NeuClone Announces Positive Results from Phase I Study of Stelara® (ustekinumab) Biosimilar Candidate

SYDNEY, AUSTRALIA, October 20, 2020 – NeuClone Pharmaceuticals Ltd (NeuClone) today announced its biosimilar candidate of Stelara® (ustekinumab), NeuLara, has successfully met all primary and secondary endpoints in a Phase I clinical trial. This includes all pre-specified criteria demonstrating the clinical pharmacokinetic (PK) similarity of NeuLara, compared to US- and EU-sourced Stelara®. Additionally, the safety, immunogenicity and tolerability profiles were similar in all three treatment arms.

NeuLara is being developed as a biosimilar of ustekinumab, an antibody targeting interleukin-12 and -23, approved under the brand name Stelara® to treat patients with plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis. In 2019, Stelara® ranked in the top 10 drugs by global sales according to FiercePharma with US$6.6 billion in sales.[1] EvaluatePharma predicts this figure will increase over the coming years, reaching US$7.8 billion in 2024.[2]

NeuLara is NeuClone's second biosimilar to have met all primary and secondary endpoints in a three-arm Phase I trial.

> "With successful completion of the Phase I trial for NeuLara, our ustekinumab biosimilar is now significantly de-risked along its development path to market," said Noelle Sunstrom, CEO of NeuClone. "We are on track for a global Phase III trial starting in 2021 and to be among the first biosimilar entrants, making this valuable antibody drug available to many more patients with psoriasis and inflammatory bowel diseases."

NeuLara is being co-developed by NeuClone and its strategic manufacturing partner, Serum Institute of India (Serum Institute).

> "Serum Institute is dedicated to making quality biological drugs available globally at competitive prices," stated Adar Poonawalla, CEO of Serum Institute. "With the Phase I of NeuLara completed in Australia, we look forward to supporting its clinical development in a global Phase III clinical trial, and, after registration in Europe and the USA, manufacture and drug supply to support global patient access."

NeuClone has a deep portfolio of biosimilar assets including the recently announced candidates referencing Opdivo® (nivolumab) and Keytruda® (pembrolizumab), as well as clinical-stage candidate NeuCeptin referencing Herceptin® (trastuzumab). Several other biosimilars are set to begin clinical development.

About the Study

The Phase I clinical trial was conducted in Australia and involved over 200 healthy volunteers in a three-arm, randomized, double-blind study, receiving a single dose of either NeuLara, US-sourced Stelara®, or EU-sourced Stelara®. Each subject was monitored clinically for comparison of adverse events (AE's) for 105 days and blood samples collected for comparison of pharmacokinetic (PK) profiles and anti-drug antibody (ADA) (immunogenicity) responses. The study met all co-primary PK endpoints for Cmax and Area Under the Curve (AUC). For all PK primary endpoints, the 90% Confidence Intervals (CI) of the Geometric Mean Ratio (GMR) were within the pre-specified 80-125% acceptance limits for all three pairwise comparisons.

About NeuClone

NeuClone is a clinical-stage biopharmaceutical company focused exclusively on developing a portfolio of biosimilar monoclonal antibodies. Eight biosimilar products have been disclosed in NeuClone's portfolio, including clinical stage biosimilars referencing Stelara® (ustekinumab) and Herceptin® (trastuzumab), as well as preclinical biosimilars referencing Perjeta® (pertuzumab), Prolia®/XGEVA® (denosumab), Opdivo® (nivolumab), Keytruda® (pembrolizumab), Synagis® (palivizumab) and Humira® (adalimumab). NeuClone develops biosimilar products using its proprietary NeuMAX® platform that facilitates low-cost manufacture of biologics, while enabling the highest product quality. NeuClone is led by a highly experienced team with state-of-the-art integrated facilities based in Sydney, Australia. For more information, please visit www.neuclone.com.

About the NeuClone and Serum Institute Partnership

NeuClone and Serum Institute have partnered to deliver ten biosimilars for global registration in accordance with the most stringent regulatory standards. Under the arrangement, Serum Institute is responsible for the manufacture of NeuClone's biosimilars, supporting clinical development and commercial supply. Serum Institute is well known as the world's largest vaccine manufacturer by number of doses produced and sold globally (over 1.5 billion annually). NeuClone and Serum Institute have a strategic and commercial vision to replicate Serum Institute's vaccine success with biosimilars – making them available at sufficient volume, quality and price to deliver globally. In September 2019, Serum Institute inaugurated their Rs 3,000 crore (US$410 million) biologics facility located at Manjri in Pune, India. The two million square foot facility will include commercial scale biosimilar manufacture and is designed for global regulatory compliance including US and European agencies.

References

[1] FiercePharma. The Top 20 Drugs by Global Sales in 2019. 2020. Available at: https://www.fiercepharma.com/special-report/top-20-drugs-by-global-sales-2019

[2] EvaluatePharma. Word Preview 2019, Outlook to 2024. 12th Edition. June 2019. Available at: https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma_World_Preview_2019.pdf

Company Contact

John Oksinski
Global Head of Business Development
j.oksinski@neuclone.com
Tel: +61 2 9209 4020