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ASIA EDITION

NeuClone announces Positive Ph I results of Herceptin® (Trastuzumab) Biosimilar

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NeuCeptin, a biosimilar candidate of Herceptin® (trastuzumab) to provide high-quality, affordable biologics for the treatment of HER2-positive breast and gastric cancer

NeuClone Pharmaceuticals Ltd, a clinical-stage biopharmaceutical company exclusively focused on developing high-quality biosimilar products, on 5 Dec 2019, announced that NeuCeptin, a biosimilar candidate of Herceptin® (trastuzumab), has successfully met all primary and secondary endpoints in Phase I clinical trial. This includes all pre-specified criteria demonstrating clinical pharmacokinetic (PK) similarity of NeuCeptin, compared to US- and EU-sourced Herceptin®. Additionally, the safety and tolerability profiles were equivalent between all three treatment arms.

Successful completion of the Phase I trial is a significant milestone in the development of a biosimilar as Phase II trials and in some instances, Phase III trials are not required to achieve regulatory approval. As of March 2019, no biosimilar found to be highly similar in analytical and human PK studies failed to be approved in the US, EU, Canada or Australia due to clinical inequivalence.

NeuCeptin is one of several biosimilars developed in partnership between NeuClone and Serum Institute of India Pvt Ltd (Serum Institute), and references trastuzumab, a HER2-targeting monoclonal antibody approved by the FDA and EMA to treat HER2-positive breast and gastric cancer. Trastuzumab was originally commercialised under the brand name Herceptin® and generated global sales of USD 7.0 billion in 2018.

“Positive results from the NeuCeptin trial reflect our dedication to providing high-quality, affordable biologics to a greater number of patients,” stated Dr Noelle Sunstrom, CEO and Founder of NeuClone. “Pharmacokinetics are pivotal to the demonstration of biosimilarity and these successful results greatly de-risk this particular program and also validate NeuClone and Serum Institute’s development approach to be replicated for many biosimilars in our pipeline.”

“It is extremely pleasing to see the progress of our biosimilar portfolio with co-development partner, NeuClone. We have now achieved successful Phase I results of NeuCeptin (trastuzumab), nearly completed dosing of the Phase I trial for NeuLara (ustekinumab), and palivizumab and pertuzumab biosimilars are both progressing into preclinical and clinical testing.” Stated Mr Adar Poonawalla, CEO of Serum Institute. “This clearly speaks of our commitment to make highly cost-

effective biosimilars available to all.”

NeuClone has 20 biosimilars in various stages of development including clinical-stage candidates NeuCeptin (trastuzumab) and NeuLara (ustekinumab). Several other biosimilars are set to begin clinical development over the coming years. As part of its strategy for biosimilar products, NeuClone remains open to potential development and commercialisation collaborations.

About the Study

The Phase I clinical trial (registration number ACTRN12618001657213) was a randomised, double-blind, single-dose, three-arm study to evaluate the pharmacokinetics (PK) and safety of NeuCeptin compared to Herceptin® (trastuzumab). Over 100 healthy volunteers were enrolled in sites across Australia and randomised (1:1:1) to receive either NeuCeptin biosimilar, Herceptin® sourced from the US, or Herceptin® sourced from the EU, administered as a single intravenous infusion. PK endpoints included: area under the concentration-time curve from first to the last timepoint measured ($AUC_{0\text{-}last}$), area under the concentration-time curve from time zero extrapolated to infinity ($AUC_{0\text{-}inf}$), and maximum serum concentration (C_{max}). The 90% confidence intervals of each endpoint were contained within pre-specified bioequivalence margins of 80% to 125%, for all 3 pairwise comparisons. The trial was conducted under the Therapeutic Goods Administration (TGA) Clinical Trial Notification (CTN) scheme offering a streamlined approach with data output supported by global regulatory agencies such as the EMA and US FDA.