Incyte Announces Acceptance of NDA for Parsaclisib for Three Types of Relapsed or Refractory Non-Hodgkin Lymphomas

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—Priority Review granted to NDA for relapsed or refractory marginal zone lymphoma and mantle cell lymphoma

—Standard Review for NDA for relapsed or refractory follicular lymphoma

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for parsaclisib, an investigational novel potent, highly selective, next-generation oral inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ), for the treatment of patients with relapsed or refractory follicular lymphoma (FL), marginal zone lymphoma (MZL) and mantle cell lymphoma (MCL).

The submission is based on data from several Phase 2 studies (CITADEL-203, -204 and -205) evaluating parsaclisib as a treatment for relapsed or refractory non-Hodgkin lymphomas (NHLs) (FL, MZL and MCL). Parsaclisib was generally well-tolerated in all studies with a manageable safety profile.

“Non-Hodgkin lymphomas are some of the most common cancers in the United States, and the FDA’s acceptance of this NDA represents an important milestone for Incyte and for NHL patients who have not responded to or who have progressed on initial therapies,” said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapies, Incyte. “We look forward to working with the FDA to bring this innovative therapy to patients who may benefit.”

Parsaclisib has been granted Priority Review by the FDA for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20-based regimen and for the treatment of adult patients with MCL who have received at least one prior therapy. The FDA grants Priority Review to medicines that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to standard applications. This designation shortens the review period by four months as compared to Standard Review so the Prescription Drug User Fee Act (PDUFA) target action date for these indications is April 30, 2022. The NDA for use of parsaclisib in adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies will have a Standard Review and a PDUFA target action date of August 30, 2022.

Confirmatory phase 3 studies are in preparation for parsaclisib in patients with MCL (CITADEL-310) and relapsed or refractory FL and MZL (CITADEL-302).

About Follicular, Marginal Zone and Mantle Cell Lymphomas

Non-Hodgkin lymphoma (NHL) is a type of cancer that starts in the lymphocytes, a type of white blood cell. Follicular lymphoma (FL), marginal zone lymphoma (MZL) and mantle cell lymphoma (MCL) are forms of B-Cell NHLs. FL and MZL are indolent or slow growing lymphomas; MCL is an aggressive or rapidly developing form. There is an unmet medical need for treatment options for patients who are relapsed or refractory to initial therapies.

About CITADEL

The CITADEL (Clinical Investigation of TArgeted PI3K-DELta Inhibition in Lymphomas) clinical trial program is evaluating parsaclisib in several ongoing studies as a treatment for adult patients with lymphomas, including:

- **CITADEL-203** (NCT03126019) is evaluating patients with relapsed or refractory follicular lymphoma (FL) Grade 1, 2 or 3a who received at least two prior systemic therapies, had an Eastern Cooperative Oncology Group performance status (ECOG PS) ≤2, and were ineligible for hematopoietic stem cell transplantation (HSCT).
- **CITADEL-204** (NCT03144674) is evaluating patients with relapsed or refractory marginal zone lymphoma (MZL) who received at least one prior systemic therapy and were Bruton’s tyrosine kinase (BTK) inhibitor treatment naive. Patients with prior ibrutinib treatment were initially allowed to enroll; however, the cohort was terminated due to slow enrollment. Eligible patients had radiologically measurable lymphadenopathy or extranodal lymphoid malignancy (or histologically confirmed bone marrow infiltration in cases of splenic MZL), and an ECOG PS ≤2.
- **CITADEL-205** (NCT03235544) is evaluating patients with relapsed or refractory mantle cell lymphoma (MCL), who received one to three prior systemic therapies and were either naive to or were previously treated with a BTK inhibitor. Eligible patients had an ECOG PS ≤2, and radiologically measurable lymphadenopathy or extranodal lymphoid malignancy.

Patients eligible for each trial were allocated to receive parsaclisib 20 mg once daily for eight weeks followed by either 20 mg once weekly (weekly-dosing group [WG]) or 2.5 mg once daily (daily-dosing group [DG]). Subsequently, daily dosing was selected as the preferred regimen and the WG patients were allowed to switch to DG. Prophylaxis for Pneumocystis jirovecii pneumonia (PJP) was required.

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 autoimmune hemolytic anemia. Pivotal trials of parsaclisib in combination with ruxolitinib for the treatment of patients with myelofibrosis are

underway; and there are plans to initiate trials to evaluate parsaclisib in combination with tafasitamab, including a pivotal trial in B-cell malignancies.

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 whether or when the FDA may approve parsaclisib for the treatment of patients with relapsed or refractory non-Hodgkin lymphomas (NHLs), including follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma; the potential of parsaclisib to provide a meaningful treatment for patients with NHLs; and the parsaclisib development program generally 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; 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 June 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

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