

Incyte and Cellenkos Enter into Global Development Collaboration Agreement for CK0804

December 30, 2020

- Incyte and Cellenkos will evaluate the combination of ruxolitinib (Jakafi®) and CK0804, cord blood-derived T-regulatory cells, in patients with myelofibrosis

- Incyte has an exclusive option to acquire sole rights to CK0804

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) and Cellenkos, Inc., a privately held, clinical stage biotech company, today announced a development collaboration to investigate the combination of ruxolitinib (Jakafi®) and CK0804, Cellenkos' cryopreserved CXCR4 enriched, allogeneic, umbilical cord blood-derived T-regulatory cells, in patients with myelofibrosis (MF). In addition, Incyte has an exclusive option to acquire sole rights to develop and commercialize CK0804, and genetically-modified variants of CK0804, in benign and malignant hematology indications.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20201230005038/en/>

"This collaboration supports our continued commitment to developing new therapeutic options that may improve and expand treatment options for patients with MF, part of a group of rare blood cancers known as myeloproliferative neoplasms (MPNs)," said Steven Stein, M.D., Chief Medical Officer, Incyte. "We are excited to partner with Cellenkos to initiate this study as part of our LIMBER clinical development program, designed to evaluate new monotherapy and combination strategies for patients with MPNs."

"We are delighted to partner with Incyte, a global biopharmaceutical company, to further study and develop CK0804. Incyte's investment in strong science and R&D excellence makes them an ideal partner to evaluate CK0804 in combination with ruxolitinib as a potential treatment for the many patients living with myelofibrosis, especially those who are transfusion dependent," said Tara Sadeghi, Vice President, Clinical Operations, Cellenkos, Inc. "Our innovative strategy of exploiting the CXCR4/CXCL12 axis to redirect the immune modulatory T-regulatory cells specifically to the diseased bone marrow holds the promise of resolving inflammation to allow for normal hematopoiesis resulting in clinical improvement. This collaboration is in line with our corporate strategy to partner with world-leading major pharma companies in order to maximize access to our innovative cellular medicines."

Per the terms of the agreement, the companies plan to initiate a Phase 1b single arm, open-label study evaluating ruxolitinib in combination with CK0804 in patients with MF. Incyte will fund the study, which will be operationalized by Cellenkos.

In addition, per the agreement, Incyte will have an option to acquire an exclusive global license to develop and commercialize the program. Upon exercising the global licensing option, Incyte would be responsible for all activities and costs associated with research, development and commercialization of the program. Cellenkos would be eligible to receive a \$20 million licensing fee and, for each distinct product under the agreement, development, regulatory and sales milestones totaling up to \$294.5 million as well as tiered royalties ranging from mid-single digit to low-double digits, if approved.

The collaboration is effective immediately.

About Myelofibrosis (MF)

MF is a rare, chronic blood cancer that is part of a group of diseases known as MPNs. In MF, scar tissue forms in the bone marrow and impairs its ability to produce normal blood cells. This can result in an enlarged spleen, and symptoms such as fatigue, itching and night sweats, which can impact a patient's quality of life. About 16,000 to 18,500 people in the United States are living with MF.

About LIMBER

Incyte is a leader in the discovery and development of therapies for patients with myeloproliferative neoplasms (MPNs). The Leadership In MPNs BEyond Ruxolitinib (LIMBER) program is designed to evaluate multiple monotherapy and combination strategies to improve and expand treatments for patients with myeloproliferative neoplasms (MPNs). The program currently has three key areas of focus: development of a new, once-daily formulation of ruxolitinib; ruxolitinib-based combinations with new targets such as PI3Kδ, BET and ALK2; and new therapeutic options.

About Ruxolitinib (Jakafi®)

Ruxolitinib (Jakafi) is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. FDA for the treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea, in adults with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF and for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older.

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States. Jakafi is a registered trademark of Incyte Corporation. Jakavi is a registered trademark of Novartis AG in countries outside the United States.

About CK0804

CK0804 is a novel allogeneic cell therapy product consisting of T-regulatory cells that exploit the CXCR4/CXCL12 axis and are derived from clinical-grade umbilical cord blood units and manufactured using Cellenkos' proprietary process. The product is cryopreserved and readily available off-the-shelf, without any requirement for HLA matching, and is infused intravenously. One manufacturing campaign can result in multiple doses of cryopreserved product that can be shipped to the clinical site, where it can be stored for an extended period or made available for immediate

treatment, as needed.

Important Safety Information for Jakafi® (ruxolitinib)

Jakafi can cause serious side effects, including:

Low blood counts: Jakafi® (ruxolitinib) may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you develop or have worsening symptoms such as unusual bleeding, bruising, tiredness, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection during treatment with Jakafi. Tell your healthcare provider if you develop any of the following symptoms of infection: chills, nausea, vomiting, aches, weakness, fever, painful skin rash or blisters.

Skin cancers: Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Tell your healthcare provider if you develop any new or changing skin lesions.

Increases in cholesterol: You may have changes in your blood cholesterol levels. Your healthcare provider will do blood tests to check your cholesterol levels during your treatment with Jakafi.

The most common side effects of Jakafi include: for certain types of MF and PV - low platelet or low red blood cell counts, bruising, dizziness, headache, and diarrhea; and for acute GVHD – low platelet, red or white blood cell counts, infections, and fluid retention.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Before taking Jakafi, tell your healthcare provider about: all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had tuberculosis (TB), or have been in close contact with someone who has TB, have or had hepatitis B, have or had liver or kidney problems, are on dialysis, have a high level of fat in your blood (high blood cholesterol or triglycerides), had skin cancer or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change or stop taking Jakafi without first talking to your healthcare provider.

Women should not take Jakafi while pregnant or planning to become pregnant. Do not breast-feed during treatment with Jakafi and for 2 weeks after the final dose.

Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi, is available at www.jakafi.com.

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](https://twitter.com/incyte).

About Cellenkos®, Inc.

Cellenkos is a clinical-stage biotechnology company located in Houston, Texas, USA, founded in 2016 with the licensing of a proprietary umbilical cord blood T-Regulatory cell therapy platform arising from the laboratory investigations of Simrit Parmar, MD, MSCI, Associate Professor in the Department of Lymphoma and Myeloma at the University of Texas at MD Anderson Cancer Center.

Being derived from umbilical cord blood, Cellenkos' T-Regulatory cells are naïve, bonafide suppressor cells that resolve inflammation through multiple direct and indirect interactions. Cellenkos is dedicated to the development and commercialization of the allogeneic, off-the-shelf cell based products for the treatment of rare inflammatory diseases and autoimmune disorders. For more information, please visit www.cellenkosinc.com.

Incyte Forward-looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding expectations regarding the combination of ruxolitinib and CK0804, the timing, design and potential results of the planned combination study, the potential benefits of the combination or of CK0804 for patients, the planned development, funding, commercialization and payments under this collaboration, and the LIMBER program, contain predictions, estimates and other forward-looking statements. These forward-looking statements are based on the 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: 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 regulatory authorities; the efficacy or safety of Incyte's or its collaborators' products; the acceptance of Incyte's products and the products of its 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 Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2020. Incyte disclaims any intent or obligation to update these forward-looking statements.



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