

# NeuClone Company Profile



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

- NeuClone is developing over 20 biosimilar antibody products for global commercialisation
- 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
- Two biosimilars successfully completed Phase I clinical development
- Several additional biosimilars to be Phase I ready by 2021
- Lead biosimilar product referencing Stelara® targeting over \$9b originator market with 'First to market' potential
- Large-scale, high quality strategic manufacturing partner secured
- Seeking partners for co-development and commercialization of biosimilar products

## BIOSIMILAR PIPELINE

Originator	Product Category	Patent Expiry (EU/US)	2019 Sales (US\$bn)	NeuClone Biosimilar Development Stage				
				Early pre-clinical	Late pre-clinical	Process scale-up	Phase I	Phase III
Stelara® (ustekinumab)	Autoimmune	2024/2023	\$6.6b	[Progress bar: Early pre-clinical to Phase I]				
Herceptin® (trastuzumab)	Breast cancer	2014/2019	\$6.3b	[Progress bar: Early pre-clinical to Phase I]				
Perjeta® (pertuzumab)	Breast cancer	2025/2025	\$3.7b	[Progress bar: Early pre-clinical to Process scale-up]				
Prolia/XGEVA® (denosumab)	Osteoporosis/ Oncology	2025/2025	\$5.1b	[Progress bar: Early pre-clinical to Process scale-up]				
Synagis® (palivizumab)	RSV prevention	2015/2015	\$1.0b	[Progress bar: Early pre-clinical to Process scale-up]				
Opdivo® (nivolumab)	Oncology	2030/2028	\$8.0b	[Progress bar: Early pre-clinical to Process scale-up]				
Keytruda® (pembrolizumab)	Oncology	2030/2028	\$11.1b	[Progress bar: Early pre-clinical to Process scale-up]				
Humira® (adalimumab)	Autoimmune	2018/2023	\$19.7b	[Progress bar: Early pre-clinical to Process scale-up]				
+12 additional products	-	-	-	[Progress bar: Early pre-clinical to Process scale-up]				

## 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

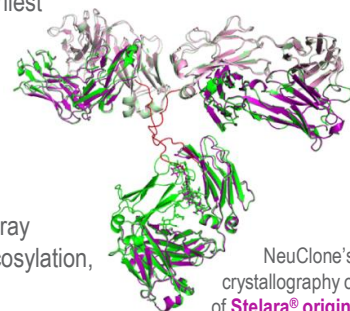
- 1) NeuPRO™ Manufacturing process
- 2) NeuCHO® Host cell line
- 3) NeuMAX™ Vectors Custom expression vectors

Enables low cost manufacture of biologics

### Industry Leading Analytic Capabilities

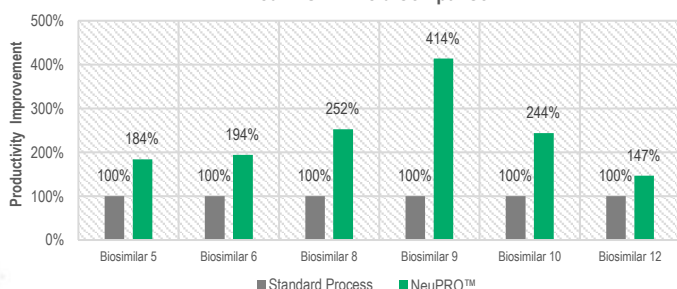
NeuClone conducts extensive in-house analytical testing from the earliest stages and throughout development to ensure a high level of biosimilarity for NeuClone's products.

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

NeuPRO™ - Yield Comparison



## 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's biosimilars, supporting clinical development and commercial supply.
- NeuClone holds commercial rights to products in the US, 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 high-quality, 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 1 billion vaccine doses developed by the University of Oxford & AstraZeneca

## 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, NeuClone delivers low cost manufacturing at large capacity for global supply
- 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® 2019 global sales were US\$6.6 billion and expected to reach over US\$ 9 billion prior to biosimilar entry in 2024
- 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 is on track to be a 'first to market' biosimilar and capture a significant share of the >US\$ 9 billion Stelara® market
- Global Phase III clinical trial planned for 2021

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