NeuClone Announces its Sixth Biosimilar Candidate Perjeta® (Pertuzumab) for use in Combination Therapy with Herceptin® (Trastuzumab)

SYDNEY, 17th Dec. 2018 – NeuClone Pharmaceuticals Ltd. (NeuClone), a clinical-stage biopharmaceutical company exclusively focused on developing high-quality biosimilar products, today disclosed the sixth biosimilar being developed in its pipeline of monoclonal antibody (mAb) products. The product is a biosimilar candidate of Perjeta® (pertuzumab) currently in preclinical development.

Perjeta® (pertuzumab) is FDA and EMA approved as a treatment for patients with HER2-positive early or metastatic breast cancer and is authorised for use only in combination with trastuzumab. In addition to the pertuzumab biosimilar, NeuClone is also developing a biosimilar of Herceptin® (trastuzumab) currently in clinical development.

NeuClone's Perjeta® (pertuzumab) biosimilar is partnered with Serum Institute of India (Serum). Under the partnership, NeuClone and Serum are developing ten biosimilars for global markets.

> "We believe biosimilar combination therapies referencing Perjeta® and Herceptin® represent an exciting development in the future of biosimilars," stated Dr. Noelle Sunstrom, CEO of NeuClone. "Current combination treatments of mAbs, while often clinically superior to monotherapies, are extremely expensive when available. We are determined to dramatically expand the number of patients able to receive these life-changing combination therapies by offering lower-priced biosimilars of both mAbs."
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> "Biosimilars are fast becoming a very important part of our pipeline," says Adar C. Poonawalla, CEO of Serum Institute of India. "NeuClone's biosimilar technology coupled with our low-cost, large-scale business model, will enable us to supply these critical antibody therapies to those previously unable to receive treatment."

Pertuzumab is an IgG1 humanized mAb that targets human epidermal growth factor receptor 2 (HER2). Approximately 20% of women diagnosed with breast cancer test positively for HER2. According to La Merie, Perjeta® recorded global sales of $2.3 billion in 2017.

Dr. Noelle Sunstrom and other NeuClone representatives will be attending the 37th Annual J.P. Morgan Healthcare Conference in San Francisco from 7-10th January 2019. As part of NeuClone's strategy for biosimilar products the company is seeking commercialisation partners.

About NeuClone

NeuClone is a clinical-stage biopharmaceutical company focused exclusively on developing a pipeline of biosimilar products. 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, 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 Partnership

NeuClone and Serum Institute of India 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 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.

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