Innovent and Incyte Announce Strategic Collaboration and Licensing Agreement for Three Clinical-stage Product Candidates in China

December 16, 2018

SUZHOU, China, Dec. 16, 2018 /PRNewswire/ -- Innovent Biologics, Inc. (Innovent) (HKEX: 01801) and Incyte (NASDAQ:INCY) today announced that the companies, through their respective subsidiaries, have entered into a strategic collaboration agreement for three clinical-stage product candidates discovered and developed by Incyte—pemigatinib (FGFR1/2/3 inhibitor), itacitinib (JAK1 inhibitor) and parsaclisib (PI3Kδ inhibitor). Under the terms of the agreement, Innovent will pay Incyte US$40 million in cash up front, and Incyte shall be eligible to receive an additional US$20 million in consideration in connection with the first investigational new drug (IND) application by Innovent in China, which is expected to be achieved in 2019. Innovent will receive the rights to develop and commercialize the three assets in hematology and oncology in Mainland China, Hong Kong, Macau and Taiwan.

"The collaboration and partnership with Innovent provides us with an important and strategic opportunity to further serve the oncology community around the world by potentially bringing new, innovative medicines to patients with high unmet medical needs in China," said Hervé Hoppenot, Chief Executive Officer of Incyte. "We believe Innovent's experienced leadership team and sizeable clinical network will expand our clinical trials for itacitinib, pemigatinib and parsaclisib, and, if any of these product candidates are approved, will provide access to our innovative therapies to patients and healthcare providers in China."

"We're very pleased to enter into this collaboration with Incyte, a well-recognized innovative global biopharmaceutical company. This collaboration not only strengthens our portfolio by adding three potentially best-in-class clinical-stage targeted therapies, but, we believe, also proves that Innovent is an ideal partner for world-class pharmaceutical companies coming to China—transforming Innovent from a company primarily focused on monoclonal antibodies to one with a broader oncology focus that develops potentially innovative treatments regardless of molecule size," said Michael DC Yu., Ph.D., Chief Executive Officer and President of Innovent. "Based on the compelling clinical data reported to-date, we believe pemigatinib, itacitinib and parsaclisib may be poised, if further development is successful and approvals in China are granted, to dramatically alter the treatment landscape for patients in China with FGFR-altered cholangiocarcinoma and urothelial carcinoma, graft-versus-host-disease after bone marrow transplant and non-Hodgkin lymphoma, respectively, and other cancers. These three novel medicines from Incyte complement our rich pipeline of immune-oncology-focused monoclonal antibodies and also enable the exploration of combination treatment approaches with the potential to further improve patient outcomes worldwide."

Per the terms of the collaboration agreement, Innovent will pay Incyte US$40 million in cash up front and Incyte will be eligible to receive an additional US$20 million in consideration in connection with the first IND filing in China, which is expected to be achieved in 2019. Innovent will receive rights to develop and commercialize three product candidates (pemigatinib, itacitinib and parsaclisib) in hematology and oncology in the Innovent territory of Mainland China, Hong Kong, Macau and Taiwan. In addition, Incyte will be eligible to receive up to US$129 million in potential development and regulatory milestones, and up to US$202.5 million in potential commercial milestones. Incyte will also be eligible to receive tiered royalties from the high teens to the low twenties on future sales of products resulting from the collaboration. Incyte retains an option to assist in the promotion of the three product candidates in China.

The transaction is effective immediately upon the execution of the strategic collaboration agreement. Further financial details were not disclosed.

About Pemigatinib (INCB54828, FGFR inhibitor)

Fibroblast growth factor receptors (FGFRs) play an important role in tumor cell proliferation and survival, migration and angiogenesis (the formation of new blood vessels). Activating mutations, translocations and gene amplifications in FGFRs are closely correlated with the development of various cancers. Pemigatinib is an oral inhibitor of FGFR isoforms 1, 2 and 3 which, in preclinical studies, has demonstrated potency and selective pharmacologic activity against cancer cells with FGFR alterations. Phase 2 studies investigating the safety and efficacy of pemigatinib monotherapy across several FGFR-driven malignancies are ongoing—the FIGHT (FIbroblast Growth factor receptor in oncology and Hematology Trials) clinical trial program currently comprises FIGHT-201 in patients with metastatic or surgically unresectable bladder cancer, including with activating FGFR3 alterations; FIGHT-202 in patients with metastatic or surgically unresectable cholangiocarcinoma who have failed previous therapy, including with activating FGFR2 translocations; and FIGHT-203 in patients with myeloproliferative neoplasms with activating FGFR1 translocations. FIGHT-302, a randomized Phase 3 trial in newly-diagnosed patients with cholangiocarcinoma and activating FGFR2 translocations, is expected to be initiated before the end of 2018 (NCT03656536).

About Itacitinib（INCB39110, JAK1 inhibitor）

Itacitinib (INCB039110) is a novel, potent, and selective JAK1 inhibitor currently in clinical studies for the treatment of treatment naïve acute and chronic GVHD, and non-small cell lung cancer in combination with osimertinib, an EGFR inhibitor. A Phase 3 study (GRAVITAS-301) of itacitinib for the treatment of acute GVHD is underway, with data expected in 2019. GRAVITAS-309 (NCT03584516) is a randomized, double-blind, placebo-controlled pivotal Phase 3 study evaluating itacitinib or placebo in combination with corticosteroids as a first-line treatment for patients with chronic graft-versus-host disease (cGVHD) which is expected to be initiated early in 2019.

About Parsaclisib (INCB50465, PI3Kδ inhibitor)

Parsaclisib (INCB50465) is an investigational novel oral inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ) isoforms. PI3Kδ is an important anticancer target implicated in malignant B-cell growth, survival and proliferation which, in preclinical studies, has demonstrated potency and selectivity in preclinical studies and has potential therapeutic utility in the treatment of patients with hematologic malignancies such as lymphoma.

Emerging data suggest that PI3Kδ may also be an important target in the solid tumor microenvironment. The CITADEL (Clinical Investigation of TArgeted PI3K-DELta Inhibition in Lymphomas) clinical trial program is currently evaluating parsaclisib in several ongoing Phase 2 trials as a treatment for non-Hodgkin lymphomas (follicular, marginal zone and mantle cell) Parsaclisib is also being studied in Phase 1 and Phase 2 trials as part of a combination therapy for patients with myelofibrosis, advanced or metastatic solid tumors and diffuse large B-cell lymphoma.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at www.incyte.com.

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About Innovent

Innovent was established in 2011. Since it was founded, Innovent has developed a fully-integrated platform which includes R&D, CMC (Chemistry, Manufacturing, and Controls), clinical development and commercialization capabilities. These capabilities have enabled us to build a robust pipeline of innovative and commercially promising monoclonal antibodies and other biologics in the fields of oncology, ophthalmology, autoimmune, and cardiovascular diseases. Leveraging our platform, we have built up a pipeline of 17 antibody drug candidates in the last seven years, led by our four core products that are in late-stage clinical development in China. In addition, out of our pipeline of 17 antibody drug candidates, ten have entered in clinical development, four have entered Phase III clinical trials and two that have New Drug Applications (NDA) accepted by the NMPA including one with priority review status for sintilimab.

Innovent has built a biopharmaceutical production facility that operates under global standards. The design and operation of our clinical and commercial facilities are in compliance with the cGMP standards of NMPA, FDA and EMA. The existing production lines have already passed GMP audits by an international pharmaceutical company. The company has also entered into various key strategic alliances with Eli Lilly and Company, Adimab and other biopharmaceutical companies. On October 31, 2018, Innovent was successfully listed on the main board of the Hong Kong Stock Exchange and the stock code is 01801.

Inspired by the spirit of "Start with Integrity, Succeed through Action", Innovent's mission is to develop and commercialize high quality biopharmaceutical products that are affordable to ordinary people. Innovent wishes to work with all relevant parties helping the advancement of China's biopharmaceutical industry, improving the drug availability to ordinary people and enhancing the quality of the patients' life.

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: the potential to bring new, innovative medicines to patients with high unmet medical needs in China; the belief that Innovent's experienced management and sizeable network will expand Incyte's clinical trials for itacitinib, pemigatinib and parsaclisib, and, if any of those assets are approved, will provide access to Incyte's therapies to patients and healthcare providers in China; the expected timing for initiation of the FIGHT-302 clinical trial; the expected timing of data from the GRAVITAS-301 trial; and the expected timing for initiation of the GRAVITAS-309 trial.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; unanticipated delays in connection with clinical trials; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA; the success of Incyte's collaboration with and the efforts in connection therewith by Innovent; the efficacy or safety of the Incyte's products; the acceptance of Incyte's products in the marketplace; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2018. Incyte disclaims any intent or obligation to update these forward-looking statements.

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