December 9, 2019

Atara Biotherapeutics Reports Updated Long-Term Clinical Results from a Tab-cel® Multicenter Expanded Access Protocol (EAP) Study for Patients with Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease (EBV+ PTLD) at the 61st American Society of Hematology (ASH) Annual Meeting

61 patients with diverse EBV-associated diseases, including 26 relapsed/refractory EBV+ PTLD patients were treated in a multicenter tab-cel® (tabelecleucel) EAP study

Tab-cel® was generally well-tolerated in all patients with EBV+ PTLD and other EBV-associated diseases

Estimated two-year overall survival rate in tab-cel® responders was 86 and 100 percent for patients with EBV+ PTLD following HCT and SOT, respectively, with median time to response of one month

Similar outcomes observed in subgroup of 22 patients with EBV+ PTLD who would have likely met eligibility criteria for Atara's ongoing tab-cel® Phase 3 studies

SOUTH SAN FRANCISCO, Calif., Dec. 09, 2019 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases, today presented long-term clinical results from a multicenter Expanded Access Protocol (EAP) study of tab-cel® (tabelecleucel) for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition in Orlando, Fla.

Results from this analysis demonstrate a high overall response rate (ORR), short time to response and favorable estimated long-term overall survival (OS) rates for tab-cel® in patients with EBV+ PTLD following hematopoietic cell transplant (HCT) or solid organ transplant (SOT) who have failed rituximab-based therapy. Tab-cel® was generally well-tolerated in all patients with EBV+ PTLD and other EBV-associated diseases.

"Patients undergoing allogeneic hematopoietic cell or solid organ transplants are at risk for developing EBV+ PTLD," said Sarah Nikiforow, M.D., Ph.D., Assistant Professor of

Medicine, Dana-Farber Cancer Institute. “Unfortunately, many patients who develop this often-aggressive lymphoma do not respond adequately to rituximab with or without chemotherapy. Data presented today demonstrate tab-cel® may provide an effective treatment option with a compelling benefit-risk profile for patients with EBV+ PTLD following HCT or SOT.”

Twenty-six EBV+ PTLD patients who failed prior rituximab treatment regimens were enrolled in EAP-201 as of June 2018, after which the study was amended (EAP-901, NCT02822495) to focus on expanded access for patients with EBV+ PTLD and other EBV+ diseases who are not eligible for Atara’s ongoing tab-cel® Phase 3 study (NCT03394365). The findings presented at the meeting are as of September 24, 2019.

In the EBV+ PTLD HCT and SOT cohorts, 92 and 63 percent of patients were intermediate/high risk according to the PTLD prognostic index[1], respectively.

Safety

Safety analyses were presented for all patients treated with tab-cel® (n=61; n=26 EBV+ PTLD and n=35 patients with other EBV-associated diseases). Consistent with prior studies, tab-cel® was generally well-tolerated in all patients, and no tab-cel® related adverse events leading to discontinuation occurred.

The most common treatment-emergent serious adverse events (TESAEs) reported in ≥ 5 percent of all patients were disease progression (16 percent), pyrexia (8 percent) and pneumonia (7 percent).

Three graft versus host disease (GvHD) adverse events were reported, all in patients with prior allogeneic HCT. No other adverse events of special interest including cytokine release syndrome were reported.

Efficacy

Median time to response of one month was seen in both EBV+ PTLD patient cohorts. In responders, two-year estimated overall survival rate was 86 percent for HCT (n=7) and 100 percent for SOT (n=10) with no patient deaths attributable to PTLD progression.

Similar outcomes were observed in the EAP-201 subgroup of EBV+ PTLD patients (n=22) with adequate ECOG performance status, no CNS disease and no PLTD-related ventilatory support who would have likely met the eligibility criteria for Atara’s ongoing tab-cel® Phase 3 studies. Overall response rate was 55 and 82 percent, with a two-year estimated overall survival of 79 and 81 percent, in the HCT (n=11) and SOT (n=11) cohorts, respectively.

“We have previously shown that EBV+ PTLD patients treated with tab-cel® resulted in high overall response rates and favorable long-term survival,” said AJ Joshi, MD, Senior Vice President and Chief Medical Officer of Atara Biotherapeutics. “The findings reported today are consistent with our previous observations, and we look forward to further clinical investigation with tab-cel® for the treatment of EBV+ PTLD and other ultra-rare EBV-associated diseases.”

Efficacy for EBV+ PTLD HCT Cohort

HCT cohort	All HCT (N=14)	Potential Ph3 subset[2] (N=11)	Responders (N=7)
ORR (investigator-assessed), n (%)	7 (50)	6 (55)	-
1-year OS, % (95% CI)	60 (29, 81)	79 (38, 94)	86 (33, 98)
2-year OS, % (95% CI)	60 (29, 81)	79 (38, 94)	86 (33, 98)

Efficacy for EBV+ PTLD SOT Cohort

SOT cohort	All SOT (N=12)	Potential Ph3 subset[2] (N=11)	Responders (N=10)
ORR (investigator-assessed), n (%)	10 (83)	9 (82)	-
1-year OS, % (95% CI)	83 (46, 95)	81 (42, 95)	100
2-year OS, % (95% CI)	83 (46, 95)	81 (42, 95)	100

Abstract/Presentation Details:

Abstract 4071: Long-Term Outcomes of Subjects with Epstein-Barr Virus-Driven Post-Transplant Lymphoproliferative Disorder (EBV+PTLD) Following Solid Organ (SOT) or Allogeneic Hematopoietic Cell Transplants (HCT) Treated with Tabelecleucel on an Expanded Access Program
Poster Presentation Date and Time: Monday, December 9, 6:00 - 8:00 p.m. EST
Session Title: 626. Aggressive Lymphoma (Diffuse Large B-Cell and Other Aggressive B-Cell Non-Hodgkin Lymphoma) – Results from Prospective Clinical Trials: Poster III
Location: Orange County Convention Center, Hall B
Authors: Susan Prockop, M.D.[1], Ran Reshef, M.D.[2], Donald E. Tsai, M.D., Ph.D.[3], Nancy Bunin, M.D.[4], Rolla Abu-Arja, M.D.[5], Kris Michael Mahadeo, M.D.[6], Wen-Kai Weng, M.D., Ph.D.[7], Koen Van Besien, M.D., Ph.D.[8], David Loeb, M.D., Ph.D.[9], Sunita Dwivedy Nasta, M.D.[10], Eneida R. Nemecek, M.D., M.B.A., M.S.[11], Minoti Hiremath, MBBS, Ph.D.[12], Susan Yue, M.D.[13], Yan Sun, Ph.D.[13], Willis H Navarro, M.D.[12] and Sarah Nikiforow, M.D., Ph.D.[14]
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References

[1]Choquet S *et al. Ann Hematol* 2007; 86:599–607

[2]Based on adequate ECOG performance status, no CNS disease, and no PTLD-related ventilatory support

About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. (@Atarabio) is a leading off-the-shelf, allogeneic T-cell

immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. Atara's technology platform leverages research collaborations with leading academic institutions with the Company's scientific, clinical, regulatory and manufacturing expertise. Atara's pipeline includes tab-cel® (tabelecleucel), which is in Phase 3 development for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) as well as in earlier stage development for other EBV-associated hematologic malignancies and solid tumors, including nasopharyngeal carcinoma (NPC); T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis; and next-generation chimeric antigen receptor T-cell (CAR T) immunotherapies. The company was founded in 2012 and is co-located in South San Francisco and Southern California. Our Southern California hub is anchored by the state-of-the-art Atara T-cell Operations and Manufacturing (ATOM) facility in Thousand Oaks, California. For additional information about the company, please visit atarabio.com.

Forward-Looking Statements

This press release contains or may imply "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For example, forward-looking statements include statements regarding: the potential effectiveness, impact and benefit-risk profile of tab-cel®; and the results from Atara's ongoing tab-cel® EAP study. These forward-looking statements are subject to risks and uncertainties, including those discussed in Atara Biotherapeutics' filings with the Securities and Exchange Commission (SEC), including in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings and in the documents incorporated by reference therein. Except as otherwise required by law, Atara Biotherapeutics disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or otherwise.

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