Bristol-Myers Squibb and Incyte Enter Clinical Collaboration Agreement to Evaluate Combination Regimen of Two Novel Immunotherapies

Release Date:
Tuesday, May 27, 2014 7:00 am EDT

Terms:
Dateline City:
NEW YORK & WILMINGTON, Del.

Phase I/II study to evaluate nivolumab, Bristol-Myers Squibb’s investigational PD-1 immune checkpoint inhibitor with Incyte’s investigational oral IDO1 inhibitor for multiple cancers

NEW YORK & WILMINGTON, Del.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) and Incyte Corporation (Nasdaq:INCY) announced today the establishment of a clinical trial collaboration to evaluate the safety, tolerability and preliminary efficacy of a combination regimen of Bristol-Myers Squibb’s investigational PD-1 immune checkpoint inhibitor, nivolumab, and Incyte’s oral indoleamine dioxygenase-1 (IDO1) inhibitor, INCB24360, in a Phase II study. Multiple tumor types will be explored in the study, which could potentially include melanoma, non-small cell lung (NSCLC), ovarian, colorectal (CRC), squamous cell carcinoma of the head and neck (SCCHN) and diffuse large B-cell lymphoma (DLBCL).

Nivolumab and INCB24360 are part of a new class of cancer treatments known as immunotherapies that are designed to harness the body’s own immune system in fighting cancer. Nivolumab and INCB24360 target distinct regulatory components of the immune system, and there is preclinical evidence suggesting that the combination of these two agents may lead to an enhanced anti-tumor immune response compared to either agent alone.

“Bristol-Myers Squibb is committed to pursuing the full potential of its immuno-oncology portfolio through the study of promising approaches to combination regimens,” stated Michael Giordano, senior vice president, Oncology and Immunosciences Development. “Given the encouraging data for Incyte’s IDO1 inhibitor and our current understanding of nivolumab’s anti-tumor immune response, we see this as an important area of study to add to our broad clinical development program.”

“The field of immunotherapy has the potential to transform the treatment of many cancers and significantly improve patient outcomes,” stated Hervé Hoppenot, President and Chief Executive Officer of Incyte. “Given the synergistic activity we have seen with our IDO1 inhibitor when combined with checkpoint inhibitors in preclinical models, and based on our emerging clinical data, we look forward to collaborating with Bristol-Myers Squibb to explore this combination across a wide range of tumor types.”

The study, which is expected to begin in the fourth quarter of 2014, will be co-funded by the companies and conducted by Incyte. Additional details of the collaboration were not disclosed.

About Nivolumab

Cancer cells may exploit “regulatory” pathways, such as checkpoint pathways, to hide from the immune system and shield the tumor from immune attack. Nivolumab is an investigational, fully-human PD-1 immune checkpoint inhibitor that binds to the checkpoint receptor PD-1 (programmed death-1) expressed on activated T-cells. By blocking this pathway, nivolumab can enable the immune system to resume its ability to recognize, attack and destroy cancer cells.

Bristol-Myers Squibb has a broad, global development program in place to study nivolumab in multiple tumor types consisting of more than 35 trials – as monotherapy or in combination with other therapies – in which more than 7,000 patients have been enrolled worldwide. Among these are several potentially registrational trials in NSCLC, melanoma and renal cell carcinoma. In 2013, the FDA granted Fast Track designation for nivolumab in these three tumor types.

About INCB24360

INCB24360 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. INCB24360 has been shown to be efficacious 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. A Phase I dose-escalation trial demonstrated that INCB24360 results in greater than 90 percent inhibition of IDO1 activity at generally well-tolerated doses.

INCB24360 is currently in Phase I/II development for metastatic melanoma in combination with ipilimumab (www.clinicaltrials.gov Identifier: NCT01604889) and as monotherapy for ovarian cancer (www.clinicaltrials.gov Identifier: NCT01685255). Incyte has also established a clinical agreement with Merck to combine INCB24360 with Merck’s novel anti-
PD-1 immunotherapy checkpoint inhibitor in a non-small cell lung cancer study.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

About Incyte

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

Bristol-Myers Squibb Forward-Looking Statement

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the compounds mentioned in this release will move into full product development, that the clinical trials of these compounds will support regulatory filings, that these compounds will receive regulatory approval or, if approved, that they will become commercially successful products. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2013 in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Incyte Forward-Looking Statement

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, and the plans and expectations regarding the Phase I/II study in the clinical trial collaboration with Bristol-Myers Squibb, 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, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, the ability to enroll sufficient numbers of subjects in clinical trials, other market or economic factors and technological advances, unanticipated delays, the ability of Incyte to compete against parties with greater financial or other resources, 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.

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English

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Ticker: BMY
Exchange: NYSE
Ticker: INCY
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