Functional Characterization of Abatacept Biosimilar

to initiate a Clinical Trial for the treatment of Rheumatoid Arthritis

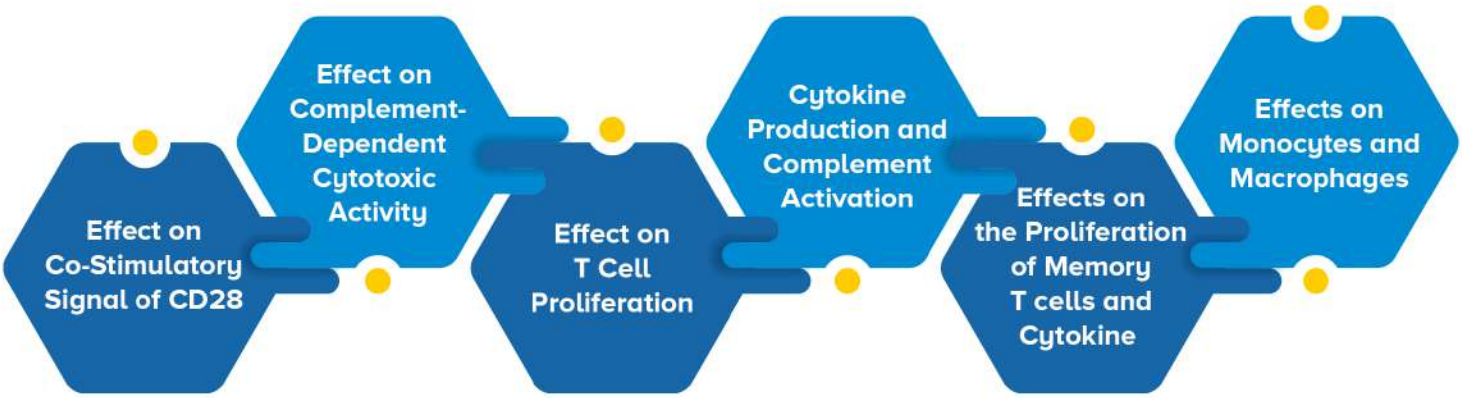
Type of Study

Pharmacodynamic Characterization of Biosimilars to initiate the Phase I clinical trials

Situational Analysis

A multinational company wanted to initiate a clinical trial on Abatacept Biosimilar but was cited for a significant deficiency in functional characterization. The sponsor was cited for a lack of an immunogenicity assay that meets current regulatory guidelines and industry best practices.

Veeda Group Supported the client in the Functional Characterization of Abatacept Biosimilar using the following assays through an Immuno-centric Approach



Highlights of Result Delivered

Reduced regulatory timelines from **18 months to 3 months**

3-D Characterization through **Intelli-b™ Technology**

Saved up to two years of **development time**

Veeda Group's Approach that helped in the Smooth Execution of the Study

After reviewing the physicochemical characteristics of the Biosimilar, we recommended an immuno-centric approach to Biosimilar development that also demonstrates the similarity of protein higher order structures.

- Flow Cytometry technology was used to demonstrate target binding similarity on the cell surface as there was a lack of sufficient data on target binding
- Utilization of the effect on Complement-Dependent Cytotoxic Activity was evaluated by using Epstein-Barr virus-transformed, CD80/CD86-positive Human B lymphoblast cell line (PM-LCL)
- T-cell Proliferation assay was performed and compared with the innovator molecule to establish Biosimilarity
- 3-D Characterization was done by Intelli-b™, which is a Biosimilar Fingerprinting Technology that offers a comparative analytical assessment of a target therapeutic complex molecule and its Biosimilar
- Utilization of the SPEAD method with double acid dissociation to improve assay drug tolerance

Results

- Functional Characterization data showed the Biosimilar was highly similar to the innovator
- The sponsor was able to respond to the regulatory inquiry regarding the characterization deficiency in less than 3 months
- Using a high-throughput, multi-parameter immuno-fingerprinting method (e.g., Intelli.b™) saved up to two years of development time and millions of dollars in costs

To know more about
our Biosimilar capabilities, mail us at
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