Leap Therapeutics Provides Update on BeiGene Option Agreement for DKN-01

March 16, 2023

DisTinGuish Trial of DKN-01 plus tislelizumab and chemotherapy to continue as a clinical collaboration

CAMBRIDGE, Mass., March 16, 2023 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that BeiGene's option under the Exclusive Option and License Agreement between Leap and BeiGene granting rights in certain Asian territories to DKN-01, Leap's anti-DKK1 monoclonal antibody, has expired in accordance with the terms of the agreement. Leap and BeiGene will continue to collaborate on the ongoing Part C of the DisTinGuish trial, a randomized controlled trial of DKN-01 in combination with BeiGene's anti-PD-1 antibody, tislelizumab, and chemotherapy in first-line gastric cancer patients, as a clinical collaboration with BeiGene supplying tislelizumab. Enrollment in the 160-patient study is expected to be completed in late 2023.

"We look forward to continuing to collaborate with BeiGene to execute on our first randomized controlled trial for DKN-01 in first-line gastric cancer patients," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "With global rights to DKN-01 and a cash runway that was enhanced into mid-2025 by our recent acquisition of Flame Biosciences, we will look to identify a new strategic partner as we generate new clinical data from our ongoing studies in first-line gastric cancer patients, second-line colorectal cancer patients, and an investigator-sponsored study in endometrial cancer patients. We will also continue the development of the newly-acquired Claudin18.2 programs as part of our focus on biomarker-targeted antibody therapies for cancer patients, particularly those with GI cancers."

About Leap Therapeutics

Leap Therapeutics (Nasdaq: LPTX) is focused on developing targeted and immuno-oncology therapeutics. Leap's most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein. DKN-01 is being developed in patients with esophagogastric, gynecologic, and colorectal cancers. FL-301, is a humanized monoclonal antibody targeting Claudin18.2, being developed in patients with gastric and pancreatic cancer. Leap also has preclinical antibody programs targeting Claudin18.2/CD137 and GDF15. For more information about Leap Therapeutics, visit http://www.leaptx.com or view our public filings with the SEC that are available via EDGAR at http://www.sec.gov or via https://investors.leaptx.com/.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of the federal securities laws. Such statements are based upon current plans, estimates and expectations of the management of Leap that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "continue," "target," "contemplate," "estimate," "forecast," "guidance," "predict," "possible," "potential," "pursue," "likely," and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding the continuation over time of our clinical collaboration with BeiGene on the ongoing Part C of the DisTinGuish trial, with BeiGene continuing to supply tislelizumab; the enhancement of our cash runway into mid-2025; our future development plans in connection with our newly-acquired Claudin18.2 programs; the potential, safety, efficacy, and regulatory and clinical progress of Leap's product candidates, including the anticipated timing for enrollment of clinical trials and release of clinical trial data and outcomes of such trials; the ability to enter into a new strategic partnership for DKN-01 or any of Leap's other programs; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from Leap's plans, estimates or expectations could include, but are not limited to: (i) Leap's ability to successfully execute its clinical trials and the cost of such clinical trials; (ii) Leap's ability to successfully enter into new strategic partnerships for DKN-01 or any of its other programs; (iii) whether any Leap clinical trials and products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; (iii) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of Leap's traded securities; (iv) that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by COVID-19, global conflict or supply chain related issues; (v) the results of Leap's clinical trials and pre-clinical studies; and (vi) Leap's ability to comply with the continued listing requirements of the Nasdaq Global Market. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or Implied) are made about the accuracy of any such forward-looking statements. Leap may not actually achieve the forecasts disclosed in such forward-looking statements, and you should not place undue reliance on such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in Leap's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither Leap, nor any of its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Leap's views as of any date subsequent to the date hereof.

CONTACT:
Douglas E. Onsi
President & Chief Executive Officer
Leap Therapeutics, Inc.
617-714-0360
donsi@leaptx.com

Matthew DeYoung
Investor Relations

Argot Partners
212-600-1902
leap@argotpartners.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/leap-therapeutics-provides-update-on-beigene-option-agreement-for-dkn-01-301774367.html

SOURCE Leap Therapeutics, Inc.