Jounce Therapeutics Announces Initiation of Phase 1 INNATE Study of JTX-8064 (LILRB2/ILT4 Inhibitor) Monotherapy and PD-1 Inhibitor Combination Therapy in Patients with Advanced Solid Tumors

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- INNATE is a robust Phase 1 study designed to dose escalate quickly and demonstrate proof of concept for JTX-8064 monotherapy and PD-1i combinations -

- Tumor-specific expansion cohorts to include PD-(L)1i resistant and sensitive tumors and PD-(L)1i naïve and experienced patients -

CAMBRIDGE, Mass., Jan. 13, 2021 (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 initiation of patient enrollment in the INNATE Phase 1 clinical study of its lead macrophage program JTX-8064 as a monotherapy and in combination with either JTX-4014, its internal PD-1 inhibitor, or pembrolizumab in patients with advanced solid tumors. JTX-8064, the first tumor-associated macrophage candidate developed from Jounce's Translational Science Platform, is a humanized IgG4 monoclonal antibody designed to specifically bind to the macrophage receptor Leukocyte Immunoglobulin Like Receptor B2 (LILRB2/ILT4), inhibiting LILRB2 binding with its ligands and reprogramming immune-suppressive macrophages to enhance anti-tumor immunity.

"We are pleased to announce we have dosed the first patient in our INNATE Phase 1 study which is designed to progress quickly through dose escalation and demonstrate proof of concept in tumor specific expansion cohorts," said Beth Trehu, M.D., chief medical officer at Jounce Therapeutics. "Expansion cohorts in INNATE will address multiple different patient populations, including PD-(L)1 inhibitor naïve patients with both PD-(L)1 inhibitor sensitive and resistant tumor types, and PD-(L)1 inhibitor experienced patients whose tumors were resistant to PD-(L)1 inhibitors. Patients with PD-(L)1 inhibitor resistant tumors represent a large and growing unmet medical need. We believe LILRB2 may function as an immune checkpoint for macrophages and JTX-8064 may have the potential to restore PD-(L)1 inhibitor activity in otherwise resistant settings. INNATE will also assess pharmacodynamic and potential predictive biomarkers to guide future development, aligning with Jounce's philosophy of developing the right immunotherapies for the right patients."

The Phase 1 INNATE study 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, and also with pembrolizumab in solid tumors
- JTX-8064 monotherapy in indication-specific expansion cohorts
- JTX-8064 in combination with JTX-4014 or pembrolizumab in indication-specific expansion cohorts

ClinicalTrials.gov identifier: NCT04669899

About JTX-8064
JTX-8064 is a humanized IgG4 monoclonal antibody designed to specifically bind to Leukocyte Immunoglobulin Like Receptor B2 (LILRB2/ILT4) and block interactions with its ligands. JTX-8064 is the first tumor-associated macrophage candidate developed 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 study named INNATE (NCT04669899), for JTX-8064 as a monotherapy and in combination with JTX-4014 or pembrolizumab, is currently enrolling patients with advanced solid tumors.

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 INNATE Phase 1 trial (NCT04669899) in combination with JTX-8064, a LILRB2 (ILT4) inhibitor. JTX-4014 is also being assessed in the SELECT Phase 2 clinical trial (NCT04549025) 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 lead macrophage program, JTX-8064, is a LILRB2 (ILT4) receptor antagonist shown to reprogram immune-suppressive tumor associated macrophages to an anti-tumor state. A Phase 1 clinical trial, named INNATE, for JTX-8064 as a monotherapy and in combination with JTX-4014, Jounce's internal PD-1 inhibitor, or pembrolizumab is currently enrolling patients with advanced solid tumors.

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 INNATE and SELECT trials and with Jounce's broader pipeline. 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 development and timing 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.

Investor and Media Contacts:
Mark Yore
+1-857-200-1255
myore@jouncetx.com

Malin Deon
+1-857-259-3843
mdeon@jouncetx.com

Source: Jounce Therapeutics, Inc.