BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

# Innovent receives IND approval to initiate Clinical Trials in China

July 26, 2018 | News

**Innovent's IBI101, is the first OX40-targeted molecule to receive IND approval in China**




Innovent Biologics, a world-class China-based biopharmaceutical company that develops and intends to commercialize high quality innovative antibody-based therapeutics, today announced that it has received Investigational New Drug (IND) approval from the China Food and Drug Administration (CFDA) to initiate clinical trials in China with IBI101, an anti-OX40 agonistic antibody, and with IBI307, an anti-RANKL antibody.

Innovent's IBI101, is the first OX40-targeted molecule to receive IND approval in China. OX40 is one of the most important targets in the field of immune-oncology. Innovent will be among one of a few companies pursuing the development of OX40 agonists in early stage clinical trials globally. IBI307 is an anti-RANKL antibody under development for the treatment of osteoporosis and lytic bone lesions associated with cancer metastasis. Currently there is no anti-RANKL inhibitors approved for marketing in China.

"The IND approvals for IBI101 and IBI307 by CFDA once again demonstrate Innovent's capability and commitment to lead the rapid development of China's biopharmaceutical market. As part of our 17 drug candidates under development, we will prepare to bring these two targeted therapeutic agents into clinical trials quickly," said Michael Yu, Founder, Chief Executive Officer and Chairman. "Innovent will continue to discover and develop new biopharmaceutical drugs to expand our portfolio of products to treat patients. With today's rapid improvements in cancer treatment modalities, we will utilize our well-established platform to discover, develop, manufacture and commercialize innovative high-quality biopharmaceutical drugs."

IBI-101 is a fully human monoclonal antibody drug candidate that was developed to treat cancers and hepatitis B. IBI101 binds to and stimulates OX40, which should increase the survival and activation of tumor specific T cells. OX40 agonists can be combined with a variety of therapeutic products, such as our PD-1 mAb, sintilimab, and other products in our pipeline, resulting in improved outcomes for patients. Innovent intends to pursue simultaneous development of this asset in China as well as outside of China. There are currently no OX40 agonists approved globally.