Leap Therapeutics to Present Updated Data from Part A of the DisTinGuish Study of DKN-01 Plus Tislelizumab and Chemotherapy in Gastric Cancer Patients at the 2023 ASCO Annual Meeting

April 26, 2023

CAMBRIDGE, Mass., April 26, 2023 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq: LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that the Company will be presenting new long-term follow-up data in first-line patients with advanced gastroesophageal adenocarcinoma (GEA) from Part A of the DisTinGuish study, a Phase 2 clinical trial evaluating Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with tislelizumab and chemotherapy, at the upcoming 2023 American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago, IL on June 2-6, 2023.

Leap Presentation Details:

Title: A phase 2 study (DisTinGuish) of DKN-01 in combination with tislelizumab + chemotherapy as first-line (1L) therapy in patients with advanced gastric or GEJ adenocarcinoma (GEA).
Presenter: Samuel J. Klempner, Harvard Medical School
Session Type: Poster Discussion Session
Session Title: Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary
Date and Time: Monday, June 5, 2023, at 11:30 a.m. ET
Abstract Number: 4027
Poster Number: 335

About the DisTinGuish Study
The DisTinGuish study (NCT04363801) is a Phase 2 study of DKN-01 in combination with tislelizumab, an anti-PD-1 antibody, with or without chemotherapy as first-line or second-line therapy in patients with inoperable, locally advanced, G/GEJ adenocarcinoma. The study is being conducted in three parts in the United States, the Republic of Korea, the United Kingdom, and Germany. Part A enrolled 25 first-line HER2+ GEA cancer patients to receive DKN-01 in combination with tislelizumab and capecitabine and oxaliplatin. Part B enrolled 52 second-line GEA cancer patients whose tumors expressed high levels of DKK1 to receive DKN-01 in combination with tislelizumab. Part C is enrolling approximately 160 first-line HER2+ GEA cancer patients in a randomized controlled trial of DKN-01 in combination with tislelizumab and chemotherapy compared to tislelizumab and chemotherapy.

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 esophageagastic, 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 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) whether the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by ongoing COVID-19 related issues, 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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