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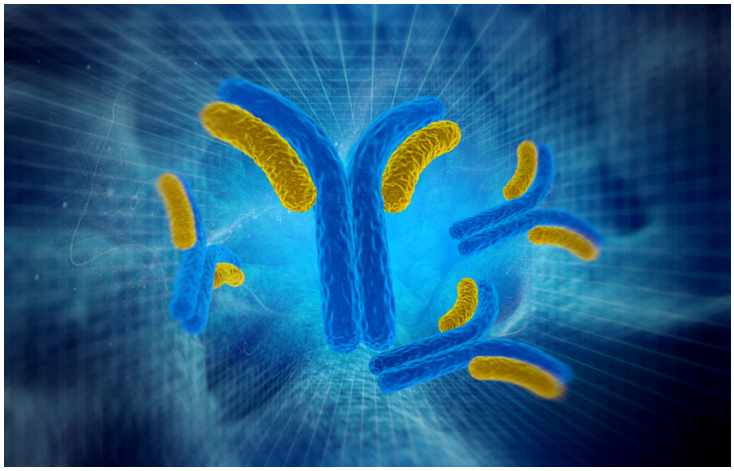
NeuClone announces First Human dose of Stelara® (Ustekinumab) Biosimilar candidate

21 October 2019 | News

The Phase I study to demonstrate the objectives of equivalent pharmacokinetics (PK) and equivalent safety of NeuLara to its biosimilar candidate ustekinumab, which is an antibody to treat patients with plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.



NeuClone, a clinical-stage biopharmaceutical company exclusively focused on developing high-quality biosimilar products, announced on 17 Oct 2019 that it has commenced dosing of Stelara® (ustekinumab) biosimilar candidate, NeuLara, in Phase I clinical trial.

The single-dose, double-blind, randomised, three-arm study is being conducted across multiple Australian sites in over 200 healthy volunteers. The primary objective is to demonstrate equivalent pharmacokinetics (PK) and the secondary objective is to demonstrate equivalent safety of NeuLara to the US- and EU-sourced Stelara®.

NeuLara is the second biosimilar from NeuClone's pipeline to enter clinical development and is developed in partnership with Serum Institute of India.

"Following several years establishing NeuClone as a leading biosimilar company, NeuLara's entry into clinical development demonstrates our ability to advance multiple biosimilar products that will provide greater access to affordable, life-changing medicines, globally," stated Dr Noelle Sunstrom, CEO and Founder of NeuClone.

The NeuLara Phase I clinical trial is being conducted under the Australian Therapeutic Goods Administration (TGA) Clinical Trial Notification (CTN) scheme. This pathway offers a streamlined approach and data output is supported by global regulatory agencies such as the EMA and U.S. FDA.

Prior to initiating the trial, NeuLara was subjected to extensive preclinical testing to confirm structural and functional similarity in comparison to the reference product Stelara®. Testing included positive PK and safety results from a non-clinical primate study, as well as comprehensive physicochemical analysis of Stelara® and NeuLara, including X-ray crystallography.

NeuLara is being developed as a biosimilar candidate of ustekinumab, an antibody targeting interleukin-12 and -23, approved under the brand name Stelara® to treat patients with plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

In 2018, Johnson & Johnson reported Stelara® global sales of USD 5.2 billion. EvaluatePharma (2019) predicts this figure will increase over the coming years, reaching USD 7.8 billion in 2024.

NeuClone representatives are attending the upcoming 2019 BIO-Europe conference in Hamburg from 11-13th November and look forward to discussing biosimilar development and commercialisation opportunities with potential partners.