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Leap Therapeutics Announces Initiation of Randomized Controlled Part B of the DeFianCe Study of DKN-01 in Colorectal Cancer Patients

July 12, 2023

CAMBRIDGE, Mass., July 12, 2023 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that, based on the early efficacy and momentum seen in the enrollment of 33 patients with colorectal cancer (CRC) in its DeFianCe study, it has initiated the 130 patient randomized controlled Part B of the Phase 2 study. The study evaluates Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced CRC.

"Part A of the DeFianCe study enrolled an aggressive heterogenous population of second-line CRC patients representative of the second-line population that we see in the clinic who have poor outcomes on standard of care drugs and are in need of new therapies," said Zev Wainberg, MD, Professor Medicine at UCLA and co-director of the UCLA GI Oncology Program. "Exceeding a 20% overall response rate with a high disease control rate in second-line CRC patients is a clinically meaningful efficacy signal and worthy of further exploration."

"The study enrolled quickly and has already exceeded the 20% overall response rate threshold. After the planned safety review meeting with our investigators, we decided to initiate the randomized controlled study," said Cynthia Sirard, MD, Chief Medical Officer of Leap. "We continue to follow these Part A patients to assess durability of response, progression-free survival, and to determine whether additional patients with stable disease may become responders over time. We very much look forward to presenting this maturing data set at an upcoming meeting."

About the DeFiance Study
The DeFianCe study (NCT05480306) is a Phase 2, open-label, global study of DKN-01 in combination with standard of care bevacizumab and chemotherapy in patients with advanced CRC who have received one prior systemic therapy for advanced disease. The Part A cohort enrolled 33 patients, including significant numbers of patients who had early progression on first-line therapy, previous exposure to bevacizumab, tumors with Ras mutations, or liver metastases. The study has expanded into a 130-patient Part B randomized controlled trial. The primary objective of the study is progression free survival. Secondary objectives include overall response rate, duration of response, and overall survival. Leap expects to be able to enroll Part B in approximately 12 months and have initial data in late 2024.

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 outcomes of patients in Part A of the DeFianCe study, the anticipated timing for initiation of or success of enrollment in Part B of the DeFianCe study and other clinical trials and 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; the continuation over time of the clinical collaboration with BeiGene on the ongoing Part C of the DisTinGuish trial, with BeiGene continuing to supply tislelizumab; the ability of NovaRock Biotherapeutics to conduct the FL-301 clinical trial in China; 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; (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 COVID-19, global conflict, or supply chain related issues; and (vii) whether Leap's cash resources will be sufficient to fund Leap's continuing operations and planned studies. 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.

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