NeuClone Announces First Human Dose of Stelara® (Ustekinumab) Biosimilar Candidate in Phase I Clinical Trial

SYDNEY, AUSTRALIA, October 17, 2019 – NeuClone, a clinical-stage biopharmaceutical company exclusively focused on developing high-quality biosimilar products, today announced it has commenced dosing of Stelara® (ustekinumab) biosimilar candidate, NeuLara, in a Phase I clinical trial.

The single-dose, double-blind, randomised, three-arm study is being conducted across multiple Australian sites in over 200 healthy volunteers. The primary objective is to demonstrate equivalent pharmacokinetics (PK) and secondary objective is to demonstrate equivalent safety of NeuLara to US- and EU-sourced Stelara®.

NeuLara is the second biosimilar from NeuClone's pipeline to enter clinical development and is developed in partnership with Serum Institute of India.

"Following several years establishing NeuClone as a leading biosimilar company, NeuLara's entry into clinical development demonstrates our ability to advance multiple biosimilar products that will provide greater access to affordable, life-changing medicines, globally." stated Dr Noelle Sunstrom, CEO and Founder of NeuClone.

The NeuLara Phase I clinical trial is being conducted under the Australian Therapeutic Goods Administration (TGA) Clinical Trial Notification (CTN) scheme. This pathway offers a streamlined approach and data output is supported by global regulatory agencies such as the EMA and U.S. FDA.

Prior to initiating the trial, NeuLara was subjected to extensive preclinical testing to confirm structural and functional similarity in comparison to the reference product Stelara®. Testing included positive PK and safety results from a non-clinical primate study, as well as comprehensive physicochemical analysis of Stelara® and NeuLara, including X-ray crystallography.

NeuLara is being developed as a biosimilar candidate 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 2018, Johnson & Johnson reported Stelara® global sales of USD 5.2 billion.[1] EvaluatePharma (2019) predicts this figure will increase over the coming years, reaching USD 7.8 billion in 2024.[2]

NeuClone representatives are attending the upcoming 2019 BIO-Europe conference in Hamburg from 11-13th November and look forward to discussing biosimilar development and commercialisation opportunities with potential partners.

About NeuClone

NeuClone is a clinical-stage biosimilar company focused exclusively on developing a pipeline of biosimilar monoclonal antibodies. Six biosimilar products have been disclosed in NeuClone's pipeline that reference Herceptin®, Stelara®, Synagis®, Prolia®/XGEVA®, Perjeta® 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 have 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 partnership, 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
1 Johnson & Johnson. Johnson & Johnson Reports 2018 Fourth-Quarter Results. 22 Jan 2019.
2 EvaluatePharma. Word Preview 2019, Outlook to 2024. 12th Edition. June 2019.