



## Jounce Therapeutics Presents New Vopratelimab Predictive Biomarker Data Supporting Use in the Upcoming SELECT Trial at the 2020 ASCO-SITC Clinical Immuno-Oncology Symposium Annual Meeting and Announces Research Collaboration with NanoString Technologies

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- Identification of a predictive biomarker – based on an 18 gene RNA signature and vopratelimab-specific threshold (TIS<sup>vopra</sup>) – for the emergence of ICOS hi CD4 T cells that predicted clinical benefit in patients from the ICONIC trial -
- Research collaboration established with NanoString to implement biomarker-based patient selection in the Phase 2 SELECT clinical trial -
- SELECT clinical trial to be initiated in mid-2020 -

CAMBRIDGE, Mass., Feb. 06, 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 new data on the identification of the predictive biomarker to be used for patient selection in the SELECT clinical trial of vopratelimab (vopra), in addition to a research collaboration with NanoString (NASDAQ: NSTG). The new data introduces TIS<sup>vopra</sup>, a baseline RNA signature with a threshold optimized for the emergence of ICOS hi CD4 T cells, a vopratelimab pharmacodynamic biomarker not associated with PD-1 inhibitor therapy. When applied to ICONIC clinical data, TIS<sup>vopra</sup> predicted clinical outcomes from the ICONIC trial better than PD-L1 immunohistochemistry (IHC). These results are being presented today at the 2020 ASCO-SITC Clinical Immuno-Oncology Symposium Annual Meeting in Orlando, Florida.

"We are excited to announce these two new developments supporting our upcoming SELECT clinical trial of vopratelimab and our own PD-1 inhibitor. The new data presented today at ASCO-SITC reveal the identification of TIS<sup>vopra</sup> as a baseline predictive biomarker associated with the emergence of ICOS hi CD4 T cells. When applied to ICONIC clinical data, TIS<sup>vopra</sup> then predicted clinical benefit in patients who received vopratelimab alone or in combination with nivolumab. This, coupled with our new research collaboration with NanoString, reflects our commitment to patient selection strategies to identify those most likely to benefit from our novel immunotherapies," said Elizabeth Trehu, M.D., chief medical officer of Jounce Therapeutics. "The identification of TIS<sup>vopra</sup> is a crucial step forward in the development of vopratelimab, and we plan to initiate the Phase 2 SELECT trial using this biomarker in mid-2020."

Key highlights from the poster, titled "Association of a Predictive RNA Signature (RS) With Emergence of ICOS hi CD4 T Cells and Efficacy Outcomes for the ICOS Agonist Vopratelimab (vopra) and Nivolumab (nivo) in Patients (pts) on the ICONIC trial" include:

- TIS<sup>vopra</sup> is an 18 gene RNA Tumor Inflammation Signature (TIS), utilized with a vopratelimab-specific threshold and was identified as a biomarker predictive of ICOS hi CD4 T cell emergence. TIS<sup>vopra</sup> positive patients treated with vopratelimab alone or in combination with nivolumab also showed improved clinical benefit (response rate, six month and nine month landmark progressive free survival and overall survival) as compared with TIS<sup>vopra</sup> negative patients in the ICONIC trial.
- TIS includes genes associated with integral elements of CD4 T cell activation that may contribute to a more comprehensive immune response.
- The TIS<sup>vopra</sup> threshold was chosen to optimize prediction of ICOS hi CD4 T cell emergence and was more predictive of clinical benefit than PD-L1 IHC in the ICONIC trial.
- The emergence of ICOS hi CD4 T cells is a vopratelimab, but not a PD-1 inhibitor, pharmacodynamic biomarker linked to clinical benefit in the ICONIC trial.
- In the upcoming SELECT trial, TIS<sup>vopra</sup> will be used to select patients for treatment with vopratelimab and JTX-4014, Jounce's PD-1 inhibitor.

The poster is available in the "Our Pipeline" section of the Jounce Therapeutics website under "Publications" at [www.jouncetx.com](http://www.jouncetx.com).

Jounce also announced a research collaboration with NanoString to support the application of the predictive biomarker to be used in the SELECT trial. Under the terms of the collaboration, Jounce and NanoString will apply an optimized selection threshold of the TIS based on the emergence of ICOS hi CD4 T cells (TIS<sup>vopra</sup>). The TIS<sup>vopra</sup> clinical trial assay will be implemented on the nCounter<sup>®</sup> Dx Analysis System.

### About the Phase 2 SELECT Clinical Trial

The Phase 2 SELECT clinical trial is a randomized, ex-U.S. trial to evaluate the efficacy of JTX-4014 alone and in combination with vopratelimab. The trial is powered to show statistical superiority of vopratelimab plus JTX-4014 compared to JTX-4014 alone in a biomarker-selected patient population. Jounce expects to enroll approximately 75 immunotherapy naïve second-line non-small cell lung cancer (NSCLC) patients. Patients will be prescreened for the TIS<sup>vopra</sup> biomarker. Jounce estimates that approximately 20% of the prescreened NSCLC patients will be above the TIS<sup>vopra</sup> threshold and potentially eligible for the trial. Jounce expects to initiate the SELECT trial in mid-2020 and report preliminary efficacy and biomarker relationships to clinical outcomes from up to 75 patients in 2021.

### About Vopratelimab

Jounce's lead product candidate, 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 Phase

2 EMERGE clinical trial in a sequenced combination with ipilimumab in patients with NSCLC who were previously treated with PD-1/PD-L1 inhibitor therapies. Jounce is also planning to initiate the Phase 2 SELECT clinical trial of vopratelimab with its investigational PD-1 inhibitor, JTX-4014, in TIS<sup>vopra</sup> biomarker-selected patients. Vopratelimab was previously assessed in the Phase 1/2 ICONIC trial and was found to be safe and well-tolerated, alone and in combination with each of the anti-PD-1 antibodies nivolumab and pembrolizumab, as well as with ipilimumab, an antibody that binds to CTLA-4.

#### **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 has three development-stage programs, two of which are clinical-stage programs, vopratelimab, a monoclonal antibody that binds to and activates ICOS, and JTX-4014, a PD-1 inhibitor intended for potential combination use with Jounce's broader pipeline. Vopratelimab is currently being assessed in a Phase 2 clinical trial, and an additional trial to assess vopratelimab in combination with JTX-4014 is planned. Phase 1 data for JTX-4014 were reported in November 2019. The next development candidate to emerge from Jounce's Translational Science Platform is JTX-1811, a monoclonal antibody designed to deplete T regulatory cells in the tumor microenvironment. JTX-1811 is currently in IND-enabling activities. In addition, Jounce has exclusively licensed worldwide rights to JTX-8064, a LILRB2 receptor antagonist, to Celgene Corporation, a wholly-owned subsidiary of Bristol-Myers Squibb Company. For more information, please visit [www.jouncetx.com](http://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 and results of the EMERGE and SELECT 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 "expects," "plan," "potential" 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; the clinical results for its product candidates, which may not support further development and marketing approval; Jounce's ability to enroll patients in its clinical trials; the potential advantages of Jounce's product candidates; 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 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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