



Lilly Announces Complete Response Letter for Sintilimab in Combination with Pemetrexed and Platinum Chemotherapy for the First-Line Treatment of People with Nonsquamous Non-Small Cell Lung Cancer

March 24, 2022

INDIANAPOLIS, March 24, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) for the Biologics License Application (BLA) for the investigational medicine sintilimab injection, a PD-1 inhibitor in combination with pemetrexed and platinum chemotherapy for the first-line treatment of people with nonsquamous non-small cell lung cancer (NSCLC). Sintilimab is being developed by Innovent Biologics, Inc. (HKEX: 01801) and Lilly.

The letter indicates that the review cycle is complete but the FDA is unable to approve the application in its current form, consistent with the outcome of the Oncologic Drugs Advisory Committee Meeting in February. The CRL includes a recommendation for an additional clinical study, specifically a multiregional clinical trial comparing standard of care therapy for first line metastatic NSCLC to sintilimab with chemotherapy utilizing a non-inferiority design with an overall survival endpoint.

Along with Innovent, Lilly is assessing next steps for the sintilimab program in the U.S.

About Sintilimab

Sintilimab, is an investigational PD-1 inhibitor developed by Innovent and Lilly. Sintilimab is a type of immunoglobulin G4 monoclonal antibody, which binds to PD-1 molecules on the surface of T-cells, blocks the PD-1 / PD-Ligand 1 (PD-L1) pathway, and reactivates T-cells to kill cancer cells. Innovent is currently conducting more than 20 clinical studies of sintilimab to evaluate its safety and efficacy in a wide variety of cancer indications, including more than 10 registrational or pivotal clinical trials.

In China, sintilimab, marketed as TYVYT[®] (sintilimab injection), has been approved for:

- The treatment of relapsed or refractory classic Hodgkin's lymphoma after two lines or later of systemic chemotherapy
- In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of nonsquamous non-small cell lung cancer
- In combination with gemcitabine and platinum chemotherapy, for the first-line treatment of squamous non-small cell lung cancer
- In combination with BYVASDA[®] (bevacizumab biosimilar injection) for the first-line treatment of hepatocellular carcinoma

Additionally, Innovent currently has regulatory submissions under review in China for sintilimab:

- In combination with cisplatin plus paclitaxel or cisplatin plus 5-fluorouracil for the first-line treatment of esophageal squamous cell carcinoma;
- In combination with chemotherapy for the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma;
- In combination with BYVASDA[®] (bevacizumab biosimilar injection) and chemotherapy (pemetrexed and cisplatin) for EGFR-mutated nonsquamous NSCLC following EGFR-TKI treatment.

Sintilimab was included in China's National Reimbursement Drug List (NRDL) for all four approved indications (listed above), according to the latest announcement from the China National Healthcare Security Administration ("NHSA").

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to create medicines to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit <http://www.lilly.com> and lilly.com/newsroom.

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About Innovent Biologics' Strategic Collaboration with Eli Lilly and Company

Innovent entered into a strategic collaboration with Lilly focused on biological medicine in March 2015 – a groundbreaking partnership between a Chinese pharmaceutical company and a multinational pharmaceutical company. Under the agreement, Innovent and Lilly are co-developing and commercializing oncology medicines, including sintilimab in China. In October 2015, the two companies announced the extension of their existing collaboration to include co-development of three additional oncology antibodies targeting oncology indications. In August 2019, Innovent further entered a licensing agreement with Lilly to develop and commercialize a potentially global best-in-class diabetes medicine in China. Its collaboration with Lilly indicates that Innovent has established a comprehensive level of cooperation between China's innovative pharmaceuticals sector and the international pharmaceuticals sector in fields such as R&D, CMC, clinical development and commercialization. In August 2020, Lilly and Innovent announced a global expansion of their strategic alliance for sintilimab, whereby Lilly obtained an exclusive license for sintilimab for geographies

outside of China.

Note:


TYVYT® (sintilimab injection; Innovent) and BYVASDA® (bevacizumab biosimilar injection; Innovent) are not approved products in the United States.

Eli Lilly and Company Forward-Looking Statement

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about sintilimab injection in combination with pemetrexed and platinum chemotherapy as a potential first-line treatment of people with nonsquamous non-small cell lung cancer and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there can be no guarantee that future study results will be consistent with study results to date, or that sintilimab will receive additional regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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The Lilly logo is rendered in a vibrant red, cursive script font. The letters are fluid and interconnected, with a classic, elegant feel. The 'L' is particularly large and prominent, leading into the 'i', 'l', 'l', 'e', and 'y' which follow in a similar flowing style. The overall appearance is that of a traditional, handwritten-style brand mark.

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