BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Innovent & Lilly release clinical trial results of sintilimab injection

10 August 2020 | News

This trial was conducted to assess the efficacy of TYVYT® in combination with ALIMTA® (pemetrexed) andplatinum chemotherapy as a first-line treatment in people with nonsquamous non-small cell lung cancer (nsqNSCLC).

China-based Innovent Biologics, Inc. (Innovent), a world-class biopharmaceutical company that develops, manufactures and commercializes high-quality medicines for the treatment of oncology, metabolic, autoimmune and other major diseases, recently announced with Eli Lilly and Company (Lilly) that interim analysis data from ORIENT-11 were released in an oral presentation at the IASLC World Conference on Lung Cancer (WCLC) 2020 Virtual Presidential Symposium. On the same day, the data was published online by the Journal of Thoracic Oncology.

This trial was conducted to assess the efficacy of TYVYT® (sintilimab injection) in combination with ALIMTA® (pemetrexed) and platinum chemotherapy as a first-line treatment in people with nonsquamous non-small cell lung cancer (nsqNSCLC) without sensitive EGFR mutation or ALK rearrangement. ORIENT-11 is a randomized, double-blind, Ph 3 clinical trial evaluating TYVYT® or placebo in combination with ALIMTA® (pemetrexed) and platinum chemotherapy as a first-line treatment for advanced or recurrent nsqNSCLC without sensitizing EGFR mutations or ALK rearrangements.

After a median follows up of 8.9 months, the median PFS of the sintilimab combination and the placebo combination assessed by the Independent Radiographic Review Committee (IRRC) was 8.9 months and 5.0 months, rspct. [HR (95%CI) = 0.482 (0.362, 0.643), P < 0.00001]. The median overall survival (OS) was not reached in both groups, but OS showed an improvement favoring the sintilimab combination (HR=0.609, 95%CI: 0.400-0.926). The confirmed objective response rate was improved from 29.8% to 51.9%, and the sintilimab combination showed a shorter time to respond. NMPA of China has accepted the supplemental New Drug Application (sNDA) for this indication.