Leap Therapeutics Announces Completion of Enrollment in Randomized Controlled Part C of the DisTinGuish Study of DKN-01 for the Treatment of Gastric Cancer Patients

January 2, 2024

CAMBRIDGE, Mass. , Jan. 2, 2024 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that enrollment has been completed in the randomized controlled Part C of the DisTinGuish study evaluating DKN-01, Leap's anti-Dickkopf-1 (DKK1) antibody, in combination with tislelizumab, BeiGene's anti-PD-1 antibody, and chemotherapy in patients with advanced gastroesophageal junction and gastric cancer.

"The completion of enrollment in Part C of the DisTinGuish study is an important milestone and continues to underscore the high level of interest from both patients and investigators in DKN-01," said Cynthia Sirard, M.D., Chief Medical Officer of Leap. "Long-term follow-up data from Part A of the study clearly demonstrated the potential to induce durable responses and clinically meaningful survival outcomes in first-line advanced gastroesophageal junction and gastric cancer patients. We expect Part C to further validate the potential of DKN-01 and tislelizumab combination therapy and look forward to having initial data from Part C over the course of this year."

Part C of the DisTinGuish study (NCT0436380) is a Phase 2, randomized, open-label, multicenter study of DKN-01 in combination with tislelizumab and chemotherapy in first-line patients with advanced gastroesophageal adenocarcinoma. Part C enrolled 170 first-line, HER2-negative patients. Patients were randomized 1:1 to evaluate DKN-01 in combination with tislelizumab and standard of care (SOC) chemotherapy, compared to tislelizumab and SOC chemotherapy alone. The primary objective is progression-free survival (PFS) in DKK1-high and in all patients. Secondary objectives of Part C include overall survival and objective response rate as measured by RECIST v1.1 in DKK1-high and in all patients.

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 anticipated timing release of clinical data, and any outcomes of such trials; the potential, safety, efficacy, and regulatory and clinical progress of Leap's product candidates; our future preclinical and clinical development plans in connection with our programs; 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 timing of enrollment in and cost of such clinical trials; (ii) the results of Leap's clinical trials and pre-clinical studies; (iii) Leap's ability to successfully enter into new strategic partnerships for DKN-01 or any of its other programs; (iv) whether any Leap clinical trials and products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; (v) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of Leap's traded securities; and (vi) that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by global conflict, or supply chain related issues. 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-announces-completion-of-enrollment-in-randomized-controlled-part-c-of-the-distinguish-study-of-dkn-01-for-the-treatment-of-gastric-cancer-patients-302023994.html

SOURCE Leap Therapeutics, Inc.