

Innovent announces first patient dosing of IBI 101 study

15 February 2019 | News

The study comprises two parts, namely a Phase la study with IBI101 as monotherapy and a Phase lb study with IBI101 in combination with Tyvyt®.



Innovent Biologics, Inc. (Innovent) , a world-class biopharmaceutical company that develops, manufactures and commercializes high quality innovative medicines for the treatment of oncology, autoimmune and other major diseases, has announced that the first patient has been dosed in a Phase I clinical trial of IBI101, a recombinant fully human anti-tumor necrosis factor receptor superfamily member 4 (anti-OX40) monoclonal antibody.

In this Phase I clinical study, the tolerance, safety and primary efficacy of IBI101, either as monotherapy or in combination with Tyvyt[®] (sintilimab injection), an anti-programmed cell death protein 1 (PD-1) antibody, will be evaluated. The study comprises two parts, namely a Phase Ia study with IBI101 as monotherapy and a Phase Ib study with IBI101 in combination with Tyvyt[®]. Patients with advanced solid tumors who have failed standard treatments will be enrolled in the study.

"The Investigational New Drug (IND) application of IBI101, indicated for patients with advanced solid tumors, was approved by the U.S. Food & Drug Administration (FDA) on 5 Dec, 2018. The mechanism of IBI101 is different from that of anti-PD-1 antibodies. IBI101 stimulates the OX40 pathway so as to activate effector T cells, thus enhancing the anti-tumor immune reaction," commented Professor XU Ruihua, Director of Sun Yat-Sen University Cancer Hospital "Worldwide clinical research on anti-OX40 antibodies is limited so far. We are looking forward to the study results of IBI101."

"Innovent, a China-based company, was established with an ambition to serve global patient needs. We are dedicated to exploring the most advanced research areas in cancer immunotherapy and providing innovative medicines that improve lives around the world. The initiation of Phase I study of IBI101 and dosing of first patient have again demonstrated our efforts and commitment. We truly anticipate further breakthroughs so that more patients will potentially benefit in the future," said Michael Yu, Founder, Chief Executive Officer and Chairman.