Leap Therapeutics Announces First Patient Enrolled in Part C of Phase 2 DisTinGuish Study of DKN-01 in Combination with Tislelizumab for the Treatment of Gastric or Gastroesophageal Junction Cancer

October 12, 2022

CAMBRIDGE, Mass., Oct. 12, 2022 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that the first patient has been enrolled in the randomized controlled Part C of the ongoing DisTinGuish study to evaluate DKN-01, Leap's anti-Dickkopf-1 (DKK1) antibody, in combination with tislelizumab, BeiGene's anti-PD-1 antibody, and chemotherapy compared to a tislelizumab and chemotherapy control arm, in patients with gastric or gastroesophageal junction cancer (G/GEJ).

"We are excited to announce another important milestone for our DKN-01 clinical program in combination with our partner BeiGene's tislelizumab, advancing this unique combination therapy into Part C of the DisTinGuish study," said Cynthia Sirard M.D., Chief Medical Officer of Leap Therapeutics. "The data to date from the DisTinGuish study show the DKN-01 plus tislelizumab combination therapy to be a compelling potential treatment for patients with G/GEJ cancer with response rates and survival outcomes that exceeded the benchmarks. This first randomized controlled study for DKN-01 will characterize the treatment effect in first-line patients, with a particular emphasis on those in the aggressive DKK1-high population."

The DisTinGuish study (NCT04363801) is a Phase 2 study of DKN-01 in combination with tislelizumab and standard of care (SOC) chemotherapy in patients with inoperable, locally advanced, G/GEJ adenocarcinoma. Part C of the DisTinGuish study will enroll approximately 160 first-line, HER2-negative patients. Patients will be randomized 1:1 to evaluate DKN-01 in combination with tislelizumab and standard of care (SOC) chemotherapy, compared to tislelizumab and SOC chemotherapy. The primary objective is progression-free survival (PFS) in DKK1-high patients. Secondary objectives of Part C include PFS in all patients regardless of DKK1 expression, as well as overall survival and objective response rate as measured by RECIST v1.1 in DKK1-high and all patients.

About DKN-01

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein. DKK1 modulates the Wnt/Beta-catenin and PI3kinase/AKT signaling pathways and has an important role in promoting tumor proliferation, metastasis, angiogenesis, and in mediating an immune suppressive tumor microenvironment through enhancing the activity of myeloid-derived suppressor cells and downregulating NK cell ligands on tumor cells. The U.S. Food and Drug Administration has granted DKN-01 Orphan Drug Designation for the treatment of gastric and gastroesophageal junction cancer and Fast Track Designation in combination with tislelizumab for the treatment of patients with gastric and gastroesophageal junction adenocarcinoma whose tumors express high DKK1 protein, following disease progression on or after prior fluoropyrimidine- and platinum- containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy.

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. Leap has entered into a strategic collaboration with BeiGene, Ltd. for the rights to develop DKN-01 in Asia (excluding Japan), Australia, and New Zealand. 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 Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include Leap's expectations with respect to the development and advancement of DKN-01, including the initiation, timing and design of future studies, enrollment in clinical studies, potential for the receipt of future option exercise, milestone, or royalty payments from BeiGene, and other future expectations, plans and prospects. Although Leap believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from our expectations. Such risks and uncertainties include, but are not limited to: 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; unstable global market and economic conditions; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the outcome, cost, and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain and maintain regulatory approval of our drug product candidates; the size and growth potential of the markets for our drug product candidates; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and other risks. Detailed information regarding factors that may cause actual results to differ materially is included in Leap Therapeutics' periodic filings with the SEC, including Leap's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on March 11, 2022 and as may be updated by Leap's Quarterly Reports on Form 10-Q and the other reports Leap files from time to time with the SEC. Any forward-looking statement contained in this release speaks only as of its date. Leap undertakes no obligation to update any forward-looking statement contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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

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