NeuClone Announces Preclinical Results for Stelara® (ustekinumab) Biosimilar Candidate

SYDNEY, May 10, 2018 /PRNewswire/ -- Biopharmaceutical company NeuClone has announced positive preclinical results of its biosimilar to Johnson & Johnson's Stelara®, including 3-dimensional (3-D) structure confirmation through X-ray crystallography analysis.

X-ray crystallography analysis confirms identity and equal structural integrity of NeuClone's biosimilar and the reference product Stelara®, in both primary amino acid sequence and 3-D folding (structure).

Stelara® is a monoclonal antibody that targets both interleukin-12 and -23 and is currently approved to treat various diseases including plaque psoriasis and Crohn's disease.

Dr Noelle Sunstrom, CEO of NeuClone, stated: "These results demonstrate our ability to create biosimilars using our *Right from the Start*® approach to biosimilarity, confirming each NeuClone product is indistinguishable from its originator at every stage of development. We develop crystals, functional cell-based assays and other tier 1 biosimilarity tests all in the same facility, allowing us to select the right candidate to go into the clinic."

NeuClone's Stelara® biosimilar is co-developed with Serum Institute of India and is currently in process scale up to support planned Phase I clinical trials in 2019. This will be the company's second product to enter clinical studies in Australia following its first product, a biosimilar of Roche / Genentech's Herceptin®.

In comparison to reference monoclonal antibody products, biosimilar approval requires more extensive analytical data packages to demonstrate structural and functional characterisation of the biosimilar candidate. Analytical studies, such as X-ray crystallography, provide the foundations for determining biosimilarity.

In 2017, Stelara® achieved global sales of USD 4.0 billion. EvaluatePharma has forecast global sales of Stelara® to reach USD 4.9 billion in 2022.

NeuClone representatives will attend the upcoming 2018 BIO International Convention in Boston from 4-7th June 2018 and look forward to meeting potential commercialisation partners.

Stelara® is marketed by Janssen, a wholly owned subsidiary of Johnson & Johnson.

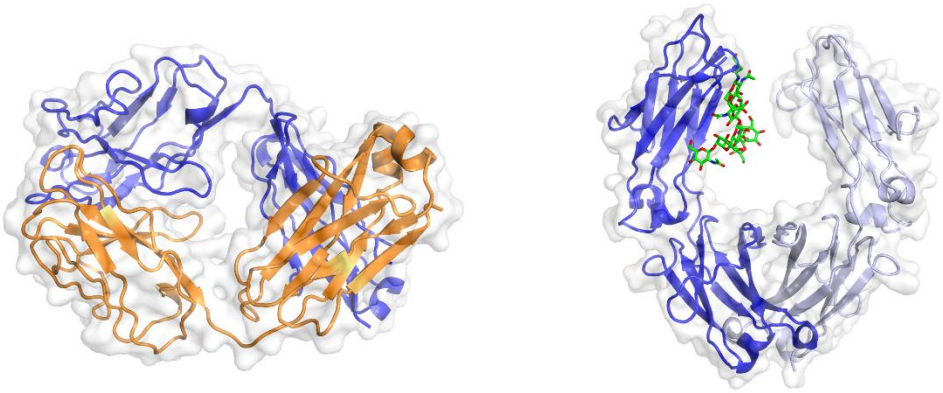

Figure 1: NeuClone's biosimilar Stelara® Fab (left) and Fc (right) structures determined by X-ray crystallography.

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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