



Jounce Therapeutics Presents Trial in Progress Posters on the INNATE and SELECT Clinical Trials at the 2021 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting

June 4, 2021

- INNATE trial to include proof-of-concept expansion cohorts in lung, renal, head and neck, triple negative breast, cutaneous squamous cell, and ovarian cancers and soft tissue sarcomas -

- SELECT TIS^{vopra} positivity rate for patient selection in-line with projections, clinical data on-track for 2022 -

CAMBRIDGE, Mass., June 04, 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 presented two trial in progress posters, on the Phase 1 INNATE clinical trial and the Phase 2 SELECT clinical trial, at the American Society of Clinical Oncology (ASCO) Virtual Annual Meeting. INNATE, a proof-of-concept (POC) trial, is evaluating Jounce's lead macrophage program JTX-8064 (anti-LILRB2/ILT4 inhibitor) as a monotherapy and in combination with pimivalimab (anti-PD-1 inhibitor, formerly known as JTX-4014) in patients with a variety of advanced solid tumors. SELECT, Jounce's second POC trial, is evaluating pimivalimab as a monotherapy and in combination with vopratelimab (ICOS agonist) in a novel biomarker selection paradigm in PD-(L)1 naïve non-small cell lung cancer patients.

"Our INNATE trial is rapidly progressing through dose escalation and we are on-track to begin indication-specific, POC, monotherapy and pimivalimab combination expansion cohorts in the second half of this year," said Elizabeth Trehu, M.D., chief medical officer of Jounce Therapeutics. "Furthermore, we are excited to announce the expansion cohort indications for INNATE, which were selected using our translational data-driven approach, linking JTX-8064's mechanism to tumor types in three groups of patients including: PD-(L)1 inhibitor experienced and resistant, PD-(L)1 inhibitor naïve and historically resistant, and PD-(L)1 inhibitor and historically more sensitive. JTX-8064 is one of only two clinical-stage LILRB2 programs in development and we expect it to be the first program to initiate expansion cohorts in four of our chosen tumor types. We are also pleased to see TIS^{vopra} positivity rates tracking with expectations in our biomarker selection trial, SELECT, and we remain on-track to report data next year."

Poster Presentation Details:

Poster Title: Phase 1, First-in-Human trial of JTX-8064, an anti-LILRB2/ILT4 monoclonal antibody, as monotherapy and in combination with anti-PD-1 in adult patients with advanced solid (INNATE)

Presenter: Kyriakos P. Papadopoulos, MD, South Texas Accelerated Research Therapeutics (START), San Antonio, TX

Session Title: Developmental Therapeutics – Immunotherapy

Abstract Number: TPS2672

Date and Time: Friday, June 4, 2021; 9:00am ET

Highlights from the trial in progress poster include the selection criteria for expansion cohorts in the ongoing Phase 1 INNATE trial and an outline the future biomarker plan:

- Expansion cohort selection was informed using human histoculture and gene signature analysis from Jounce's Translational Science Platform and includes PD-(L)1 naïve and experienced patients as well as PD-(L)1 sensitive and resistant tumor types.
- The INNATE trial is divided into 4 stages with indication-specific expansion cohorts intended to establish proof-of-concept for JTX-8064:
 1. JTX-8064 monotherapy dose escalation in relapsed / refractory solid tumors
 2. JTX-8064 plus pimivalimab dose escalation in relapsed / refractory solid tumors
 3. JTX-8064 monotherapy expansion in PD-(L)1i naïve platinum resistant ovarian cancer
 4. JTX-8064 plus pimivalimab expansions in:
 - PD-(L)1i naïve platinum resistant ovarian cancer
 - PD-(L)1i naïve head and neck squamous cell carcinoma (HNSCC)
 - PD-(L)1i naïve undifferentiated pleomorphic sarcoma (UPS) and liposarcoma (LPS)
 - PD-(L)1i experienced non-small cell lung cancer (NSCLC)
 - PD-(L)1i experienced clear cell renal cell carcinoma (ccRCC)
 - PD-(L)1i experienced triple negative breast cancer (TNBC)
 - PD-(L)1i experienced cutaneous squamous cell carcinoma (cSCC).
- The dose for expansion cohorts will be selected based on safety, pharmacokinetic and receptor occupancy data from the monotherapy dose escalation stage of INNATE.

- Archival and pre-treatment tumor biopsies as well as pre- and post-treatment blood samples will be collected to evaluate a number of potential predictive and pharmacodynamic biomarkers using Jounce's Translational Science Platform.

Poster Title: Phase 2 Study of PD-1 Inhibitor JTX-4014 (Pimivalimab) Alone and in Combination with Vopratelimab, an ICOS Agonist, in Biomarker-selected Subjects with Metastatic NSCLC After One Prior Platinum-containing Regimen (SELECT)

Presenter: Oleh Kobziev, MD, Regional Center of Oncology, Kharkiv, 61070, Ukraine

Session Title: Lung Cancer – Non-Small Cell Metastatic

Abstract Number: TPS9137

Date and Time: Friday, June 4, 2021; 9:00am ET

The SELECT trial is currently enrolling approximately 75 immunotherapy naïve NSCLC patients who have been pre-selected with the TIS^{vopra} predictive biomarker

- TIS^{vopra} may serve as a unique biomarker for potential increased benefit for both pimivalimab monotherapy as well as pimivalimab in combination with vopratelimab.
- Data from Jounce and a third-party ICOS agonist program support an ICOS-focused biomarker selection strategy to identify patients that may benefit from ICOS agonism.
- Early screening data from SELECT support Jounce's estimate that approximately 20% of PD-(L)1 naïve non-small cell lung cancer patients tested for TIS^{vopra} in the study would meet the TIS^{vopra} positivity threshold.
- SELECT is on-track to report clinical data in 2022.

Both posters will be available on the "Our Pipeline" section of the Jounce Therapeutics website under "Publications" at www.jouncetx.com.

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](https://clinicaltrials.gov/ct2/show/study/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.

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](https://clinicaltrials.gov/ct2/show/study/NCT04669899)) in combination with JTX-8064, a LILRB2 (ILT4) inhibitor. Pimivalimab is also being assessed in the SELECT Phase 2 clinical trial ([NCT04549025](https://clinicaltrials.gov/ct2/show/study/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 Vopratelimab

Vopratelimab is 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. Vopratelimab is currently being assessed in the SELECT Phase 2 clinical trial ([NCT04549025](https://clinicaltrials.gov/ct2/show/study/NCT04549025)) in combination with Jounce's internal investigational PD-1 inhibitor, pimivalimab (formerly JTX-4014), compared to pimivalimab alone. The SELECT trial is currently enrolling approximately 75 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. SELECT is powered to demonstrate the statistical superiority of the combination of vopratelimab plus pimivalimab compared to pimivalimab.

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 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 timing, progress, results and release of data for clinical trials of vopratelimab, pimivalimab and JTX-8064, identification, selection and enrollment of patients for Jounce's clinical trials, and the use of pimivalimab in combination with Jounce's other product candidates, 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," "goal," "plan," "on track," "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, 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; actions of regulatory agencies, which may affect the initiation, timing and progress of 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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