NeuMAX<sup>®</sup> technology, incorporated at the start of development, allows for the low-cost manufacture of biosimilars and contributes to affordability and pricing flexibility.

## NEUCLONE TECHNOLOGY

- NeuClone's NeuMAX<sup>®</sup> platform allows for the low cost manufacture of biologics and includes a proprietary vector system, medium and robust parental cell line. The parental cell line, NeuCHO<sup>®</sup>, delivers increased viable cell density and extends culture life, allowing for increased yields on harvest compared to standard CHO cells.
- Cell Expression System - US and Australia patent granted



## QUALITY, CAPACITY, COST

- NeuClone ensures biosimilar quality downstream by focussing on the earliest and most risk intensive stages of development.
- SIPL complements this with process experience and large cGMP manufacturing capacity for global supply.
- The NeuClone-SIPL collaboration 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, at any stage, grow these markets and maintain ROI despite competitors.
- We encourage our licensing partners to propose a supply price and allow us to demonstrate our market-leading supply price commitment.
- In addition to the five disclosed, NeuClone has fifteen other biosimilar products initiated as at 3Q 2018 also available for partnering.

## COMMERCIAL OPPORTUNITY

### 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 SIPL will 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.

## NEUCLONE

- Upstream development and characterisation
- Initial process development and biosimilarity
- Marketing rights to Developed World

## SIPL

- Process development and scale up
- cGMP manufacture, fill and finish
- Marketing and distribution to RoW

## NEUCLONE & SIPL

- Pre-clinical analytics (top 5 CRO)
- PK/PD clinical program (top 5 CRO)

# UNIQUE DIFFERENTIATION OF NEUCLONE THROUGH PARTNERING WITH SIIPL



- Multiple biosimilar mAb products across various therapeutic classes available for global partnering.
- Simplified path to commercialisation as NeuClone and SIIPL take on all CAPEX and operating requirements of product manufacture.
- Industry leading team in upstream biologics development and analytics.
- Quality indistinguishable from originator based on Right from the Start® approach.
- As SIIPL has achieved in its historical business as the world's largest

supplier of vaccines (by number of doses supplied), SIIPL is committed to introducing game-changing, disruptive supply pricing to biosimilar mAbs, and hence the global competitive landscape.

- NeuClone leverages the Australian R&D Tax Incentive scheme to reduce the cost of clinical development by up to 41%.
- Serum Institute will supply FDA/EMA cGMP quality product below the supply pricing level possible by any current or projected future biosimilars supplier. SIIPL is committed to drive unique affordability.

## WHO IS SIIPL?

### WORLDWIDE LEADER IN BIOLOGICALS

- Largest volume and doses manufacturer of vaccines globally (used in 170 countries)
- 65% of the world's children receive at least one SIIPL vaccine
- Produces over 50 vaccine products each with different production processes.
- Experienced in all steps of scale-up, manufacture and formulation.
- SIIPL aims to replicate its vaccine success with biosimilars through high quality, affordable, large scale production, for global supply

### PROVEN BIOSIMILARS CAPACITY

- Successful scale up to commercial volumes of biosimilar erythropoetin and a fully human rabies monoclonal antibody
- Scale up of NeuClone's HERCEPTIN biosimilar

### CONFORMING TO THE HIGHEST STANDARDS

- Compliance with US FDA and EMA requirements
- Facilities in Holland (EU certified), Czech Republic and India
- Large capacity with purpose built facility exclusively for NeuClone biosimilar mAbs

## NC-SIIPL PIPELINE

ORIGINATOR	EARLY PRECLINICAL	LATE PRECLINICAL	PROCESS SCALE-UP	PHASE I	PHASE III
Herceptin (trastuzumab)	█	█	█	2018	█
Stelara (ustekinumab)	█	█	█	2019	█
Prolia/XGEVA (denosumab)	█	█	█	2019	█
Synagis (palivizumab)	█	█	█	2019	█
Humira (adalimumab)	█	█	█	█	█

[AS AT AUG 2018; 15 MORE PRODUCTS IN DEVELOPMENT]

## SEEKING PRODUCT LICENSING AND CLINICAL DEVELOPMENT COLLABORATIONS

- Channel to global markets to maximize our long term commercial return
- Capacity and commitment to co-develop products globally
- Early engagement to allow coordinated design of clinical program

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COMMERCIAL IN CONFIDENCE

