Jounce Therapeutics Receives Study May Proceed Letter from US FDA to Initiate Phase 1 Clinical Trial of JTX-8064 Targeting the LILRB2/ILT4 Mechanism

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-Phase 1 INNATE trial will evaluate JTX-8064 as a monotherapy and in combination with Jounce's PD-1 inhibitor, JTX-4014-

-On track to begin enrollment by year-end 2020-

CAMBRIDGE, Mass., Nov. 16, 2020 (GLOBE NEWSWIRE) -- Jounce Therapeutics, Inc. (NASDAQ: JNCE), a clinical-stage company focused on the discovery and development of novel cancer immunotherapies and predictive biomarkers, today announced the company has received a Study May Proceed Letter from the United States Food and Drug Administration (FDA) to begin a Phase 1 trial, named INNATE, for JTX-8064. JTX-8064 is an anti-Leukocyte Immunoglobulin Like Receptor B2 (LILRB2/ILT4) antibody and is the first tumor-associated macrophage candidate from Jounce's Translational Science Platform. Through the Study May Proceed Letter, the FDA has cleared the original Investigational New Drug (IND) application for JTX-8064. Preclinical data presented at the 2020 Society for Immunotherapy of Cancer's Annual Meeting and the 2019 American Association for Cancer Research Annual Meeting support the development of JTX-8064 as a novel immunotherapy to reprogram immune-suppressive macrophages and enhance anti-tumor immunity.

The Phase 1 INNATE trial will consist of 4 parts:

- JTX-8064 monotherapy dose escalation in solid tumors
- JTX-8064 dose escalation in combination with Jounce's PD-1 inhibitor, JTX-4014, or with pembrolizumab in solid tumors
- JTX-8064 monotherapy in indication-specific expansion cohorts
- JTX-8064 + JTX-4014 or pembrolizumab in indication-specific expansion cohorts

"Our INNATE trial represents the first time we are combining two wholly owned Jounce immunotherapies targeting two different immune cells in the tumor microenvironment," said Elizabeth Trehu, M.D., chief medical officer of Jounce Therapeutics. "We believe that targeting multiple immune cell types including immunosuppressive macrophages in the tumor microenvironment may offer new promise for patients, particularly those with PD-(L)1 inhibitor resistant tumors, where IO therapies have yet to make a substantial impact. Expansion cohorts in INNATE will include PD-(L)1 resistant and sensitive tumor types, and PD-(L)1 naïve and experienced patients. INNATE is designed to advance rapidly to initiation of indication-specific JTX-8064 monotherapy and PD-1 inhibitor combination expansion cohorts, with a goal to establish proof-of-concept as quickly as possible, and we are on track to begin enrollment in INNATE by the end of the year."

About JTX-8064
JTX-8064 is a humanized anti-LILRB2 (ILT4) antibody and is the first tumor-associated macrophage candidate to emerge from Jounce's Translational Science Platform. Preclinical data presented at the 2020 Society for Immunotherapy of Cancer's Annual Meeting and the 2019 American Association for Cancer Research Annual Meeting support the development of JTX-8064 as a novel immunotherapy to reprogram immune-suppressive macrophages and enhance anti-tumor immunity. A Phase 1 clinical trial, named INNATE, for JTX-8064 as a monotherapy and in combination with a PD-1 inhibitor is planned to begin enrollment by year-end 2020.

About JTX-4014
JTX-4014 is a well-characterized fully human IgG4 monoclonal antibody designed to block binding to PD-L1 and PD-L2. JTX-4014 demonstrated a 17% durable overall response rate in a Phase 1 trial of 18 heavily pre-treated PD-(L)1 inhibitor naïve patients which excluded all tumor types for which PD-(L)1 inhibitors were approved. In this Phase 1 trial, JTX-4014 was shown to have an acceptable safety profile. JTX-4014 is currently being assessed in the SELECT Phase 2 clinical trial in combination with vopratelimab, a clinical-stage monoclonal antibody that binds to and activates ICOS, the Inducible T cell CO-Stimulator, a protein on the surface of certain T cells commonly found in many solid tumors. The SELECT trial compares vopratelimab plus JTX-4014 to JTX-4014 alone in immunotherapy naïve NSCLC patients who have been pre-selected with the TIS^{vopra} predictive biomarker, an 18 gene RNA tumor inflammation signature which predicted the emergence of ICOS hi CD4 T cells and clinical benefit in the ICONIC trial of vopratelimab alone and in combination with a PD-1 inhibitor.

About Jounce Therapeutics
Jounce Therapeutics, Inc. is a clinical-stage immunotherapy company dedicated to transforming the treatment of cancer by developing therapies that enable the immune system to attack tumors and provide long-lasting benefits to patients through a biomarker-driven approach. Jounce currently has multiple development stage programs ongoing while simultaneously advancing additional early-stage assets from its robust discovery engine based on its Translational Science Platform. Jounce's most advanced product candidate, vopratelimab, is a monoclonal antibody that binds to and activates ICOS, and is currently being studied in the SELECT Phase 2 trial. JTX-4014 is a PD-1 inhibitor intended for combination use in the SELECT trial and with Jounce's broader pipeline. Jounce's next development stage product candidate, JTX-8064, is a LILRB2 (ILT4) receptor antagonist shown to reprogram immune-suppressive tumor associated macrophages to an anti-tumor state. A Phase 1 trial evaluating JTX-8064 is planned to begin enrollment in the fourth quarter of 2020. Additionally, Jounce exclusively licensed worldwide rights to JTX-1811, a monoclonal antibody targeting CCR8 and designed to selectively deplete T regulatory cells in the tumor microenvironment, to Gilead Sciences, Inc. For more information, please visit www.jouncetx.com.

Cautionary Note Regarding Forward-Looking Statements
Various statements in this release concerning Jounce's future expectations and plans, including without limitation, Jounce's expectations regarding the timing and initiation of clinical trials of JTX-8064 and JTX-4014, may constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws and are subject to substantial risks,

uncertainties and assumptions. You should not place reliance on these forward-looking statements, which often include words such as “expect,” “plan” or similar terms, variations of such terms or the negative of those terms. Although Jounce believes that the expectations reflected in the forward-looking statements are reasonable, Jounce cannot guarantee such outcomes. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, risks that the COVID-19 pandemic may disrupt Jounce’s business and/or the global healthcare system more severely than anticipated, which may have the effect of delaying enrollment and completion of Jounce’s clinical trials, or delaying timelines or data disclosures and regulatory submissions for its product candidates; Jounce’s ability to successfully demonstrate the efficacy and safety of its product candidates; Jounce’s ability to successfully manage its clinical trials; the development plans of its product candidates and any companion or complementary diagnostics; management of Jounce’s supply chain for the delivery of drug product and materials for use in clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of preclinical studies and clinical trials of Jounce’s product candidates; and those risks more fully discussed in the section entitled “Risk Factors” in Jounce’s most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission as well as discussions of potential risks, uncertainties, and other important factors in Jounce’s subsequent filings with the Securities and Exchange Commission. All such statements speak only as of the date made, and Jounce undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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