NeuClone Company Profile



A clinical-stage biopharmaceutical company focused on high quality, affordable biosimilars.

- NeuClone is developing over 20 biosimilar antibody products for global commericalisation
- Vision to provide affordable life-saving and life-extending therapies, globally
- Vision made possible by 'Right from the Start[®]' biosimilar approach, including the NeuMAX[®] platform and industry leading analytic capabilities

BIOSIMILAR PIPELINE

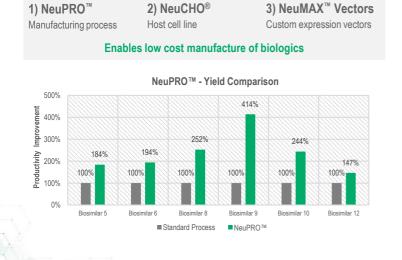
- Two biosimilars successfully completed Phase I clinical development
- Lead biosimilar product referencing US\$8.0 billion Stelara[®] market with 'First to market' potential
- Large-scale, high quality strategic manufacturing partner secured
- Seeking partners for co-development and commercialization of biosimilar products

Originator	Product Category	Patent Expiry (EU/US)	2020 Sales (US\$bn) ¹	NeuClone Biosimilar Development Stage				
				Early pre-clinical	Late pre-clinical	Process scale-up	Phase I	Phase III
Stelara® (ustekinumab)	Autoimmune	2024/2023	\$8.0b					
Herceptin [®] (trastuzumab)	Breast cancer	2014/2019	\$4.0b					
Perjeta® (pertuzumab)	Breast cancer	2025/2025	\$4.2b					
Prolia/XGEVA® (denosumab)	Osteoporosis/ Oncology	2025/2025	\$5.1b					
Synagis [®] (palivizumab)	RSV prevention	2015/2015	\$1.1b					
Opdivo [®] (nivolumab)	Oncology	2030/2028	\$7.9b					
Keytruda [®] (pembrolizumab)	Oncology	2030/2028	\$14.4b					
Humira® (adalimumab)	Autoimmune	2018/2023	\$20.4b					
+12 additional products	-	-	-					

1) Source: La Merie (2021)

KEY DIFFERENTIATORS

NeuClone's '*Right from the Start*[®]' development approach enables efficient production of high quality biosimilars at low cost by incorporating the **NeuMAX**[®] technology platform and **industry leading analytic capabilities**.



NeuMAX[®] Technology Platform

Industry Leading Analytic Capabilities

NeuClone conducts extensive in-house analytical testing from the earliest stages and throughout development to ensure a high level of biosimilarity for NeuClone's products.

Deep in-house capabilities include cell based assays, X-ray crystallography analysis, glycosylation, potency and more.

NeuClone's X-ray crystallography overlay of Stelara[®] originator & NeuLara biosimilar

NEUCLONE BIOSIMILAR ACTIVITIES

Biosimilar expression and upstream development Analytical characterisation and biosimilarity confirmation

Clinical and non-clinical trials

STRATEGIC MANUFACTURING COLLABORATION

NeuClone and Serum Institute Collaboration

- Agreement initiated in 2014 to collaboratively develop 10 biosimilars
- Serum Institute is responsible for the manufacture of NeuClone biosimilars, supporting clinical development and commercial supply.
- NeuClone holds commercial rights to products in the US, Canada, Europe, Japan, Australia, New Zealand, South Korea and China. Serum Institute holds rights to the rest of the world
- Product supply to meet US FDA and EMA regulatory standards
- Large-scale manufacturing facility dedicated to NeuClone biosimilars
- Two biosimilars (trastuzumab & ustekinumab) developed through Phase I under the collaboration

About Serum Institute of India

- Largest manufacturer of vaccines globally by volume
 - over 1.5 billion doses annually across 50 vaccine products
 - exports to over 170 countries
 - 65% of the world's children receive a Serum Institute vaccine
- Aims to replicate its vaccine success with biosimilars through highquality, affordable, large-scale production, for global supply
- Experienced in all steps of scale-up, manufacture and formulation, including commercial erythropoietin biosimilar and a fully human rabies monoclonal antibody
- Facilities in India and Netherlands (EU certified)
- Leader in the global response to COVID-19, both in development and mass production of multiple vaccine candidates, such as supplying over 2 billion vaccine doses developed by AstraZeneca and Novavax

NEUCLONE ADVANTAGE: QUALITY, CAPACITY, COST

- NeuClone's expertise is in the most risk-intensive stages of biosimilar development (before Phase I completion)
- Through its unique platform technology and manufacturing partnership with Serum Institute, NeuClone delivers low-cost manufacturing at large capacity for global supply. Additionally, for NeuClone's biosimilars not partnered with Serum Institute, NeuClone retains global commercial and manufacturing rights
- Additionally, NeuClone benefits from the Australian R&D Tax Incentive scheme to reduce development costs by up to 41%
- Lowest drug supply price globally allows for pricing flexibility and return on investment in price competitive markets

NEULARA (USTEKINUMAB)

NeuClone's Lead Biosimilar 'NeuLara' Referencing Stelara® (ustekinumab)

- Stelara® (ustekinumab) is approved for plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis
- Stelara[®] 2020 global sales were US\$8.0 billion and expected to reach up to US\$10 billion prior to biosimilar entry
- NeuClone's ustekinumab biosimilar, designated as 'NeuLara', was the first ustekinumab biosimilar to enter clinical development in the **Developed World**
- NeuLara successfully completed a Phase I clinical trial in October 2020. Results demonstrate NeuLara is similar to Stelara-EU and Stelara-US in terms of pharmacokinetics (PK), safety and immunogenicity
- NeuLara has potential to be 'first to market' and capture a significant share of the >US\$8 billion Stelara® market

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