Leap Therapeutics to Present Initial Data from the Investigator-Sponsored Study of DKN-01 Plus Docetaxel in Patients with Prostate Cancer at the 2022 ASCO Annual Meeting

May 26, 2022

CAMBRIDGE, Mass., May 26, 2022 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq: LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that initial clinical data from the investigator-sponsored Phase 1b/2a dose escalation and dose expansion study testing Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, as monotherapy or in combination with docetaxel in metastatic castration-resistant prostate cancer (mCRPC) will be presented at the upcoming 2022 American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago, IL on June 3-7, 2022.

"As the initial data show, DKN-01 in combination with docetaxel is a promising therapy option for prostate cancer patients, particularly for those with aggressive variant prostate cancer," said David Wise, MD, PhD, Medical Oncologist at Perlmutter Cancer Center, NYU Langone Health and principal investigator on the study. "DKN-01, as a monotherapy and in combination with docetaxel, was well tolerated by patients, with partial responses in all of the patients treated with DKN-01 in combination with docetaxel who had measurable disease. Accrual into the Phase 2 portion of this study is ongoing, alongside preclinical and correlative studies aiming to further investigate the mechanism of action of DKN-01 in prostate cancer and to identify the best clinical path forward."

Key Initial Findings from the Investigator-Sponsored Phase 1b/2a Clinical Trial:

Data that will be presented at ASCO is from the completed Phase 1 portion of the study. Thirteen patients were enrolled, with 7 patients in the DKN-01 monotherapy cohort and 6 patients in the DKN-01 plus docetaxel combination cohort. The primary endpoint of the Phase 1 dose escalation cohorts was safety, characterized by dose-limiting toxicity (DLT). The study also aims to study correlations between DKK1 expression and tumor genetics, histology and anti-tumor activity.

Highlights from the data include:

- No DLTs were observed at DKN-01 300mg or 600mg dose levels as monotherapy or in combination with docetaxel, and no treatment-related adverse events occurred in either cohort
- No partial responses (PR) were seen in the monotherapy cohort with best overall response of stable disease in 2 out of 5 evaluable patients
- In the combination cohort, all 5 evaluable patients had a PR as measured by RECIST (3 confirmed, 2 unconfirmed) and by PSA50
- Confirmed partial responses in the combination cohort were observed in both DKK1 high and low expressing tumors, including in 2 out of 3 patients with aggressive variant prostate cancer (AVPC)

Further accrual into the phase 2 part of this study is ongoing, alongside preclinical and correlative studies aimed at investigating the mechanism of action of DKN-01 in prostate cancer.

Details:

Title: A Phase 1/2 Multicenter Investigator-Initiated Trial of DKN-01 as Monotherapy or in Combination with Docetaxel for the Treatment of Metastatic Castration-Resistant Prostate Cancer (mCRPC)
First Author: David Wise, MD, PhD, Perlmutter Cancer Center, NYU Langone Health
Session Category: Poster Session
Session Title: Genitourinary Cancer – Prostate, Testicular, and Penile
Date and time: Monday, June 6 at 2:15 p.m. ET
Abstract Number: 5048
Poster Number: 232

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 prostate 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 in patients with prostate cancer, including the outcomes, status and timing of current or future studies. 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: the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; 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 related issues; unstable global market and economic conditions; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the benefits to be derived from our agreement with BeiGene, Ltd. ("BeiGene") or any other collaborations, license agreements, or other acquisition efforts; the market acceptance of DKN-01; the success of other competing therapies that may become available; the manufacturing capacity for DKN-01; our ability to maintain and protect our intellectual property rights; 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.

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