



## Press release

# BiosanaPharma announces successful outcome of comparative phase I study of BP001, a biosimilar candidate to Xolair® (omalizumab)

**Study evaluated safety and pharmacokinetics of BP001 compared to Xolair® in healthy volunteers.**

**Sydney/Leiden, March 30, 2020** – BiosanaPharma, an Australian/Dutch biotech company, today announced the successful outcome of a comparative phase I clinical study in healthy volunteers of BP001, a biosimilar candidate to Xolair®. The study was conducted in Australia, with 84 healthy male volunteers. The results of the study show that bioavailability, safety, tolerability and immunogenicity of BP001 are comparable to those of Xolair®.

BP001 is produced by utilising BiosanaPharma's innovative '3C process', a fully continuous manufacturing process, cutting production costs by up to 90%. This makes BP001 the first *clinical* monoclonal antibody in the world to be produced with a fully continuous process, according to available market information.

This phase I study supports the further clinical development of BP001, where the next step will be a phase III study comparing BP001 to the originator in patients with allergic asthma. This study is planned to start early 2021.



**Ard Tijsterman, CEO of BiosanaPharma:**

"We are very proud that we now have successful phase I results for our first biosimilar product. This validates our use of fully-continuous manufacturing for biologics and allows us to move forward in our quest to deliver low cost mAb biosimilars."

### **About BiosanaPharma:**

BiosanaPharma is a biotechnology company with operations in Australia, The Netherlands and Singapore. The company is headed by a team of entrepreneurs on a mission to make monoclonal antibody therapeutics more **affordable and accessible** for patients through smart, disruptive technology. The company aims to increase affordability by using its proprietary 3C process, and to improve accessibility with its novel oral formulation and delivery technology for biologics via its subsidiary BiOraliX.

**About omalizumab:**

BP001 is a biosimilar candidate of omalizumab. Omalizumab is an antibody targeted towards free IgE; it is used to improve the control of severe persistent asthma that is caused by an allergy, and chronic (long-term) spontaneous urticaria (itchy rash) in patients with elevated IgE who do not respond to treatment with antihistamines.

The only currently-approved product containing omalizumab is Xolair®, marketed by Novartis and Roche since 2006. Annual sales of Xolair® are ~USD 3.2B (2019). Xolair® is delivered via subcutaneous injections.

For more information, please have a look at <https://www.biosanapharma.com>, or contact:

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