

NeuClone Announces Preclinical Results for Stelara Biosimilar Candidate

11 May 2018 | News

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



Australian 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.

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.

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.

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

Headquartered in Australia, NeuClone focusses 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