Karuna Therapeutics Reports First Quarter 2020 Financial Results and Provides General Business Update

May 7, 2020

- *End of Phase 2 meeting scheduled with the U.S. Food and Drug Administration (FDA) with feedback from the meeting expected to be announced in the second quarter*
- *Additional data from Phase 2 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia to be presented at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting*
- *CNS pipeline programs in pain and healthy elderly volunteers remain on track*
- *$383.5 million in cash, cash equivalents and short-term investments, funding operations for at least the next three years*
- *Appointed Christopher J. Coughlin to the board of directors and as chair of the audit committee*

BOSTON--(BUSINESS WIRE)--May 7, 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 first quarter of 2020 and provided a general business update.

“We are off to a strong start in 2020 and continue to make significant progress advancing our lead program, KarXT for the treatment of acute psychosis in patients with schizophrenia,” stated Steve Paul, M.D., chief executive officer, president and chairman of Karuna Therapeutics. “On the heels of completing a Phase 2 clinical trial that demonstrated statistically significant and clinically meaningful efficacy and tolerability, we look forward to sharing the outcome from our upcoming end of Phase 2 meeting with the FDA in the second quarter. We plan to highlight KarXT’s potential best-in-class clinical profile by presenting additional data at the ASCP Annual Meeting. We are also excited to welcome Chris Coughlin to our board of directors.”

Dr. Paul continued: “The COVID-19 global pandemic has dramatically changed the landscape for biotech companies and has, in many cases, impacted timelines. Karuna has adopted all recommendations in line with guidance from health authorities to protect the safety of our employees and our community. Like so many other companies, we have implemented work-from-home policies and restricted on-site activities when possible. At this point, we remain confident in our ability to deliver upon all stated timelines. Given the dynamic nature of the situation, we will continue to regularly monitor and assess the possible impact of the pandemic on our business and look forward to providing updates over the course of this year.”

Business Highlights

- **KarXT for 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, if approved, has the potential to usher in a new treatment paradigm and dramatically impact patients with schizophrenia and other psychotic disorders by providing a differentiated mechanism of action relative to current D2 dopamine and serotonin receptor-targeting antipsychotic drugs.
    - **KarXT Phase 2 data highlighting details of efficacy, tolerability and safety will be presented at the ASCP Annual Meeting scheduled for the end of May.** The presentation will include both efficacy and safety data, including the relative rates (versus placebo) and time-course of treatment emergent adverse events.
    - **End of Phase 2 meeting with the FDA has been scheduled and is expected to be held virtually**; **the Company plans to provide feedback from the meeting in the second quarter.**
    - **On track to initiate Phase 3 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia in 2020.** Subject to the outcome of the upcoming end of Phase 2 meeting with the FDA, the Company expects to initiate its Phase 3 clinical trial by the end of 2020.
    - **Currently evaluating the KarXT development strategy for use as adjunctive therapy in patients with persistent negative and cognitive symptoms and those with inadequate response to their current antipsychotic therapy.** Based on clinical and preclinical data supporting the potential of KarXT to augment traditional antipsychotic drugs, the Company intends to pursue clinical trials to determine the safety and efficacy of KarXT when dosed in conjunction with background antipsychotics to improve negative and cognitive symptoms, and to further improve positive symptoms in patients who remain symptomatic on existing therapies. There are no FDA approved therapies for these indications. The Company had previously planned to initiate a Phase 1b study to assess potential Drug-Drug Interactions (DDI) with a selection of currently marketed antipsychotics in healthy volunteers in order to enable the initiation of Phase 2 adjunctive therapy trials. However, the Company is reevaluating the need to conduct a Phase 1b DDI study and will provide further guidance by mid-year on its strategy and timeline to enter Phase 2 trials.
- **CNS pipeline.** The Company’s clinical development pipeline is built on the therapeutic potential of KarXT and the established link between the 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 safety and tolerability 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 multi-cohort, placebo-controlled, two-week Phase 1b trial utilizes a 3:1 randomization of KarXT to placebo.
- **Dosing completed for Phase 1b clinical trial of KarXT in experimentally induced pain; data expected in mid-2020.** Preclinical data published in peer-reviewed scientific journals link the stimulation of xanomeline to analgesic benefits. Xanomeline in particular has demonstrated robust non-opioid analgesic activity in several animal models of pain, including post-operative, inflammatory and neuropathic pain. Based on these data, the Company has recently completed enrollment of a Phase 1b clinical trial of KarXT in experimentally induced pain in healthy volunteers. The results of this trial are expected to help guide the prioritization of pain conditions for potential clinical trials of KarXT in the future.
- **Expansion of organizational capacity to support KarXT product development and regulatory objectives.** Karuna continues to grow its leadership team with the addition of new strategic hires across multiple functional areas including Clinical Operations, Medical, Human Resources and Legal. Recruitment of top talent remains a key organizational priority as the Company expands its capacity to meet KarXT development objectives in 2020.

- **Christopher J. Coughlin appointed to Karuna's board of directors.** In April 2020, Karuna appointed Christopher J. Coughlin to the board of directors and named him chair of the audit committee. He previously served as advisor to the chairman and CEO of Tyco International Ltd., a global provider of diversified products, services and industries, and as executive vice president and chief financial officer of Tyco during a period of significant international growth and restructuring. Mr. Coughlin currently serves on the boards of Allergan plc, Alexion Pharmaceuticals, Inc. and Prestige Consumer Healthcare Inc. He previously served on the boards of The Dun & Bradstreet Corp, Hologic, Inc., Covidien Ltd, Dipexium Pharmaceuticals, Inc., Forest Laboratories, Inc., Interpublic Group of Companies, Monsanto Company and Perrigo Company.
- **Cash and cash equivalents of $383.5 million sufficient to fund operations for at least the next three years and achieve multiple data catalysts**. Current funding is sufficient to fund all development activities leading to the filing of a New Drug Application with the FDA for the treatment of psychosis in schizophrenia, including two Phase 3 clinical efficacy studies and a required long-term safety study. Additional activities funded include the completion of Phase 1b and 2 trials for the treatment of dementia-related psychosis, completion of Phase 1b and 2 trials for the treatment of pain, and continued investment into pipeline expansion.

First Quarter 2020 Financial Results

The Company reported a net loss of $8.7 million for the first quarter of 2020, as compared to $12.0 million for the prior year period. The decrease in net loss for the period was due to phasing of research and development expenses related to our schizophrenia program as well as higher interest income generated from our cash equivalents and short-term investments.

Research and development expenses were $4.4 million for the first quarter of 2020, as compared to $7.0 million for the prior year period. The decrease in research and development expenses for the period was primarily driven by unrepeated spending related to the Company's Phase 2 clinical trial for the treatment of schizophrenia, which was completed in 2019. This decrease was partially offset by additional expenses related to 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 $5.6 million for the first quarter of 2020, as compared to $4.6 million for the prior year period. The increase in general and administrative expenses primarily resulted from an increase in employee headcount and higher costs related to the support of business operations as a publicly traded company.

The Company ended the quarter with $383.5 million in cash, cash equivalents, and short-term investments compared to $389.4 million as of December 31, 2019. The Company expects that current cash, cash equivalents, and short-term investments as of March 31, 2020, 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 for the treatment of acute psychosis in patients with schizophrenia, pending the outcomes of the Company's planned clinical trials.

About Karuna

Karuna is a clinical-stage biopharmaceutical company committed to developing and delivering first-in-class therapies with the potential to transform the lives of people with CNS disorders – which remain among the most disabling and potentially fatal disorders worldwide. Galvanized by the understanding that today's neuropsychiatric and pain management patients deserve better, Karuna's mission is to harness the untapped potential of the brain's complex biology in pursuit of novel therapeutic pathways that will advance the standard of care. For more information, please visit karunatx.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, 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 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 March 31,	
	2020	**2019**
Revenue	—	—
Operating expenses:		
Research and development	$ 4,420	$ 6,967
General and administrative	5,635	4,606
Total operating expenses	10,055	11,573
Loss from operations	(10,055)	(11,573)
Other income (expense):		
Interest income	1,397	115
Interest income, net	—	11
Accretion of debt discount	—	(423)
Change in fair value of derivative	—	(135)
Total other income (expense), net	1,397	(432)
Net loss before income taxes	(8,658)	(12,005)
Income tax provision	—	—
Net loss attributable to common stockholders	$ (8,658)	$ (12,005)
Net loss per share, basic and diluted	$ (0.33)	$ (4,484)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	26,042,434	2,677

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

	March 31, 2020	**December 31, 2019**
Cash, cash equivalents and short-term investments	$ 383,491	$ 389,397
Working capital	384,016	389,748
Total assets	389,718	393,024
Total stockholders’ equity	$ 384,941	$ 389,916

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