Leap Therapeutics Announces Completion of Enrollment in Part A of the DeFianCe Study of DKN-01 for the Treatment of Colorectal Cancer Patients

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CAMBRIDGE, Mass., April 12, 2023 /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 Part A of the Phase 2 DeFianCe study evaluating DKN-01, Leap's anti-Dickkopf-1 (DKK1) antibody, in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced colorectal cancer (CRC).

"The completion of enrollment of Part A of the DeFianCe study is an important milestone for the DKN-01 colorectal cancer development program," said Cynthia Sirard, M.D., Chief Medical Officer of Leap. "We were very pleased with the enthusiasm of our investigators and patients for participating in Part A, which reflects the unmet medical need of second-line CRC patients and their conviction in the DKN-01 preclinical data and mechanism of action. We look forward to initial data from the study in mid-2023."

The DeFianCe study (NCT05480306) is a Phase 2, randomized, open-label, multicenter 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 study began with an initial Part A cohort that has enrolled 33 patients and is designed to expand into a 130-patient Part B randomized controlled trial. The primary objective is progression free survival. Secondary objectives include overall response rate, duration of response, and overall survival.

About DKN-01
DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein. DKK1 has an important role in mediating an immune suppressive tumor microenvironment and in promoting tumor proliferation, metastasis, and angiogenesis. By removing free DKK1 from the tumor microenvironment, DKN-01 activates NK cells, reduces immune suppressor cells, and stimulates an immune-mediated anti-tumor response. In addition to the DeFianCe study, DKN-01 is being evaluated in the randomized controlled DisTinGuish study in first-line gastric cancer patients in combination with tislelizumab and chemotherapy and in an investigator-sponsored trial in advanced endometrial cancer patients in combination with pembrolizumab.

About Colorectal Cancer
Colorectal cancer (CRC) includes colon cancer, rectal cancer, and anal cancer. When the symptoms of CRC appear, such as rectal bleeding, anemia, or abdominal pain, most patients are already in the advanced stage where cancers are aggressive, malignant, and metastatic. CRC is the third most frequent cancer globally and the second leading cause of cancer-related death. According to the WHO, there were nearly 2,000,000 new cases of CRC in 2020, with nearly 1,000,000 deaths. It is estimated that there will be approximately 150,000 cases of CRC in the US in 2023, resulting in more than 50,000 deaths.

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, a humanized monoclonal antibody targeting Claudin18.2, is 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 Part A of the DeFianCe trial; the anticipated timing for the release of clinical data, and any outcomes of such trial; 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; 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; (vii) whether Leap's stockholders approve the conversion of the Series X Non-Voting Convertible Preferred Stock; (viii) whether Leap's cash resources will be sufficient to fund Leap's continuing operations; and (ix) 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.

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