Karuna Therapeutics Reports Fourth Quarter and Year End 2019 Financial Results and Provides General Business Update

March 24, 2020

- *Met primary endpoint in Phase 2 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia and demonstrated favorable safety profile with no significant weight gain, somnolence or extrapyramidal side effects relative to placebo*
- *Met secondary endpoints on both PANSS positive and negative symptom subscales, PANSS Marder factor and CGI-S*
- *Raised more than $430 million in gross proceeds during 2019, funding operations for at least the next three years*
- *Initiated a Phase 1b clinical trial to evaluate the safety and tolerability of KarXT in healthy elderly volunteers in order to select the most appropriate doses to study KarXT in dementia-related psychosis patients, with data expected in the second half of 2020*
- *Initiated a Phase 1b clinical trial of experimentally induced pain in healthy volunteers, with data expected mid-2020*
- *Expanded discovery research efforts through collaboration with Charles River*

BOSTON--(BUSINESS WIRE)--Mar. 24, 2020-- Karuna Therapeutics, Inc. (Nasdaq: KRTX), an innovative clinical-stage biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with disabling and potentially fatal neuropsychiatric disorders and pain, today announced financial results for the fourth quarter and year ended 2019 and provided a general business update.

“2019 has been a transformational year for Karuna. Following our initial public offering in June, we were pleased to announce that the Phase 2 data from our lead program, KarXT, in acute psychosis in patients with schizophrenia demonstrated a highly significant and clinically meaningful reduction in total Positive and Negative Syndrome Scale (PANSS) scores when compared to placebo, the trial’s primary efficacy endpoint, while demonstrating overall good tolerability – importantly, KarXT treatment was not associated with the undesirable adverse events commonly observed with currently marketed antipsychotics, namely weight gain, sedation, or extrapyramidal symptoms,” stated Steve Paul, M.D., chief executive officer, president and chairman of Karuna Therapeutics. “In addition to completing our pivotal Phase 2 trial in schizophrenia, we initiated a Phase 1b trial of KarXT to evaluate its safety and tolerability in healthy elderly volunteers, in order to select the most appropriate doses to study KarXT’s efficacy and safety in dementia related psychosis. In addition, we initiated a second Phase 1b trial to assess KarXT’s analgesic effect on experimentally induced pain in healthy volunteers. Our momentum in 2019 carried over into 2020 as we increased our R&D efforts to expand our early pipeline to move forward as a multi-program CNS research and clinical development-focused company that is well funded for at least the next three years.”

2019 Business Highlights

- **KarXT for the treatment of acute psychosis in patients with schizophrenia.** KarXT, a proprietary oral modulator of muscarinic cholinergic receptors, is the Company’s lead product candidate that combines xanomeline, a novel muscarinic agonist, with trospium, an FDA approved muscarinic antagonist that does not appreciably cross the blood-brain-barrier, to preferentially stimulate muscarinic receptors in the central nervous system (CNS). This novel product candidate has the potential to create a new class of antipsychotic drug and produce a differentiated therapy relative to current D2 dopamine and serotonin receptor-based antipsychotic drugs that could dramatically impact patients with schizophrenia and other psychotic disorders, if approved.
    - **KarXT met primary and multiple secondary endpoints in Phase 2 clinical trial.** In November 2019, the Company announced results of its Phase 2 trial that demonstrated a statistically significant and clinically meaningful 11.6 point mean reduction in total Positive and Negative Syndrome Scale (PANSS) score, the trial’s primary efficacy endpoint, when compared to placebo ($p<0.0001$). The Company has also confirmed that KarXT achieved statistical significance ($p<0.001$) in the first four of the trial’s secondary endpoints (PANSS-Positive, CGI-S, PANSS-Negative and PANSS Marder Factor scores). The Company reported a 4:1 ratio of CGI-S responders between KarXT and placebo, which was the fifth prespecified secondary endpoint ($p=0.151$). KarXT was well tolerated in the Phase 2 trial, with similar discontinuation rates between KarXT (20%) and placebo (21%). The number of discontinuations due to treatment emergent adverse events (AEs) were equal in the KarXT and placebo arms (n=2 in each group). Notably, in the study KarXT did not result in adverse events commonly associated with currently marketed antipsychotics including weight gain, sedation, or extrapyramidal symptoms.
    - **On track to initiate Phase 3 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia in 2020.** The Company is completing final analysis of the Phase 2 data and expects to announce additional details of safety and tolerability at upcoming medical meetings and in a peer-reviewed publication. The

Company anticipates holding an end-of-Phase 2 meeting with the FDA in Q2 2020. Based on the outcome of this meeting, the Company expects to initiate its Phase 3 clinical trial by the end of 2020.

- **Advanced CNS pipeline in 2019.** The Company's pipeline is built on the therapeutic potential of KarXT and the established link between stimulation of muscarinic receptors in the CNS and its ability to beneficially impact a wide range of disorders including schizophrenia, dementia-related psychosis and various forms of pain.
    - **Data from Phase 1b clinical trial of KarXT in healthy elderly volunteers expected by the end of 2020.** In December 2019, the Company initiated a Phase 1b clinical trial of KarXT designed to demonstrate the safety and tolerability of KarXT in healthy elderly volunteers with the goal of selecting the most appropriate doses to carry forward into future studies in patients with dementia-related psychosis. The placebo-controlled two-week Phase 1 trial utilizes a 3:1 randomization of KarXT to placebo respectively. Top line data from this trial are expected by the end of 2020.
    - **Data from the Phase 1b clinical trial of KarXT in experimentally induced pain expected in mid-2020.** Preclinical data published in peer-reviewed scientific journals link the stimulation of muscarinic receptors, and specifically xanomeline, to analgesic benefits. Xanomeline has demonstrated robust non-opioid analgesic activity in several animal models of different types of pain including post-operative, inflammatory and neuropathic pain. Based on these data, the Company has initiated a Phase 1b clinical trial of KarXT in experimentally induced pain in healthy volunteers with the goal of translating the preclinical analgesic effects to human to help guide the prioritization of pain conditions for potential future Phase 2 clinical trials. Data from this trial are expected by mid-2020.
    - **Expanded discovery research efforts in CNS.** In February 2020, the Company announced a new multi-year drug discovery collaboration with Charles River, a leading early-stage contract research organization. In addition, the Company announced the opening of a new office in Indianapolis to support continued growth in its drug discovery efforts and further build a pipeline of product candidates that target key neurotransmitter receptors to treat a broad range of CNS disorders.
- **Completed successful Series B financing, initial public offering, and follow-on offering funding operations for at least the next three years**. In November 2019, the Company raised net proceeds of approximately $234 million from its follow-on public offering. The November follow-on offering adds to the strong fundraising year in which the Company raised $75 million in net proceeds from its Series B financing and $93 million in net proceeds from its initial public offering.

Fourth Quarter and Year End 2019 Financial Results

The Company reported a net loss of $7.8 million for the fourth quarter 2019, and a net loss of $44.0 million for the year ended 2019, as compared to $8.3 million and $17.5 million for the prior year periods. The increase in net loss for the year was due to increased research and development expenses, increased personnel expenses as a result of an increase in employee headcount, as well as an increase in general and administrative expenses primarily related to investments in the Company's infrastructure as a publicly traded company.

Research and development expenses were $5.0 million for the fourth quarter 2019, and $24.5 million for the year ended 2019, as compared to $6.7 million and $11.5 million for the prior year periods, respectively. The increase in research and development expenses for the year was primarily driven by increased spending related to the Company's Phase 2 clinical trial for the treatment of schizophrenia, Phase 1b trials in healthy elderly volunteers and experimentally induced pain, increased personnel-related costs due to the increase in employee headcount, as well as expenses associated with consulting fees and our discovery programs.

General and administrative expenses were $3.9 million for the fourth quarter 2019, and $20.9 million for the year ended 2019, as compared to $1.4 million and $3.0 million for the prior year periods, respectively. The increase in general and administrative expenses was primarily due to an increase in employee headcount inclusive of the impact of stock-based compensation and higher costs related to the support of business operations as a publicly traded company.

The Company ended the year with $389.4 million in cash, cash equivalents and short-term investments compared to $13.9 million as of December 31, 2018. The increase was primarily the result of the completion of the Company's follow-on public offering which generated $234.2 million in net proceeds, the completion of the initial public offering which generated $93.0 million in net proceeds, and Series B Preferred Stock Financing which generated net proceeds of $74.8 million. The Company expects that current cash, cash equivalents, and short-term investments as of December 31, 2019, will enable the Company to fund its operating expenses and capital expenditure requirements for at least the next three years. This includes multiple potential clinical and development milestones, including an NDA submission of KarXT in psychosis related to schizophrenia, pending the outcomes of the Company's planned clinical trials.

About Karuna

Karuna is an innovative clinical-stage biopharmaceutical company primarily focused on developing novel therapies to address disabling neuropsychiatric conditions characterized by significant unmet medical need. Karuna is currently conducting a Phase 2 clinical trial of its lead product candidate, KarXT (Karuna-Xanomeline-Trospium), for the treatment of acute psychosis in patients with schizophrenia. Karuna also plans to initiate clinical trials of KarXT to evaluate its potential therapeutic benefit in other central nervous system disorders, including psychosis in Alzheimer's disease, as well as pain.

Forward Looking Statements

This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E

of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations about our cash resources, the timing of advancing of our planned clinical trials and regulatory filings, interim trial results, our goals to develop and commercialize our product candidates, and other statements identified by words such as “could,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “will,” “would,” or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to obtain necessary funding, our ability to generate positive clinical trial results for our product candidates, the costs and timing of establishing, equipping, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, risks relating to business interruptions resulting from the coronavirus (COVID-19) pandemic and other risks set forth under the heading “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2019. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

Karuna Therapeutics, Inc.
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue	—	—	—	—
Operating expenses:				
Research and development	$ 4,992	$ 6,720	$ 24,536	$ 11,536
General and administrative	3,874	1,426	20,869	2,974
Total operating expenses	8,866	8,146	45,405	14,510
Loss from operations	(8,866)	(8,146)	(45,405)	(14,510)
Other income (expense):				
Interest income (expense)	—	(11)	11	(407)
Interest income	1,092	25	2,517	25
Accretion of debt discount	—	(180)	(945)	(2,176)
Change in fair value of derivative	—	(15)	(135)	(444)
Total other income (expense), net	1,092	(181)	1,448	(3,002)
Net loss before income taxes	(7,774)	(8,327)	(43,957)	(17,512)
Income tax provision	—	—	—	—
Net loss attributable to common stockholders	$ (7,774)	$ (8,327)	$ (43,957)	$ (17,512)
Net loss per share, basic and diluted	$ (0.32)	$(693,917)	$ (3.68)	$(4,378,000)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	24,430,145	12	11,958,152	4

Karuna Therapeutics, Inc.
Unaudited Consolidated Balance Sheet Data
(in thousands)

	December 31, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 389,397	$ 13,887
Working capital	389,748	14,400
Total assets	393,024	15,857
Redeemable convertible preferred stock	-	41,965
Total stockholders’ equity (deficit)	$ 389,916	$ (29,922)

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