



## **Karuna Therapeutics Announces Topline Data From Phase 1b Trial Evaluating KarXT on Experimentally Induced Pain in Healthy Volunteers**

August 3, 2020

*Topline results of exploratory trial do not provide conclusive evidence of an analgesic benefit of KarXT on experimentally induced pain in healthy volunteers*

*The Company will not move forward to evaluate KarXT for the treatment of pain*

*The safety and tolerability profile of KarXT was consistent with previous trials*

BOSTON--(BUSINESS WIRE)--Aug. 3, 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, today announced results from KAR-020, its Phase 1b trial evaluating the analgesic effects of KarXT on experimentally induced pain in healthy volunteers. Topline results of this exploratory trial were inconclusive and do not provide sufficient evidence of an analgesic benefit of KarXT compared to placebo. The Company will not move forward to develop KarXT in pain.

The KAR-020 trial employed an intra-individual cross-over design to evaluate objective and subjective pain measurements of KarXT and placebo in three different skin conditions meant to model nociceptive (normal skin), inflammatory (UVB-irradiated skin) and neuropathic (capsaicin-treated skin) pain in 24 healthy volunteers. The safety and tolerability profile of KarXT was consistent with previous clinical trials of KarXT. There were no serious adverse events observed in the trial, and no clinically meaningful changes in vital signs or clinical laboratory values.

"Today's results do not provide compelling evidence of the analgesic benefit observed in preclinical trials," said Steve Paul, M.D., chief executive officer, president and chairman of Karuna Therapeutics. "While this data does not support the continued development of KarXT in pain, we will continue to evaluate data from this trial to better assess the potential role of muscarinic-targeted receptor treatments in pain management."

Dr. Paul continued: "Looking ahead, we remain focused on developing KarXT for the treatment of severe neuropsychiatric disorders, including schizophrenia and dementia-related psychosis, where robust evidence from previous clinical trials supports the potential of KarXT to provide a new, unique and mechanistically differentiated therapeutic for the treatment of these disorders. We remain on track to initiate Phase 3 development in schizophrenia later this year."

### **About KarXT**

KarXT, a proprietary oral modulator of muscarinic cholinergic receptors, is Karuna'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 is currently being evaluated in clinical development as a potential treatment for serious neuropsychiatric disorders, including schizophrenia and dementia-related psychosis.

### **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 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](http://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 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 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.

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