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

October 7, 2021

- Enrollment initiated in tumor-specific monotherapy and pimivalimab combination expansion cohorts –

- Monotherapy and pimivalimab combination dose escalation enrollment completed -

CAMBRIDGE, Mass., Oct. 07, 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 INNATE tumor-specific expansion cohorts for both JTX-8064 monotherapy and combination therapy of JTX-8064 with its internal PD-1 inhibitor, pimivalimab. 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). By inhibiting LILRB2 binding with its ligands, JTX-8064 reprograms immune-suppressive macrophages to an immune-active state in preclinical studies, potentially enhancing the T cell response and anti-tumor immunity.

"We are very pleased to announce that we have started dosing patients in the tumor-specific JTX-8064 monotherapy and pimivalimab combination expansion cohorts of our INNATE study," said Beth Trehu, M.D., chief medical officer at Jounce Therapeutics. "We have made enormous progress in INNATE, having advanced the study from initiation of monotherapy dose escalation to the opening of tumor-specific, proof-of-concept, combination expansion cohorts in just nine months. This progress has been driven by the continued dedication of our employees, enthusiasm from investigators and, based on the science, our belief that the mechanism of action of JTX-8064 has the potential to address the major emerging unmet need in immuno-oncology, overcoming PD-(L)1 inhibitor resistance. We look forward to sharing updates on our continued execution of the INNATE study."

Proof-of-concept (POC) expansion cohorts in INNATE will address three different segments of IO patient populations; first, patients whose tumors progressed on or after a prior PD-1 or PD-L1 inhibitor (PD-(L)1i) and whose tumors exhibited primary or acquired resistance; second, IO naïve patients with tumors where no PD-(L)1i treatment is approved; and third, IO naïve patients with tumors that have a PD-(L)1i approval. POC expansion cohorts in INNATE follow a Simon's two-stage design with the potential to enroll up to 29 patients per combination cohort and 47 patients in the monotherapy cohort if pre-specified criteria are met. If POC is established after evaluation of 29 or 47 patients, respectively, Jounce intends to move JTX-8064 rapidly into registrational trials on a cohort by cohort basis. 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 INNATE trial (NCT04669899) is divided into 4 parts:

- Part 1: JTX-8064 monotherapy dose escalation in solid tumors (completed July 2021)
- Part 2: JTX-8064 + pimivalimab dose escalation in solid tumors (enrollment completed)
- Part 3: JTX-8064 monotherapy expansion cohort in 2nd- to 4th-line PD-(L)1i naïve, platinum-resistant ovarian cancer (initiated August 2021)
- Part 4: JTX-8064 + pimivalimab in indication-specific expansion cohorts (initiated October 2021)
    - Combination expansion cohorts include:
        - 2nd- to 3rd-line non-small cell lung cancer that has progressed on or after a PD-(L)1i
        - 2nd-line+ clear cell renal cell carcinoma that has progressed on or after a PD-(L)1i
        - 2nd- to 4th-line triple-negative breast cancer that has progressed on or after a PD-(L)1i
        - 2nd- to 3rd-line cutaneous squamous cell carcinoma that has progressed on or after a PD-(L)1i
        - 1st-line PD-(L)1i naïve, PD-L1+ head and neck squamous cell carcinoma
        - 2nd- to 4th-line PD-(L)1i naïve, platinum-resistant, ovarian cancer
        - 2nd- to 4th-line PD-(L)1i naïve, undifferentiated pleomorphic sarcoma and liposarcoma

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 and 2021 American Association for Cancer Research Annual Meetings 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 (NCT04669899) of JTX-8064 as a monotherapy and in combination with Jounce's internal anti-PD-1 inhibitor, pimivalimab (formerly JTX-4014) is currently enrolling patients with advanced solid tumors into tumor-specific expansion cohorts.

About Pimivalimab
Pimivalimab (formerly JTX-4014) is a well-characterized fully human IgG4 monoclonal antibody designed to block binding to PD-L1 and PD-L2. Pimivalimab 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, pimivalimab was shown to have an acceptable safety profile. Pimivalimab is currently being assessed in the INNATE Phase 1 trial (NCT04669899) in combination with JTX-8064, a LILRB2 (ILT4) inhibitor. Pimivalimab 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.

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 highest priority program, JTX-8064, is a LILRB2 (ILT4) receptor antagonist shown to reprogram immune-suppressive tumor associated macrophages to an anti-tumor state in preclinical studies. 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. Pimivalimab 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 GS-1811 (formerly 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, plans and prospects, including without limitation, Jounce's expectations regarding the progress and results of clinical trials of Jounce's product candidates, including JTX-8064 and pimivalimab; and enrollment of patients for Jounce's clinical trials 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 "potential," "will" 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 ongoing 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 and future product candidates; the preclinical and clinical results for its product candidates, which may not support further development and marketing approval; the potential advantages of Jounce's 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 and research and development activities; actions of regulatory agencies, which may affect the initiation, timing and progress of preclinical studies and clinical trials of Jounce's product candidates; Jounce's ability to obtain, maintain and protect its intellectual property; Jounce's ability to manage operating expenses and capital expenditures; 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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