Incyte Provides Update on Parsaclisib and MCLA-145

January 25, 2022

WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 25, 2022-- Incyte (Nasdaq:INCY) today announced updates regarding the clinical development of parsaclisib, the Company's next-generation oral inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ), and MCLA-145, its CD137/PD-L1 bispecific antibody co-developed under a global collaboration and license agreement with Merus.

Incyte is withdrawing the New Drug Application (NDA) for parsaclisib for the treatment of patients with relapsed or refractory follicular lymphoma (FL), marginal zone lymphoma (MZL) and mantle cell lymphoma (MCL). The decision to withdraw the NDA follows discussions with U.S. Food and Drug Administration (FDA) regarding confirmatory studies to support an accelerated approval, which Incyte determined cannot be completed within a time period that would support the investment. The withdrawal of the NDA is a business decision and is not related to any changes in either the efficacy or safety of parsaclisib. The decision impacts only the FL, MZL and MCL indications in the U.S., and does not affect other ongoing clinical trials in the U.S. or other countries.

Additionally, as part of its ongoing portfolio prioritization and capital allocation review, Incyte has decided to opt-out of the continued development of MCLA-145. Incyte will continue to collaborate with Merus and leverage their platform to develop a pipeline of novel agents.

About Parsaclisib

Parsaclisib is a potent, highly selective, next-generation investigational novel oral inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ). It is currently under evaluation as a monotherapy in several ongoing Phase 2 trials as a treatment for non-Hodgkin lymphomas (follicular, marginal zone and mantle cell); and in a Phase 3 study for autoimmune hemolytic anemia (AIHA). Pivotal trials of parsaclisib in combination with ruxolitinib for the treatment of patients with myelofibrosis are also underway.

In December 2018, Innovent and Incyte entered into a strategic collaboration for three clinical-stage product candidates, including parsaclisib. Under the terms of the agreement, Innovent has received the rights to develop and commercialize parsaclisib and two other assets in Mainland China, Hong Kong, Macau and Taiwan.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements about the potential of parsaclisib to provide a meaningful treatment for patients with non-Hodgkin lymphomas (NHLs), the parsaclisib development program generally and Incyte's ongoing collaboration with Merus and ability to leverage the Merus platform to develop a pipeline of novel agents contain predictions, estimates and other forward-looking statements.

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: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA or other regulatory authorities; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220125006021/en/

Media
Catalina Loveman +1 302 498 6171
cloveman@incyte.com

Jenifer Antonacci +1 302 498 7036
jantonacci@incyte.com

Investors
Christine Chiou +1 302 274 4773
cchiou@incyte.com

Source: Incyte