NeuClone Completes Dosing in Phase I Clinical Trial of Stelara® (ustekinumab) Biosimilar Candidate

SYDNEY, AUSTRALIA, Dec. 18, 2019 – NeuClone Pharmaceuticals Ltd (NeuClone), a clinical-stage biopharmaceutical company exclusively focused on developing high-quality biosimilar products, today announced successful recruitment and dosing of all subjects in the Phase I clinical trial for its Stelara® (ustekinumab) biosimilar candidate, NeuLara. The final subject was dosed last week. No serious treatment related adverse events have been reported to date.

A total of 210 subjects were randomized into three arms (1:1:1) to receive a single dose of either NeuLara, Stelara® sourced from the US, or Stelara® sourced from the EU. Recruitment was completed ahead of schedule, with all doses successfully administered within two months. The final clinical study report is anticipated in 3Q 2020.

> "We are very excited to see faster than anticipated enrolment of subjects into our NeuLara Phase I clinical trial", stated Dr Noelle Sunstrom, CEO and Founder of NeuClone. "Our aim is to bring NeuLara to market as soon as possible so patients suffering from psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis are provided with affordable treatment alternatives beyond the reference product."

NeuLara is one of several biosimilars developed in partnership between NeuClone and Serum Institute of India Pvt Ltd (Serum Institute). Biosimilars stimulate price competition following loss of the reference product's exclusivity. Since launching in the US in 2009, the Wholesale Acquisition Cost (WAC) of NeuLara's reference product, Stelara®, has increased by 136%.[1,2]

NeuClone representatives will be attending the 38th Annual J.P. Morgan Healthcare Conference in San Francisco from 13-16th January 2020. As part of its strategy for biosimilar products, NeuClone remains open to potential development and commercialisation collaborations.

About NeuClone

NeuClone is a clinical-stage biopharmaceutical 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 1.5 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. 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 2 million square foot facility will include commercial scale biosimilar manufacture and is designed for global regulatory compliance including US and European agencies.

Stelara® is a registered trademark of Johnson & Johnson.
Herceptin® is a registered trademark of Genentech Inc.
Prolia® and XGEVA® are registered trademarks of Amgen Inc.
Synagis® is a registered trademark of MedImmune Inc.
Perjeta® is a registered trademark of Genentech Inc.
Humira® is a registered trademark of AbbVie Inc.

[1] Engert, E. (2019). Biologics Pricing: A Deep-Dive Into Dynamics And Behaviors Over Time. https://www.biosimilardevelopment.com/doc/biologics-pricing-a-deep-dive-into-dynamics-and-behaviors-over-time-0001

[2] Johnson & Johnson (2010), Annual Report 2009. http://jnj-annualreports.s3-website-us-east-1.amazonaws.com/2009annualreport/pdf/2009-annual-report.pdf

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