Incyte and Calithera Biosciences Announce Global Collaboration to Develop and Commercialize CB-1158, a First-in-class, Small Molecule Arginase Inhibitor

January 30, 2017

- *Incyte gains worldwide rights to CB-1158 for hematology and oncology indications*
- *Calithera to receive a $45 million up-front payment and an $8 million equity investment*
- *Incyte and Calithera to co-fund global development of CB-1158; Calithera eligible to receive share of profits in the U.S., potential milestones and royalties on future sales of CB-1158*
- *Calithera conference call scheduled today at 8:30 a.m. ET, 5:30 a.m. PT*

WILMINGTON, Del. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 30, 2017-- Incyte Corporation (NASDAQ:INCY) and Calithera Biosciences, Inc. (NASDAQ:CALA) announce today that the companies have entered into a global collaboration and license agreement for the research, development and commercialization of Calithera's first-in-class, small molecule arginase inhibitor CB-1158 in hematology and oncology. CB-1158 is currently being studied in a monotherapy dose escalation trial and additional studies are expected to evaluate CB-1158 in combination with immuno-oncology agents, including anti-PD-1 therapy.

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"Arginase-expressing tumor-infiltrating myeloid cells have been shown to play an important role in orchestrating the immune suppressive microenvironment in cancer; but, to date, therapeutic targeting of the arginase enzyme has remained elusive," said Reid Huber, Ph.D., Incyte's Chief Scientific Officer. "The addition of this first-in-class, small molecule arginase inhibitor, CB-1158, to our portfolio expands our innovative immuno-oncology pipeline and allows us to continue to advance our mission of discovering and developing immune-active combination therapies to treat patients with cancer."

"In this strategic partnership with Incyte, CB-1158 is expected to be evaluated in multiple trials of novel therapeutic combinations, accelerating its development across hematological and oncology indications," said Susan Molineaux, Ph.D., Calithera's Chief Executive Officer.

Terms of the Collaboration

Under the terms of the collaboration and license agreement, Calithera will receive an up-front payment of $45 million from Incyte. In addition, Incyte will make an equity investment in Calithera of $8 million through the purchase of shares at a price of $4.65 per share.

Incyte will receive worldwide rights to develop and commercialize CB-1158 in hematology and oncology and Calithera will retain certain rights to research, develop and commercialize certain other arginase inhibitors in certain orphan indications.

Incyte and Calithera will jointly conduct and co-fund development of CB-1158, with Incyte leading global development activities. Incyte will fund 70 percent of global development and Calithera will be responsible for the remaining 30 percent. In the event of regulatory approvals and commercialization of CB-1158, Incyte and Calithera will share in any future U.S. profits and losses (receiving 60 percent and 40 percent, respectively) and Calithera will be eligible to receive over $430 million in potential development, regulatory and commercialization milestones from Incyte. Per the terms of the agreement, Calithera will have the right to co-detail CB-1158 in the U.S. and also be eligible to receive from Incyte tiered royalties based on future ex-U.S. sales, with rates ranging from low-to-mid double-digits.

The agreement also provides that Calithera may choose to opt out of its co-funding obligations. In this scenario, Calithera would no longer be eligible to receive future U.S. profits and losses but would be eligible to receive up to $750 million in potential development, regulatory and commercialization milestones from Incyte and, if the product is approved and commercialized, also be eligible to receive reimbursement based on previous development expenditures incurred by Calithera and tiered royalty payments on future global sales of CB-1158, with rates ranging from low-to-mid double-digits.

The transaction is expected to close in the first quarter of 2017, subject to customary closing conditions.

Conference Call and Webcast Information

Calithera will host a conference call today to discuss this collaboration at 8:30 a.m. ET, 5:30 a.m. PT. Participants may access the call by dialing (855)783-2599 (domestic) or (631)485-4877 (international) and referencing conference ID 58716954. The conference call will also be available by webcast in the Investor Relations page of Calithera's website, www.calithera.com. The archived webcast will remain available for replay for 30 days.

About Arginase

Arginase is an enzyme produced by immunosuppressive myeloid cells, including myeloid-derived suppressor cells (MDSCs) and neutrophils, which prevents T-cell and natural killer (NK) cell activation in tumors. Arginase exerts its immunosuppressive effect by depleting the amino acid arginine in the tumor microenvironment which subsequently prevents activation and proliferation of the immune system's cytotoxic T-cells and NK-cells. Inhibition of arginase activity reverses this immunosuppressive block and restores T-cell function. In preclinical models, arginase inhibition has been shown to enhance anti-tumor immunity and inhibit tumor growth.

About Incyte

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

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About Calithera Biosciences

Calithera Biosciences, Inc. is a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. Calithera's lead product candidate, CB-839, is a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839 takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. It is currently being evaluated in Phase 1/2 clinical trials in combination with standard of care agents. CB-1158 is a first-in-class immuno-oncology metabolic checkpoint inhibitor targeting arginase, a critical immunosuppressive enzyme responsible for T-cell suppression by myeloid-derived suppressor cells. Arginase depletes arginine, a nutrient that is critical for the activation, growth and survival of the body's cancer-fighting immune cells, known as cytotoxic T-cells. CB-1158 is currently in a Phase I clinical trial. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: whether CB-1158 will successfully advance through clinical studies or will ever be approved for use in humans anywhere or will be commercialized anywhere successfully or at all; whether CB-1158 will be effective in the treatment of cancer; and whether and when any of the milestone payments or royalties under this collaboration will ever be paid by Incyte. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: obtaining approval for this planned collaboration; research and development efforts related to the collaboration programs; the possibility that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; other market or economic factors; unanticipated delays; each company's ability to compete against parties with greater financial or other resources; greater than expected expenses; and such other risks detailed from time to time in each company's reports filed with the Securities and Exchange Commission, including the Form 10-Q for the quarter ended September 30, 2016 filed by each company. Each party disclaims any intent or obligation to update these forward-looking statements.

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