Incyte Announces Clinical Trial Agreement to Evaluate Combination of Two Novel Cancer Immunotherapies

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- Incyte's investigational oral IDO1 inhibitor INCB24360 to be evaluated with Genentech's investigational PD-L1 immune checkpoint inhibitor MPDL3280A

WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 30, 2014-- Incyte Corporation (Nasdaq: INCY) announced today that it has entered into a clinical trial agreement with Genentech to evaluate the safety, tolerability and preliminary efficacy of Incyte's oral indoleamine dioxygenase-1 (IDO1) inhibitor, INCB24360, in combination with Genentech's PD-L1 immune checkpoint inhibitor, MPDL3280A, in patients with non-small cell lung cancer (NSCLC).

Both INCB24360 and MPDL3280A are part of a new class of cancer treatments known as immunotherapies that are designed to enhance the body's own defenses in fighting cancer; both agents target distinct regulatory components of the immune system.

"This collaboration with Genentech is a further illustration of our desire to investigate the therapeutic value of our IDO1 inhibitor in multiple tumor types as rapidly as possible," stated Hervé Hoppenot, President and Chief Executive Officer of Incyte. "We believe the combination of INCB24360 with other novel immunotherapies represents a promising new approach to treating cancer, and research collaborations such as this have the potential to accelerate our understanding and support our goal of addressing the needs of patients with a wide range of cancers."

Under the terms of the collaboration, Incyte and Genentech will collaborate on a non-exclusive basis to evaluate the combination. Incyte will be responsible for conducting the study and the results will be used to determine whether further clinical development of this combination is warranted. Further details of the agreement were not disclosed.

About INCB24360

INCB24360 is a member of a new class of cancer treatments known as immunotherapies. It is an orally bioavailable small molecule inhibitor of IDO1 that has nanomolar potency in both biochemical and cellular assays, potent activity in enhancing T lymphocyte, dendritic cell and natural killer cell responses in vitro, with a high degree of selectivity.

There is a growing body of evidence to suggest that IDO1 inhibitor-based combination immunotherapy may improve clinical response. INCB24360 has been shown to be active in mouse models of cancer as a single agent and in combination with cytotoxic and immunotherapy agents, and its ability to reduce tumor growth is dependent on a functional immune system – consistent with its proposed mechanism of action. Preliminary clinical data from an ongoing Phase I/II trial evaluating INCB24360 in combination with the approved immunotherapy checkpoint inhibitor Yervoy® (ipilimumab) in metastatic melanoma, recently presented at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO), suggest anti-tumor synergy between the two agents, establishing proof of concept for the combination. Thus far, 42 percent of the immunotherapy-naïve patients receiving INCB24360 combined with ipilimumab achieved an objective response and 75 percent achieved disease control. The poster for this presentation can be accessed at 2014 ASCO - INCB24360 poster.

In addition to the Phase I/II study in metastatic melanoma in combination with ipilimumab (www.clinicaltrials.gov Identifier: NCT01604889), described in the ASCO presentation, Incyte has also established clinical research agreements to study INCB24360 in combination with the investigational anti-PD-1 immunotherapy checkpoint inhibitor MK-3475 (Merck), the investigational anti-PD-L1 immune checkpoint inhibitor MEDI4736 (AstraZeneca/MedImmune), and the investigational anti-PD-1 immune checkpoint inhibitor nivolumab (Bristol-Myers Squibb).

About MPDL3280A

MPDL3280A (also known as anti-PDL1) is an investigational monoclonal antibody designed to interfere with a protein called PD-L1 (Programmed Death-Ligand 1). MPDL3280A is designed to make cancer cells more vulnerable to the body's own immune system by interfering with PD-L1. PD-L1 is expressed on tumor cells and tumor-infiltrating immune cells, preventing them from binding to two receptors, PD-1 and B7.1, on the surface of T cells. By inhibiting PD-L1, MPDL3280A may enable the activation of T cells, restoring their ability to effectively detect and attack tumor cells.

The FDA has granted MPDL3280A Breakthrough Therapy Designation. This designation is designed to expedite the development and review of medicines intended to treat serious diseases and to help ensure patients have access to them through FDA approval as soon as possible.

About Incyte

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

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements with respect to the potential efficacy, safety and therapeutic value of, and Incyte's plans for, INCB24360, the plans and expectations regarding the combination study, and the potential value of research collaborations, contain predictions and estimates and are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on Incyte'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 the efficacy or safety of INCB24360, the results of further research and development, the high degree of risk and uncertainty associated with

drug development, clinical trials and regulatory approval processes, other market or economic factors, competitive and technological advances, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2014. Incyte disclaims any intent or obligation to update these forward-looking statements.

Source: Incyte Corporation

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