Innovent and Lilly Announce Successful Expansion of Sintilimab in China National Reimbursement Drug List to Include Three Additional First-Line Indications

December 3, 2021

SAN FRANCISCO, INDIANAPOLIS, and SUZHOU, China, Dec. 2, 2021 /PRNewswire/ -- Innovent Biologics, Inc. ("Innovent") (HKEX: 01801), a world-class biopharmaceutical company that develops, manufactures and commercializes high quality medicines for the treatment of oncology, metabolic, autoimmune and other major diseases, and Eli Lilly and Company ("Lilly") (NYSE: LLY), announce that the innovative PD-1 inhibitor sintilimab has been successfully included in the updated National Reimbursement Drug List ("NRDL") for all approved indications, according to the latest announcement from the China National Healthcare Security Administration ("NHSA"). The updated NRDL will officially take effect on January 1, 2022.

A total of four approved indications for sintilimab are now included in the updated NRDL:

- Three indications for sintilimab have been included in the NRDL for the first time, as follows: in combination with pemetrexed and platinum chemotherapy for the first-line treatment of advanced or recurrent nonsquamous non-small cell lung cancer (nsq NSCLC) without sensitizing EGFR mutations or ALK rearrangements; in combination with gemcitabine and platinum chemotherapy for the first-line treatment of advanced or recurrent squamous non-small cell lung cancer (sq NSCLC); and in combination with BYVASDA® (bevacizumab biosimilar injection) for the first-line treatment of unresectable or advanced hepatocellular carcinoma (HCC).
- An indication for relapsed or refractory classic Hodgkin's lymphoma (cHL) after two lines or later of systemic chemotherapy, which was first included in the NRDL in 2019, has been successfully renewed this year.

Dr. Michael Yu, Founder, Chairman and CEO of Innovent, stated, "Two years ago, sintilimab was the first and only PD-1 inhibitor included in the NRDL. This year, three additional first-line indications for sintilimab have been successfully included in the NRDL, further enhancing the accessibility of this anti-cancer drug and alleviating financial burden for Chinese patients and their families. We have witnessed the profound reform and rapid development of pharmaceutical industry in China, driven by the government's commitment to continuously support innovation and emphasize a healthier and better life for the people of China. Innovent is honored to be a part of the Chinese government's initiative to improve health, and are devoted to the deepening of the national health care reform. With our company's mission 'to develop and commercialize high quality biopharmaceuticals that are affordable to ordinary people,' we hope to continue to work together with all relevant parties to improve drug affordability and accessibility, and contribute to the 'Healthy China 2030' initiative."

Julio Gay-Ger, President and General Manager, Lilly China, stated, "In recent years, China has continued to intensify medical insurance reform, giving strategic priority to safeguarding people's health. As a multinational pharmaceutical company tied with China for over 100 years, Lilly always adheres to the philosophy of 'In China, For China', and actively participates in China's health reform, especially in the drug supply system. The indication expansion of sintilimab in the National Reimbursement Drugs List (NRDL) can further reduce the burden of healthcare, enabling the patients to afford innovative drugs and have a higher quality of life through persistent treatment. Lilly will continue to keep a close eye on the major healthcare challenges in China in the future, and play an important role in the country's 'all-round and full-cycle health' ecosystem, to support the accelerated implementation of the 'Healthy China 2030' initiatives."

Mr. Min Liu, Chief Commercial Officer of Innovent, stated, "Sintilimab is the only PD-1 inhibitor in China with four major indications (1L nsq NSCLC, 1L sq NSCLC, 1L HCC and cHL) approved and included in China's NRDL. Particularly, lung cancer and liver cancer are two of the most prevalent tumor types in China, accounting for the first and third largest numbers of new cases each year – representing a large unmet medical need. We will proactively support the work of the government departments at all levels, cooperate with the implementation of medical insurance policies in all regions, and help relieve patients' economic burden to a further extent, to allow this high-quality immunotherapy product to benefit more lives of Chinese patients and their families."

About Sintilimab

Sintilimab, marketed as TYVYT® (sintilimab injection) in China, is an innovative PD-1 inhibitor with global quality standards jointly developed by Innovent and Eli Lilly and Company. Sintilimab is an 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 worldwide, 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 has been approved and included in the National Reimbursement Drug List (NRDL) for four indications, including:

- 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 unresectable or advanced

hepatocellular carcinoma

Additionally, Innovent currently has two regulatory submissions under review in China for sintilimab, for the first-line treatment of esophageal squamous cell carcinoma, and the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma.

Additionally, three clinical studies of sintilimab have met their primary endpoints:

- Phase 2 study as second-line treatment of esophageal squamous cell carcinoma
- Phase 3 study as second-line treatment for squamous NSCLC with disease progression following platinum-based chemotherapy
- Phase 3 study in combination with BYVASDA® (bevacizumab biosimilar injection) and chemotherapy (pemetrexed and cisplatin) for EGFR-mutated nonsquamous NSCLC following EGFR-TKI treatment

In May 2021, the U.S. FDA accepted for review the Biologics License Application (BLA) for sintilimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of nonsquamous non-small cell lung cancer.

About Innovent

Inspired by the spirit of "Start with Integrity, Succeed through Action," Innovent's mission is to develop, manufacture and commercialize high-quality biopharmaceutical products that are affordable to ordinary people. Established in 2011, Innovent is committed to developing, manufacturing and commercializing high-quality innovative medicines for the treatment of cancer, autoimmune, metabolic and other major diseases. On October 31, 2018, Innovent was listed on the Main Board of the Stock Exchange of Hong Kong Limited with the stock code: 01801.HK.

Since its inception, Innovent has developed a fully integrated multi-functional platform which includes R&D, CMC (Chemistry, Manufacturing, and Controls), clinical development and commercialization capabilities. Leveraging the platform, the company has built a robust pipeline of 26 valuable assets in the fields of cancer, metabolic, autoimmune disease and other major therapeutic areas, with 6 products officially approved for marketing in China – TYVYT® (sintilimab injection), BYVASDA® (bevacizumab biosimilar injection), SULINNO® (adalimumab biosimilar injection), HALPRYZA® (rituximab biosimilar injection), Pemazyre® (pemigatinib oral inhibitor) and olverembatinib (BCR ABL TKI), a Biologics License Application (BLA) for sinitilimab accepted for review in the U.S., 5 assets in Phase 3 or pivotal clinical trials, and an additional 15 molecules in clinical studies.

Innovent has built an international team with advanced talent in high-end biological drug development and commercialization, including many global experts. The company has also entered into strategic collaborations with Eli Lilly and Company, Adimab, Incyte, MD Anderson Cancer Center, Hanmi and other international partners. Innovent strives to work with many collaborators to help advance China's biopharmaceutical industry, improve drug availability and enhance the quality of the patients' lives. For more information, please visit: www.innoventbio.com. and www.linkedin.com/company/innovent-biologics/.

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 lilly.com and lilly.com/newsroom. P-LLY

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 antibodies targeting oncology indications. In August 2019, Innovent further entered into a licensing agreement with Lilly to develop and commercialize a potentially global best-in-class diabetes medicine in China. The collaboration with Lilly is an example of how 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 and plans to pursue registration of sintilimab in the U.S. and other geographies outside of China.

Note:

TYVYT® (sintilimab injection) is not an approved product in the United States.

BYVASDA® (bevacizumab biosimilar injection), SULINNO®, and HALPRYZA® (rituximab biosimilar injection) are not approved products in the United States.

TYVYT® (sintilimab injection, Innovent)

BYVASDA® (bevacizumab biosimilar injection, Innovent)

HALPRYZA® (rituximab biosimilar injection, Innovent)

SULINNO® (adalimumab biosimilar injection, Innovent)

Pemazyre® (pemigatinib oral inhibitor, Incyte Corporation). Pemazyre® was discovered by Incyte Corporation and licensed to Innovent for development and commercialization in Mainland China, Hong Kong, Macau and Taiwan.

Innovent Biologics Forward-Looking Statements

This news release may contain certain forward-looking statements that are, by their nature, subject to significant risks and uncertainties. The words "anticipate", "believe", "estimate", "expect", "intend" and similar expressions, as they relate to Innovent, are intended to identify certain of such forward-looking statements. Innovent does not intend to update these forward-looking statements regularly.

These forward-looking statements are based on the existing beliefs, assumptions, expectations, estimates, projections and understandings of the management of Innovent with respect to future events at the time these statements are made. These statements are not a guarantee of future developments and are subject to risks, uncertainties and other factors, some of which are beyond Innovent's control and are difficult to predict. Consequently, actual results may differ materially from information contained in the forward-looking statements as a result of future changes or developments in our business, Innovent's competitive environment and political, economic, legal and social conditions.

Innovent, the Directors and the employees of Innovent assume (a) no obligation to correct or update the forward-looking statements contained in this site; and (b) no liability in the event that any of the forward-looking statements does not materialize or turn out to be incorrect.

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 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.

SOURCE Innovent Biologics

Related Links

www.innoventbio.com