March 31, 2019

Atara Biotherapeutics Announces Collaborator Presentation of Positive Phase 1 Clinical Results for a Mesothelin-Targeted CAR T Immunotherapy in Patients with Advanced Mesothelioma

Memorial Sloan Kettering Cancer Center collaborators presented results that a regionally delivered mesothelin-targeted, autologous CAR T was well-tolerated and showed encouraging anti-tumor activity in combination with pembrolizumab, a PD-1 checkpoint inhibitor

Best overall response rate for a subset of 11 malignant pleural mesothelioma patients with minimum follow-up time of 3 months who also received pembrolizumab and lymphodepleting chemotherapy was 72% including 2 durable complete metabolic responses and 6 partial responses

Clinical findings presented in Advances in Novel Immunotherapeutics oral session at the American Association of Cancer Research (AACR) Annual Meeting 2019

SOUTH SAN FRANCISCO, Calif., March 31, 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 announced that the Company's collaborators at Memorial Sloan Kettering Cancer Center (MSK), Prasad S. Adusumilli, M.D., and Michel Sadelain, M.D., Ph.D., presented encouraging results from an ongoing MSK investigator-sponsored Phase 1 clinical study (NCT02414269) of a mesothelin-targeted CAR T immunotherapy for patients with mesothelin-associated malignant pleural solid tumors, primarily mesothelioma, who progressed following prior standard platinum-containing chemotherapy. Mesothelin-targeted, autologous CAR T cells delivered regionally were well-tolerated and showed encouraging anti-tumor activity in combination with pembrolizumab, a PD-1 checkpoint inhibitor. The findings will be presented today in the Advances in Novel Immunotherapeutics oral session at the American Association of Cancer Research (AACR) Annual Meeting 2019 in Atlanta, Georgia.

"Clinical results presented by our MSK collaborators reaffirm mesothelin as a promising target for patients with advanced mesothelioma and establish an important proof-of-concept advance for CAR T immunotherapy in solid tumors," said Dietmar Berger, M.D., Ph.D., Global Head of Research and Development of Atara Biotherapeutics. "These encouraging safety results and anti-tumor responses observed by lead investigator Dr. Adusumilli in combination with a PD-1 checkpoint inhibitor, support our plans to progress development of a next-generation, mesothelin-targeted CAR T immunotherapy using MSK's novel 1XX CAR signaling domain and PD-1 dominant negative receptor (DNR) checkpoint inhibition

technologies for patients with mesothelin-associated solid tumors."

The Phase 1 clinical study recruited 21 patients, 19 with malignant pleural mesothelioma (MPM), one with metastatic lung cancer and one with metastatic breast cancer, who received a median of 3 prior treatment regimens, to evaluate the safety and potential anti-tumor activity of a CD28-costimulated, mesothelin-targeted autologous CAR T immunotherapy. The study included six dose cohorts with administration directly to the tumor site using regional delivery techniques, initially at a low CAR T dose without lymphodepleting chemotherapy, followed by increasing CAR T dose cohorts with lymphodepletion. A subset of these patients was subsequently treated with pembrolizumab, a PD-1 checkpoint inhibitor.

Mesothelin-targeted, autologous CAR T administration was found to be generally well-tolerated with no CAR T-related toxicities higher than grade 2 observed based on monitoring multiple clinical, radiological, and laboratory parameters. CAR T cells were found to be persistent in the peripheral blood for 13 of the 21 patients during the 38-week evaluation, and their presence was associated with evidence of tumor regression on imaging studies.

Best overall response rate (ORR) for a subset of 11 MPM patients with minimum follow-up time of 3 months who also received pembrolizumab and lymphodepleting chemotherapy was 72% including 2 durable complete metabolic responses (CMR) on PET imaging and 6 partial responses (PR). Six of the 11 patients in this subset were programmed cell death ligand 1 (PD-L1) negative, defined as undetectable expression of PD-L1 in tumor cells by immunohistochemistry, with 4 of the 8 total responses observed in PD-L1 negative patients (1 CMR and 3 PR).

Following progression on standard platinum-containing chemotherapy, the expected ORR for patients with MPM treated with a checkpoint inhibitor is estimated between 5%-29% with one patient achieving a CR across multiple studies.[1-5]

MSK is also investigating mesothelin-targeted CAR T cells for patients with mesothelin-associated advanced breast cancer (NCT02792114). Additional results from these ongoing studies are expected to be presented at upcoming scientific congresses.

Presentation CT036: A Phase I clinical trial of malignant pleural disease treated with regionally delivered autologous mesothelin-targeted CAR T cells: Safety and efficacy
Session CTMS01: Advances in Novel Immunotherapeutics
Presentation Date and Time: Sunday, March 31, 2019 from 3:20 pm - 3:35 pm EDT
Location: Room A411 - Georgia World Congress Center
Authors: Prasad S. Adusumilli, Marjorie Zauderer, Valerie Rusch, Roisin O'Cearbhaill, Amy Zhu, Daniel Ngai, Erin McGee, Navin Chintala, John Messinger, Alain Vincent, Elizabeth Halton, Claudia Diamonte, John Pineda, Shanu Modi, Steve Solomon, David R Jones, Renier Brentjens, Isabelle Riviere, Michel Sadelain
Affiliations: Memorial Sloan Kettering Cancer Center

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 disorder (EBV+ PTLD) as well as 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 for cancer as well as targets in other therapeutic areas. 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.

References

[1]Vogelzang NJ, *et al.* Phase III study of pemetrexed in combination with cisplatin versus cisplatin alone in patients with malignant pleural mesothelioma. *J Clin Oncol.* 2003 Jul 15;21(14):2636-44.

[2]Maio M, *et al.* Tremelimumab as second-line or third-line treatment in relapsed malignant mesothelioma (DETERMINE): a multicentre, international, randomised, double-blind, placebo-controlled phase 2b trial. *Lancet Oncol.* 2017 Sep;18(9):1261-1273.

[3]Scherpereel A, *et al.* Nivolumab or nivolumab plus ipilimumab in patients with relapsed malignant pleural mesothelioma (IFCT-1501 MAPS2): a multicentre, open-label, randomised, non-comparative, phase 2 trial. Lancet Oncol. 2019 Feb;20(2):239-253.

[4]Alley EW, *et al.* Clinical safety and activity of pembrolizumab in patients with malignant pleural mesothelioma (KEYNOTE-028): preliminary results from a non-randomised, open-label, phase 1b trial. *Lancet Oncol.* 2017 May;18(5):623-630.

[5]Hassan R, *et al.* Avelumab in patients with previously treated mesothelioma: Updated phase 1b results from the JAVELIN Solid Tumor trial. Abstract 166, ASCO 2018.

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 applicability of results of MSK’s Phase 1 study to programs being developed by Atara; the status of mesothelin as a promising immunotherapy target; Atara’s ability to develop a next-generation, mesothelin-targeted CAR T immunotherapy using MSK’s novel 1XX CAR signaling domain and PD-1 DNR checkpoint inhibition technologies for patients with mesothelin-associated solid tumors. Because such statements deal with future events and are based on Atara Biotherapeutics' current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Biotherapeutics could differ materially from those described in or implied by the statements in this press release. 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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Source: Atara Biotherapeutics, Inc.