



BiosanaPharma

PRESS RELEASE

BiosanaPharma gets approval to start phase I clinical trial for a biosimilar version of omalizumab, the first monoclonal antibody produced with a fully continuous biomanufacturing process

Leiden/Sydney, February 21 2019 – Biosana Pty Ltd (a 100% subsidiary of BiosanaPharma BV) has received permission from the Australian Bellberry Human Research Ethics Committee HREC to start a phase I clinical trial of their first pipeline product. The trial consists of a bioequivalence double-blind, randomized, two-parallel-group phase I study of a humanized anti-immunoglobulin E monoclonal antibody 'BP001' as lyophilized powder formulation compared with the standard omalizumab (Xolair®) lyophilized powder formulation in healthy male volunteers. Prior to the submission of the Investigative Brochure to the HREC an extensive comparability exercise was performed between BP001 and Xolair®, indicating functional, binding and structural similarity between the two molecules. This extensive laboratory exercise was also sufficient for Biosana to obtain a waiver for preclinical studies in animal models from the EMA.

The Phase I trial is expected to be concluded and fully reported in Q4 2019.

Ard Tijsterman, CEO of BiosanaPharma:

"We are extremely happy and proud that we've been able to develop our first biosimilar product, produced by our innovative '3C process', the first fully continuous process to deliver a product entering phase I. We will start negotiations with potential marketing & sales partners now to perform phase III studies and secure future global distribution of the product."

About omalizumab:

Omalizumab is marketed by Roche/Genentech (USA) and Novartis (ROW) as Xolair® since 2006. It is used to treat moderate to severe allergic asthma and chronic idiopathic urticaria in patients aged 12 years and above in the US and the EU. Additionally, it is approved for paediatric patients aged 6 to 11 years in the EU. Xolair® is delivered via subcutaneous injections. Total sales for Xolair® in 2018 were US\$ 2.9M with a consistent growth in both indications of 11-13% annually. The US market accounted for roughly 2/3 of total Xolair® sales. The patent on Xolair® has expired in 2017 in the US and Europe (Novartis, 2016).

About BiosanaPharma:

BiosanaPharma is a Dutch/Australian biotechnology company with a disruptive approach to the manufacture and delivery of monoclonal antibody therapeutics (mAbs). BiosanaPharma's "3C process" offers a 90% reduction in the cost of developing and manufacturing EMA/FDA quality mAbs. The 3C process is a fully-continuous, small footprint platform and produced BiosanaPharma's first pipeline drug BP001, now approved to enter Phase I (see above).

BiosanaPharma is also developing a platform for oral delivery of biologicals, which has delivered successful preclinical results. The current pipeline consists of biosimilars and oral versions of blockbuster biologics.

For more information, please have a look at <http://www.biosanapharma.com>
or contact:
Nettie Buitelaar, Chief Business Officer BiosanaPharma
Nettie.buitelaar@biosanapharma.com; +31610026742