Leap Therapeutics Presents at Society of Gynecologic Oncology 50th Annual Meeting on Women's Cancer

March 18, 2019

- DKN-01 Monotherapy and Combination Partial Responses in heavily pre-treated patients
- Enhanced benefit in patients with Wnt Pathway Alterations

CAMBRIDGE, Mass., March 18, 2019 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX) today announced the presentation of clinical data from its ongoing Phase 2 clinical trial of DKN-01 in patients with advanced gynecological malignancies at the Society of Gynecologic Oncology 50th Annual Meeting on Women's Cancer. Patients, including those with carcinosarcoma and Wnt pathway alterations, have experienced partial responses and durable clinical benefit in both the monotherapy and combination arms of the study. The complete data set will become available in the coming months as the most recently enrolled patients have yet to be evaluated. The complete poster is available on Leap's website at https://www.leaptx.com/our-pipeline.

"We are very pleased with the single agent and combination activity of DKN-01 in this heavily pre-treated population. Allowing patients to achieve partial responses and durable stable disease with a favorable safety profile reflects meaningful clinical benefit," commented Rebecca C. Arend, M.D., Ph.D., Department of Obstetrics and Gynecology at the University of Alabama at Birmingham School of Medicine. "With the rapid enrollment of this study since the beginning of the year, we are looking forward to robust data maturing during the year."

"It is encouraging to see the mechanism-based strategy of enriching the study with patients with Wnt pathway alterations lead to impressive clinical outcomes," commented Michael Birrer, M.D., Ph.D., Director of the Comprehensive Cancer Center at the University of Alabama at Birmingham. "We are also particularly interested in the early activity in carcinosarcoma patients, who are in need of new and better treatment options."

- ***DKN-01 single agent partial response*:** Twenty-one patients (who had previously received one to ten lines of therapy) have been enrolled in two monotherapy arms of the study. Twelve patients are currently evaluable. One patient has experienced a partial response (PR), and six patients have had stable disease (SD) for greater than six weeks. Seven patients have been recently enrolled and have not yet had their first imaging assessment. This study marks the third different tumor type where DKN-01 has had single agent activity.

- ***Partial response and tumor reductions in DKN-01/Paclitaxel combination*:** Forty-one patients (who had previously received one to nine lines of prior therapy) have been enrolled in two combination arms of the study. Twenty-one patients are currently evaluable. One patient has experienced a PR, and fifteen patients have had SD for greater than six weeks. Thirteen patients have been recently enrolled and have not yet had their first imaging assessment.

- ***Patients whose tumors had confirmed Wnt pathway alterations experienced a greater duration of clinical benefit:*** In eight evaluable monotherapy patients with confirmed Wnt pathway alterations, one patient has experienced a PR and four have had SD. In the fourteen evaluable combination therapy patients, one patient has experienced a PR and seven have had SD. The patient with a partial response on DKN-01 combination therapy has a tumor with a CTNNB1 mutation. Tumor CTNNB1 mutations stabilize the transcription factor beta-catenin and are correlated with increased levels of DKK1 and poor clinical outcomes. In this study, eight CTNNB1 patients are evaluable, and six experienced clinical benefit.

- ***Carcinosarcoma partial response leads to new expansion cohort at higher dose:*** Carcinosarcoma is a rare and difficult-to-treat form of uterine cancer. Four carcinosarcoma patients have been enrolled, and the three evaluable patients had tumor reductions and one experienced a PR. To explore a new treatment option for these patients, the Company will expand the study and provide a higher dose of DKN-01 as a monotherapy and in combination with paclitaxel.

About P204
The P204 study is a Phase 2 basket study evaluating DKN-01 as a monotherapy and in combination with paclitaxel in patients with relapsed/refractory endometrioid endometrial cancer (EEC) or endometrioid ovarian cancer (EOC). The study contains four groups and is designed to evaluate the efficacy, safety, and pharmacodynamics of DKN-01 monotherapy and combination therapy in both EEC and EOC, with each group following a 2-stage Simon Minimax design. The study will enroll approximately 94 patients, of which approximately 50% will be required to have documented activating mutations of beta-catenin or other Wnt signaling alterations.

About DKN-01
DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein, a modulator of Wnt/Beta-catenin signaling, a signaling pathway frequently implicated in tumorigenesis and suppressing the immune system. DKK1 has an important role in tumor cell signaling and in mediating an immuno-suppressive tumor microenvironment through enhancing the activity of myeloid-derived suppressor cells and downregulating NK ligands on tumor cells.

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/.

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 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 Therapeutics' Annual Report on Form 10-K for the fiscal year ended December 31, 2017 that Leap filed with the SEC on February 23, 2018 and Leap Therapeutics' Quarterly Reports on Form 10-Q for each of the quarters ended March 31, 2018, June 30, 2018 and September 30, 2018 that Leap filed with the SEC on each of May 11, 2018, August 8, 2018 and November 9, 2018, respectively. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors. 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.

CONTACT:

Douglas E. Onsi
Chief Financial Officer
Leap Therapeutics, Inc.
617-714-0360
donsi@leaptx.com

Heather Savelle
Investor Relations
Argot Partners
212-600-1902
heather@argotpartners.com

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