NeuClone Announces Completion of Subject Visits in Stelara® (ustekinumab) Biosimilar Phase I Clinical Trial

SYDNEY, AUSTRALIA, April 8, 2020 – NeuClone Pharmaceuticals Ltd (NeuClone), a clinical-stage biopharmaceutical company exclusively focused on developing high-quality biosimilar products, today announced successful completion of monitoring visits and blood sampling for subjects in the Phase I clinical trial for its Stelara® (ustekinumab) biosimilar candidate, NeuLara.

Over 200 healthy volunteers received a single dose of either NeuLara, US-sourced Stelara®, or EU-sourced Stelara®. Each subject was monitored for up to 105 days and samples collected for pharmacokinetic (PK) and anti-drug antibody (ADA) similarity testing.

Interim analysis indicates the safety and tolerability profiles were comparable between all three blinded treatment arms. The final clinical study report is anticipated in 3Q 2020.

> "We are delighted with the progress of NeuLara through its Phase I clinical trial," stated Dr Noelle Sunstrom, CEO and Founder of NeuClone. "Our attention now shifts to the final stages of development required for approval and supply of NeuLara to patients globally."

NeuLara is one of several biosimilars developed by NeuClone in partnership with Serum Institute of India Pvt Ltd (Serum Institute).

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® achieved global sales of USD 6.6 billion.[1] EvaluatePharma predicts this figure will continue increasing over the coming years, reaching USD 7.8 billion in 2024.[2]

About NeuClone
NeuClone is a clinical-stage biopharmaceutical company focused exclusively on developing a portfolio of biosimilar monoclonal antibodies. Six biosimilar products have been disclosed in NeuClone's pipeline that reference Stelara®, Herceptin®, Perjeta®, Synagis®, Prolia®/XGEVA® and Humira®. 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 are partnered to develop multiple biosimilars for global registration in accordance with the most stringent regulatory standards. Serum Institute is well known in the vaccine industry as the world's largest vaccine manufacturer by number of doses produced and sold globally (over 1.6 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. Under the arrangement, NeuClone is responsible for initial biosimilar development, analytical characterisation and biosimilarity confirmation. Serum Institute is responsible for clinical and commercial manufacture. In September 2019, Serum Institute inaugurated their new $450 million biologics facility located in Manjri, 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.

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References

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[2] EvaluatePharma. World Preview 2019, Outlook to 2024. 12th Edition. June 2019.