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

SYDNEY, October 23, 2018: NeuClone Ltd, a biopharmaceutical company exclusively focused on developing high-quality biosimilar products, today announced it has commenced first-in-human dosing of its Herceptin® (trastuzumab) biosimilar candidate, in a Phase I clinical trial.

The single-dose, randomized, three-arm, double-blind study is being conducted in Australia in over 100 healthy volunteers. The objective of the study is to demonstrate equivalent PK and safety of NeuClone's trastuzumab biosimilar to Herceptin®.

NeuClone's trastuzumab biosimilar is one of ten biosimilar products being developed in partnership with Serum Institute of India (Serum Institute).

> "This major milestone offers significant validation of our biosimilar pipeline and partnership with Serum Institute", stated Dr. Noelle Sunstrom, CEO and Founder of NeuClone. "Over the coming years we will progress multiple biosimilar products through clinical trials and toward registration."
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> Mr. Adar Poonawalla, CEO of Serum Institute of India stated: "This is only the beginning of our long-term biosimilar partnership with NeuClone. Following the trastuzumab biosimilar Phase I trial, the Stelara® (ustekinumab) biosimilar Phase I will be conducted in 2019. We are determined to replicate the success of our low-cost, large-scale vaccine business model with all ten biosimilars partnered with NeuClone."

The Phase I clinical trial is being conducted under the Australian 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.

> NeuClone Executive Chairman Dr. Russell Howard stated: "We recognise that our trastuzumab biosimilar is not a first to market candidate, however we are confident that in partnership with Serum Institute, we have the capabilities to enter the market with ultra-competitive prices, large-scale supply, and the highest quality standards that adhere to global regulatory requirements.

Herceptin® is marketed in the U.S. by Genentech, in Japan by Chugai Pharmaceutical and internationally by Roche. Herceptin® is approved for HER2-overexpressing breast and gastric cancer. In 2017, Herceptin® generated USD 7.4 billion in global sales (La Merie).

NeuClone representatives will attend the upcoming 2018 BIO-Europe conference in Copenhagen from 5-7th November 2018 and look forward to meeting potential commercialisation partners.

About NeuClone

NeuClone is a biopharmaceutical company focused exclusively on developing a pipeline of biosimilar products. Five biosimilar products have been disclosed in NeuClone's pipeline that reference Herceptin®, Stelara®, Humira®, Synagis® and Prolia®/XGEVA®. NeuClone develops biosimilar products using its proprietary NeuMAX® platform that facilitates low-cost manufacture of biologics, whilst 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-Serum Institute Partnership

NeuClone and Serum Institute have partnered to develop ten 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 1.3 billion annually). Together with NeuClone, Serum Institute has a strategic and commercial vision to replicate its success in vaccines 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 scale manufacture.

Contact

John Oksinski, Head of Global Business Development - j.oksinski@neuclone.com, +61429133767.