Leap Presents Positive Clinical Results for the Combination of DKN-01 plus Keytruda® and Provides DKN-01 Program Update

August 6, 2019

-- Enhanced survival outcomes in DKK1-high gastroesophageal junction and gastric cancer patients -
-- DKK1-high biomarker enables future patient selection -
-- Live conference call and webcast with clinical investigators at 8:30 AM ET --

CAMBRIDGE, Mass., Aug. 6, 2019 /PRNewswire/ -- Leap Therapeutics, Inc. (NASDAQ: LPTX) today announced that its anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with Merck's anti-PD-1 antibody, Keytruda® (pembrolizumab), demonstrated higher survival and objective response outcomes in patients with advanced gastroesophageal junction and gastric cancer (GEJ/GC) whose tumors expressed high levels of DKK1 (DKK1-high). DKN-01 plus Keytruda therapy achieved over 22 weeks median progression-free survival (PFS) and nearly 32 weeks median overall survival (OS) with a 50% overall response rate (ORR) and 80% disease control rate (DCR) in patients with DKK1-high GEJ/GC who had not received prior anti-PD-1/PD-L1 therapy. Leap will host a DKN-01 Clinical Perspectives and Program Update for the investment community through a live conference call and webcast with two clinical investigators today at 8:30 AM US Eastern Time.

"Gastric and gastroesophageal junction cancers represent a major global cancer burden with significant unmet needs, particularly in patients with advanced disease. Outside of rare microsatellite instable tumors and EBV-associated cancers the response rates to immune checkpoint inhibitors are low and median progression free survival remains short, in the range of 6-8 weeks. Oncologists and patients are eager for new therapeutic combinations and biomarkers to help predict patients most likely to benefit from a given treatment," stated Samuel J. Klempner, MD, Assistant Professor, Massachusetts General Hospital Cancer Center and Harvard Medical School.

"The responses and early survival data seen in DKK1-high patients treated with DKN-01 plus pembrolizumab are highly encouraging," commented Dr. Klempner. "This study builds on previously reported positive monotherapy and paclitaxel combination data and importantly suggests that elevated DKK-1 expression is a potential predictive biomarker. DKN-01 warrants further study in gastroesophageal cancers in combination with immune checkpoint inhibitors and with chemotherapy."

Key Findings from KEYNOTE-731 DKN-01 plus Keytruda Combination

The esophagogastric cancer clinical trial is a multipart study of DKN-01 as a monotherapy and in combination with paclitaxel or pembrolizumab. Sixty-three patients were treated with DKN-01 plus Keytruda combination therapy across all arms and dose groups of the study. Fifty-three patients had not received prior PD-1/PD-L1 therapy, and ten patients were refractory to PD-1/PD-L1 therapy. All of the patients enrolled had tumors that were microsatellite stable or unknown. Patients in the study were heavily pretreated having had received one to five prior lines of therapy, with nearly 64% having received a prior taxane regimen, 37% having received prior ramucirumab, and 24% having received prior trastuzumab. The combination therapy was well tolerated with no new safety signals.

The combination of DKN-01 and Keytruda in GEJ/GC patients demonstrated improved outcomes in patients whose tumors are DKK1-high and who were PD-1/PD-L1 naïve. DKK1-high patients experienced over 22 weeks median PFS and nearly 32 weeks OS, with a 50% ORR and 80% DCR in ten evaluable patients. DKK1-low patients experienced nearly 6 weeks median PFS and over 17 weeks OS, with a 20% DCR in fifteen evaluable patients.

PD-L1 Combined Positive Scores (CPS) did not predict efficacy on the combination of DKN-01 plus Keytruda. In multi-variate analysis, DKK1-high status correlated with longer PFS independent of PD-L1 CPS scores. One-third of patients in the study were DKK1-high.

Among the six GEJ/GC patients who were refractory to PD-1/PD-L1 therapy, three DKK1-high patients had a best response of stable disease, whereas the three patients with DKK1-low tumors had progressive disease.

DKN-01 Clinical Perspectives Conference Call and Webcast

Samuel J. Klempner, MD, Assistant Professor, Massachusetts General Hospital Cancer Center and Harvard Medical School, will describe his experience with treating esophagogastric cancer patients in the DKN-01 study. In addition, Rebecca C. Arend, MD, Assistant Professor and Associate Scientist, Gynecologic Oncology Clinic, UAB Comprehensive Cancer Center Experimental Therapeutics Program, will discuss her experience with endometrial cancer and carcinosarcoma patients treated with DKN-01.

To access the conference call, please dial (866) 589-0108 (US/Canada Toll-Free) or (409) 231-2048 (international) and refer to conference ID 3571417. The presentation will also be webcast live and will be available under "Events & Presentations" in the Investor section of Leap's website, https://www.leaptx.com/program-webcasts. A replay of the webcast will be available on Leap's website shortly after the event and will be available for a limited time.

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, a Wnt pathway modulator. DKN-01 is in clinical trials in patients with esophagogastric, hepatobiliary, gynecologic, and prostate cancers. Leap's second clinical candidate, TRX518, is a humanized GITR agonist monoclonal antibody designed to enhance the immune system's anti-tumor response that is in advanced solid tumor studies. For more information about Leap Therapeutics, visit http://www.leaptx.com or our public filings with the SEC that are available via EDGAR at http://www.sec.gov or via https://investors.leaptx.com/.

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FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include statements regarding Leap's intended use of proceeds from the offering, Leap's expectations with respect to the development and advancement of DKN-01, TRX518, and other programs, including the initiation, timing and design of future studies, enrollment in future studies, business development, and other future expectations, plans and prospects. Leap has attempted to identify forward looking statements by such terminology as "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. 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 accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the ability to complete a financing or form business development relationships to fund our expenses; 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; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; 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 will be 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, 2018, as filed with the SEC on April 1, 2019 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, as filed with the SEC on May 15, 2019. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements 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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