

Incyte Announces Updated Data Demonstrating Rapid and Durable Responses of Parsacalisib in Patients with Relapsed or Refractory B-Cell Non-Hodgkin Lymphomas

December 11, 2021

- Data from the CITADEL program of parsacalisib in patients with follicular, marginal zone and mantle cell lymphomas were accepted as oral presentations at the 63rd American Society of Hematology Annual Meeting and Exposition (ASH 2021)

- Data supported Incyte's New Drug Application (NDA) for parsacalisib accepted by the U.S. FDA

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced data from three ongoing Phase 2 studies evaluating parsacalisib, 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) (CITADEL-203), marginal zone lymphoma (MZL) (CITADEL-204) and mantle cell lymphoma (MCL) (CITADEL-205). These data were accepted as oral presentations at the 63rd American Society of Hematology Annual Meeting and Exposition (ASH 2021), held December 11–14, 2021 in Atlanta, Georgia and virtually.

The primary endpoint for the CITADEL-203, -204 and -205 studies is objective response rate (ORR). Key secondary endpoints include complete response rate (CRR), duration of response (DOR), progression-free survival (PFS), overall survival (OS), safety and tolerability. All radiology-based endpoints are based on independent review committee (IRC) assessment.

Building on [previous findings](#) presented at ASH 2020, these updated data from the primary analysis continue to show treatment with parsacalisib resulted in a rapid and durable response with an acceptable safety profile, and supported the New Drug Application (NDA) for parsacalisib, [recently accepted](#) by the U.S. Food and Drug Administration (FDA).

Key results from the CITADEL studies include:

	ORR (95% CI), %	CRR (95% CI), months	mDOR (95% CI), months	mPFS (95% CI), months	mOS (95% CI), months
CITADEL-203: R/R Follicular Lymphoma					
DG (N=103)	77.7 (68.4–85.3)	19.4 (12.3-28.4)	14.7 (10.4-NE)	15.8 (11.0-NE)	NR (NE-NE)
All (N=126)	75.4 (66.9-82.6)	18.3 (11.9-26.1)	14.7 (12.0-20.3)	14.0 (11.3-19.6)	NR (NE-NE)
CITADEL-204: R/R Marginal Zone Lymphoma					
DG (N=72)	58.3 (46.1-69.8)	4.2 (0.9-11.7)	12.2 (8.1-17.5)	16.5 (11.5-20.6)	NR (NE-NE)
All (N=100)	58.0 (47.7-67.8)	6.0 (2.2-12.6)	12.2 (8.1-17.5)	16.5 (13.5-19.6)	NR (NE-NE)
CITADEL-205: R/R Mantle Cell Lymphoma (BTK Inhibitor Treatment Naïve)					
DG (N=77)	70.1 (58.6-80.0)	15.6 (8.3-25.6)	12.1 (9.0-NE)	13.6 (10.0-16.9)	NR (NE-NE)
All (N=108)	68.5 (58.9-77.1)	17.6 (10.9-26.1)	13.7 (9.0-19.9)	11.99 (8.3-16.9)	NR (NE-NE)
R/R: relapsed or refractory; ORR: objective response rate; CRR: complete response rate; mDOR: median duration of response (reported for responders); mPFS: median progression-free survival; mOS: median overall survival; DG: daily dosing group; NE: not estimable; NR: not reached.					

Parsacalisib was generally well tolerated in all studies with a manageable safety profile.

"We are pleased to share these updated results from the CITADEL studies with the oncology community," said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapies, Incyte. "The promising data add to the body of evidence that support parsacalisib, which has the potential to become a meaningful treatment for patients with relapsed or refractory follicular, marginal zone or mantle cell lymphomas, and we look forward to working with the FDA as we strive to bring this therapy to patients."

"Non-Hodgkin lymphoma is composed of varying subtypes and is one of the most common cancers in the United States. Given the fact that a significant subset of those afflicted will not be cured with current options, we need new treatment options," said Tycel Phillips, M.D., Primary Investigator, CITADEL-204 and Associate Professor, Division of Hematology and Oncology, Rogel Cancer Center, University of Michigan. "I am encouraged to see parsacalisib result in rapid and durable responses with a manageable safety profile in patients with a variety of non-Hodgkin lymphomas. The results observed across several key endpoints of the CITADEL studies suggest that parsacalisib may be a favorable treatment option for patients."

Presentations can be accessed via the ASH website at <https://www.hematology.org/meetings/annual-meeting>; #813 (Oral presentation, CITADEL-203), #44 (Oral presentation, CITADEL-204), #382 (Oral presentation, CITADEL-205).

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 parsacalisib 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 the potential of parsaclisib to provide a meaningful treatment for patients with non-Hodgkin lymphomas, including follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma, the CITADEL clinical program and other development plans for parsaclisib, including in combination with tafasitamab and with ruxolitinib, and the safety and efficacy of parsaclisib in patients with non-Hodgkin lymphomas 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 and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers, sales and marketing efforts and business, development and discovery operations; determinations made by the FDA or other regulatory authorities; the efficacy or safety of the Company's products; the acceptance of the Company's products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses, including 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 quarterly report on Form 10-Q for the quarter ended September 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.



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