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Innovent & Lilly announce acceptance of new drug application for TYVYT® (sintilimab injection)

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The NMPA accepted sNDA for TYVYT® (sintilimab injection) as first-line therapy in non-squamous NSCLC on Apr23, 2020.

China-based Innovent Biologics, Inc. (Innovent), jointly announced with Eli Lilly and Company (Lilly) that the National Medical Products Administration (NMPA) of China has accepted the supplemental New Drug Application (sNDA) for TYVYT® (sintilimab injection) in combination with Gemzar® (gemcitabine) and platinum as first-line therapy in squamous non-small cell lung cancer (squamous NSCLC). Recently, the NMPA accepted sNDA for TYVYT® (sintilimab injection) as first-line therapy in non-squamous NSCLC on Apr 23, 2020.

The sNDA was based on the analysis of a randomized, double-blind, Phase 3 clinical study (ORIENT-12)—TYVYT® (sintilimab injection) or placebo in combination with Gemzar® (gemcitabine) and platinum as first-line therapy for advanced or metastatic squamous NSCLC. Based on the analysis conducted by the Independent Data Monitoring Committee (IDMC), TYVYT® (sintilimab injection) in combination with Gemzar® (gemcitabine) and platinum demonstrated a statistically significant improvement in progression-free survival (PFS) compared with placebo in combination with Gemzar® (gemcitabine) and platinum, which met the pre-defined efficacy criteria.

The safety profile is consistent with previously reported sintilimab studies, and no new safety signals were identified. Detailed data will be released in an upcoming international academic conference and journal.