NeuClone Discloses Details of its Fifth Product: A Biosimilar Candidate for Prolia®/XGEVA® (Denosumab)

SYDNEY, 5th Jan. 2018 - Australian biopharmaceutical company NeuClone Pty. Ltd. today disclosed the fifth biosimilar candidate being developed in its pipeline of monoclonal antibody (mAb) products. The product is a biosimilar candidate for denosumab (branded as Prolia® and XGEVA®) currently in preclinical development. The announcement of the Prolia®/XGEVA® biosimilar follows on from the four previously disclosed biosimilars being developed that reference Herceptin® (trastuzumab), Stelara® (ustekinumab), Humira® (adalimumab) and Synagis® (palivizumab).

Denosumab is an IgG2 fully human mAb that is a RANK ligand (RANKL) inhibitor. Prolia®/XGEVA® was developed by Amgen and first approved in the United States in 2010. Prolia® and XGEVA® are approved for various indications including the treatment of osteoporosis, treatment-induced bone loss, metastases to bone, giant cell tumour of bone and hypercalcemia of malignancy.

In 2016, Prolia® and XGEVA® achieved combined global sales of US$ 3.5 billion and are forecasted to reach US$ 5.6 billion in 2022 according to EvaluatePharma (2017).

NeuClone has been developing the denosumab biosimilar in parallel with several other biosimilar candidates and has partnered with Serum Institute of India for the low-cost manufacture of ten biosimilars including denosumab. As part of this collaboration, NeuClone is responsible for preclinical development and biosimilar product characterisation, whilst Serum Institute of India is responsible for process development and supply of commercial and clinical product.

NeuClone CEO Dr Noelle Sunstrom sees the progression of the denosumab biosimilar as a reflection of the company's position at the forefront of early stage biosimilar development. "We are dedicated to broaden patient access to biological medicines globally by making affordable products of the highest quality. At all stages of development, we are focused on global approval from the most stringent regulatory bodies including the U.S. and European agencies."

Executive Chairman Dr Russell Howard believes that "As a third wave biosimilar, with patent protection likely for several more years, the progression of our denosumab biosimilar and its potential as an early market entrant is incredibly exciting and demonstrates our long-term focus on developing a pipeline of multiple mAb biosimilar products."

NeuClone representatives will be attending the 36th J.P. Morgan Annual Healthcare Conference in San Francisco from 8-11th January 2018. As part of NeuClone's commercial strategy for its biosimilar products the company is seeking commercialisation partners with expertise in Phase III clinical trials, experience in regulatory filing and a channel to market.

About NeuClone Pty. Ltd.
NeuClone Pty. Ltd. is a private 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.

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