Leap Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results

March 16, 2020

CAMBRIDGE, Mass., March 16, 2020 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq: LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for the fourth quarter and year ended December 31, 2019.

Leap Highlights:

- Entered into an exclusive option and licence agreement with BeiGene, Ltd. for the clinical development and commercialization of DKN-01, Leap's anti-Dickkopf-1 (DKK1) antibody, in Asia (excluding Japan), Australia, and New Zealand
- Completed a $27 million equity financing with BeiGene, Perceptive Advisors, and a lead institutional investor
- Presented final data from its Phase 1/2 clinical trial of DKN-01 plus Keytruda® (pembrolizumab) in patients with advanced or recurrent esophagogastric cancer at the American Society of Clinical Oncology 2020 Gastrointestinal Cancers Symposium
- Presented updated data from its Phase 2 clinical trial of DKN-01 as monotherapy and in combination with paclitaxel chemotherapy in patients with advanced gynecological malignancies at the 2019 International Gynecologic Cancer Society Annual Global Meeting and at the Society of Gynecologic Oncology 50th Annual Meeting on Women's Cancer
- Announced investigator-initiated study of DKN-01 in patients with DKK1+ advanced prostate cancer
- Announced investigator-initiated study of DKN-01 plus Opdivo® (nivolumab) in patients with advanced biliary tract cancer that is partially supported by Bristol-Myers Squibb
- Announced investigator-initiated study of DKN-01 plus Tecentriq® (atezolizumab) in patients with advanced esophagogastric cancer that is funded by Roche

"We ended 2019 having made significant progress in the clinical development of DKN-01 as both a monotherapy and in combination with other therapies as a treatment for cancer. We've generated an abundance of data that continues to demonstrate DKN-01's activity against multiple difficult-to-treat tumor types," said Christopher K. Mirabelli, Ph.D., President and Chief Executive Officer of Leap. "We've carried this momentum into the new year, having achieved our top corporate goal of securing a strategic partner for development of DKN-01 in the Asia-Pacific region. We look forward to working with BeiGene to bring DKN-01 to patients in this geographic area where the incidence of esophagogastric cancer is highly prevalent and to develop DKN-01 in combination with tizlelizumab, their anti-PD-1 antibody."

Business Update

- ***Leap and BeiGene Sign Exclusive Option and License Agreement for DKN-01*** - Leap and BeiGene announced an exclusive option and license agreement for the clinical development and commercialization of DKN-01. Under the terms of the agreement, Leap will receive an upfront cash payment of $3 million from BeiGene in exchange for granting BeiGene an option to an exclusive license to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand, and will be eligible to receive an additional payment from BeiGene upon BeiGene's exercise of the option following initial proof-of-concept studies. Leap will retain exclusive rights for the development, manufacturing, and commercialization of DKN-01 for the rest of the world. Additionally, Leap is eligible to receive payments from BeiGene based upon the achievement of certain development, regulatory, and sales milestones for a total deal value of up to $132 million, together with tiered royalties on any product sales of DKN-01 in the licensed territory.

- ***Leap Completes $27 Million Equity Financing with BeiGene, Perceptive Advisors and another institutional investor*** - In connection with the licensing agreement with BeiGene, Leap has also entered into a securities purchase agreement to issue and sell in a private placement 1,421,801 shares of Series A mandatorily convertible preferred stock to a lead institutional investor and 1,137,442 shares of Series B mandatorily convertible preferred stock to BeiGene and Perceptive Advisors. On March 5, 2020, the Leap stockholders approved the conversion of the Series A preferred stock into a pre-funded warrant to purchase 14,413,902 shares of common stock and the conversion of the Series B preferred stock into 11,531,133 shares of common stock. Each investor also received a warrant to purchase an equal number of shares at an exercise price of $2.11 per share.

DKN-01 Clinical Update

DKN-01 is a humanized monoclonal antibody targeting the DKK1 protein, a Wnt pathway modulator. DKN-01, as a single agent, has achieved partial responses in three different cancer indications. In combination with immune checkpoint inhibitors and with chemotherapy, DKN-01 has achieved overall response rates and survival data that is greater than the historical benchmarks, particularly in biomarker targeted patient populations.

- ***ESOPHAGOGASTRIC CANCER (EGC):*** Leap completed a multi-part Phase 1/2 clinical study of DKN-01 as a monotherapy and in combination with paclitaxel or KEYTRUDA® (pembrolizumab) in advanced EGC. Two DKN-01 monotherapy patients experienced partial responses (PRs) by central imaging assessment, one of whom had previously been treated with prior immunotherapies, including an anti-PD-L1 antibody, was on therapy for one year. Six additional monotherapy patients were determined to have had a best response of stable disease (SD). The combination of DKN-01 and pembrolizumab in gastroesophageal junction cancer (GEJ) and gastric cancer (GC) patients demonstrated improved outcomes in DKK1-high patients and who had not previously been treated with PD-1/PD-L1 therapy. DKK1-high patients experienced over 22 weeks median progression-free survival (PFS) and nearly 32 weeks overall survival (OS), with a 50% overall response rate (ORR) and 80% disease control rate (DCR) in ten evaluable patients. DKK1-low patients experienced nearly 6 weeks median PFS and over 17 weeks OS, with a 20% DCR in 15 evaluable patients.

  As part of the collaboration with BeiGene, Leap plans to study the combination of DKN-01 and BeiGene's anti-PD-1 antibody, tislelizumab and will evaluate approximately 40 DKK1-high patients with second-line GC or GEJ. In addition, Leap plans to evaluate the combination of DKN-01 with tislelizumab and chemotherapy in approximately 20 patients with first-line GC/GEJ. These clinical trials are expected to initiate in the first half of 2020.

- ***GYNECOLOGICAL CANCERS:*** The ongoing Phase 2 clinical study of DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced gynecological cancers has recently completed patient enrollment. As of September 2019, twenty-two patients who had previously received one to ten lines of therapy have been enrolled to receive DKN-01 monotherapy. In the cohort of sixteen monotherapy patients with epithelial endometrial cancer with identified Wnt signaling mutations, one patient had a complete response and one patient had a partial response, seven patients had a best response of SD, and seven patients had progressive disease. Patient follow-up is continuing in this study, which has been expanded to include focused cohorts of patients with carcinosarcoma.

  In light of the global emergency of the new coronavirus, COVID-19, the Society of Gynecologic Oncology will not conduct its 2020 Annual Meeting on Women's Cancer, previously scheduled for March 28-31, 2020, in Toronto, Canada. Leap is currently awaiting additional information about the oral presentation that was to be made at the conference and evaluating other data presentation opportunities for the study in gynecologic cancers.

Selected Year-End and Fourth Quarter 2019 Financial Results

Net loss was $32.9 million for the year ended December 31, 2019, compared to $23.1 million for the year ended December 31, 2018. This increase was primarily due to increased research and development expenses and a change in warrant liability accounting.

Research and development expenses were $24.4 million for the full year 2019, compared to $21.8 million for the same period in 2018. This increase was primarily due to increased full-year clinical trial costs due to increased patient enrollment, payroll and stock-based compensation expense, offset by reduced manufacturing expenses of our clinical product candidates and consulting expenses. Research and development expenses were $5.7 million for the fourth quarter of 2019, compared to $6.9 million for the same period in 2018. This decrease was primarily due to reduced clinical trial costs in the fourth quarter of 2019 resulting from the maturing of our clinical trials and from lower manufacturing and consulting expenses.

General and administrative expenses were $9.1 million for the full year 2019, compared to $8.9 million for the same period in 2018. General and administrative expenses were $2.6 million for the fourth quarter of 2019, compared to $2.1 million for the same period in 2018. These increases were due to increases in performance-based and stock-based compensation expense.

Cash, cash equivalents and marketable securities totaled $3.9 million at December 31, 2019. Research and development incentive receivables totaled $0.2 million. Subsequent to the financial year end, Leap completed a $27.0 million private placement and received $3.0 million from the agreement with BeiGene.

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 has formed a partnership 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 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 expectations with respect to the development and advancement of DKN-01, including the initiation, timing and design of future studies, enrollment in future studies, potential for the receipt of future option exercise, milestones 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: 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 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, 2019, as filed with the SEC on March 16, 2020. 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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Leap Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31		(Unaudited) Three Months Ended December 31	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 24,366	$ 21,830	$ 5,668	$ 6,908
General and administrative	9,085	8,921	2,604	2,063
Total operating expenses	33,451	30,751	8,272	8,971
Loss from operations	(33,451)	(30,751)	(8,272)	(8,971)
Interest income	313	447	32	120
Interest expense	(23)	(19)	(2)	(1)
Australian research and development incentives	132	756	3	(432)
Foreign currency gains (loss)	126	(835)	240	(220)
Change in fair value of warrant liability	-	7,284	-	11,004
Income (loss) before income taxes	(32,903)	(23,118)	(7,999)	1,500
Income taxes	3	(20)	3	(20)
Net income (loss)	(32,900)	(23,138)	(7,996)	1,480
Dividend attributable to down round feature of warrants	(359)	-	-	-
Net income (loss) attributable to common stockholders	$ (33,259)	$ (23,138)	$ (7,996)	$ 1,480
Net income (loss) per share				
Basic	$ (1.47)	$ (1.64)	$ (0.33)	$ 0.10
Diluted	$ (1.47)	$ (2.11)	$ (0.33)	$ 0.10
Weighted average common shares outstanding				
Basic	22,582,687	14,144,287	24,194,877	14,703,159
Diluted	22,582,687	14,412,695	24,194,877	14,764,282

Leap Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2019	**2018**

Assets		
Current assets:		
Cash and cash equivalents	$ 3,891	$ 16,284
Research and development incentive receivable	185	836
Prepaid expenses and other current assets	165	202
Total current assets	4,241	17,322
Property and equipment, net	124	86
Right of use assets	1,026	-
Deferred tax assets	127	124
Deferred offering costs	831	162
Deposits	1,099	1,380
Total assets	$ 7,448	$ 19,074
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	$ 4,571	$ 3,579
Accrued expenses	3,441	2,872
Lease liability - current portion	474	-
Total current liabilities	8,486	6,451
Non current liabilities:		
Warrant liability	-	3,448
Restricted stock liability	159	-
Lease liability, net of current portion	552	-
Total liabilities	9,197	9,899
Stockholders' equity (deficiency):		
Common stock, $0.001 par value; 100,000,000 shares authorized, 24,194,877 and 14,703,159 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	24	15
Additional paid-in capital	193,319	162,393
Accumulated other comprehensive income	76	302
Accumulated deficit	(195,168)	(153,535)
Total stockholders' equity (deficiency)	(1,749)	9,175
Total liabilities and stockholders' equity (deficiency)	$ 7,448	$ 19,074

Leap Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		(Unaudited) Three Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Cash used in operating activities	$ (26,902)	$ (26,033)	$ (5,894)	$ (7,050)
Cash provided by (used in) investing activities	(85)	-	15	-
Cash provided by (used in) financing activities	14,817	15,906	(19)	(40)
Effect of exchange rate changes on cash and cash equivalents	(223)	674	(269)	125
Net decrease in cash and cash equivalents	(12,393)	(9,453)	(6,167)	(6,965)
Cash and cash equivalents at beginning of period	16,284	25,737	10,058	23,249
Cash and cash equivalents at end of period	$ 3,891	$ 16,284	$ 3,891	$ 16,284

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