



Atreca Presents Initial Clinical Data from Phase 1b Trial of ATRC-101 in Select Advanced Solid Tumors

July 29, 2021

Completed dose escalation portion of Phase 1b trial; ATRC-101 was well-tolerated with no dose-limiting toxicities observed

Disease control associated with ATRC-101 target expression; preliminary biomarker data support the proposed mechanism of action (MOA) as elucidated in preclinical studies

Phase 1b monotherapy dose expansion ongoing; developing diagnostic to select patients based on target expression

Conference call and webinar scheduled for today at 8:00 a.m. ET

SAN CARLOS, Calif., July 29, 2021 (GLOBE NEWSWIRE) -- Atreca, Inc. (Atreca) (NASDAQ: BCEL), a clinical-stage biotechnology company focused on developing novel therapeutics generated through a unique discovery platform based on interrogation of the active human immune response, today announced initial data from the dose escalation portion of its ongoing Phase 1b trial evaluating ATRC-101 in select solid tumor types that displayed greater than 50% target expression in preclinical studies.

"We are pleased to present initial summary data from our first-in-human study of ATRC-101," said Jonathan Benjamin, M.D., Ph.D., Sr. Vice President, Clinical Research. "We are very encouraged by the results observed thus far in a relatively small set of heavily pre-treated participants. ATRC-101, which targets a novel tumor antigen and acts via a novel MOA in oncology, was well-tolerated at all doses evaluated in the study with no dose-limiting toxicities observed. Furthermore, disease control is associated with ATRC-101 target expression, and the preliminary biomarker analysis is consistent with the proposed MOA for ATRC-101. We anticipate reporting additional data from monotherapy dose expansion cohorts in the Phase 1b trial and from combination cohorts evaluating ATRC-101 with pembrolizumab in 2022, and initiating additional combination cohorts evaluating ATRC-101 with chemotherapy later this year."

"ATRC-101 represents a new approach in cancer research," said Dr. John Powderly, M.D., Founder and President of the Carolina BioOncology Institute. "While these data are from a limited number of treatment-refractory patients, I was pleased to see that ATRC-101 was well-tolerated and appears to have an informative biomarker. I look forward to continue investigating the potential of ATRC-101 in cancer patients."

ATRC-101 Phase 1b Study Design

The Phase 1b trial is a first-in-human, open-label study of ATRC-101 in patients with select solid tumor cancers, utilizing a 3+3 design for the dose escalation portion. Enrollment is limited to patients with tumor types reactive to ATRC-101 in more than 50% of historical patient samples evaluated preclinically, which includes non-small cell lung, breast, ovarian, and colorectal cancer, as well as acral melanoma. The objectives of the study are to characterize safety, determine a maximum tolerated or recommended dose for expansion, measure initial clinical activity, and characterize potential biomarkers of activity in tumors, plasma, and peripheral blood mononuclear cells (PBMC).

Initial Study Results

A total of 26 participants had been dosed in the trial as of the data cut-off date of July 16th, including 24 participants treated at five once-every-21-day (q21d) dose levels, 0.3 mg/kg (n = 3), 1 mg/kg (n = 3), 3 mg/kg (n = 9), 10 mg/kg (n = 6), and 30 mg/kg (n = 3), and two participants treated at one once-every-14-day (q14d) dose level, 1 mg/kg (n = 2). Tumor types enrolled in the q21d cohorts were colorectal (n = 13), ovarian (n = 5), breast (n = 3), non-small cell lung (n = 2) and acral melanoma (n = 1). Participants enrolled in the study had received a median of five prior lines of treatment. Of the 26 participants dosed, 24 participants treated with any dose of ATRC-101 were evaluable for safety, 19 for PK, 20 for clinical response, and 18 participants for target expression.

Pharmacokinetics (PK)

The peak concentration of ATRC-101 was dose proportional and minimal accumulation was observed following multiple doses. ATRC-101's half-life was 10.5 days and was relatively consistent across all dose levels.

Safety

ATRC-101 was generally well-tolerated, with no dose-limiting toxicities at doses \leq 30 mg/kg. Thirty-three percent of participants (n = 8) had at least one grade \geq 3 adverse event (AE). Respiratory failure (n = 2) and sepsis (n = 2) were the only grade \geq 3 AEs observed in more than one participant, and the one grade 4 treatment-emergent AE observed was a case of acute respiratory failure. The most common treatment-related AEs were fatigue (n = 5, 21%), nausea (n = 4, 17%), and tumor pain (n = 4, 17%).

Disease Efficacy Observations

Eight of the 20 participants (40%) evaluable prior to the data cut-off in this analysis experienced stable disease (SD) as their best RECIST response, including four with tumor reduction observed. The remaining 12 participants had progressive disease as their best RECIST response. Disease control observed in the study was associated with target expression, as 3 of 6 (50%) of participants with evaluable response assessments and baseline tumor

H-scores ≥ 50 achieved SD, compared with 1 of 9 (11%) evaluable participants with an H-score < 50 .

Biomarkers

Preliminary biomarker evaluation supports the proposed MOA of ATRC-101 initially proposed from preclinical studies. Expansion of peripheral blood CD8+ T cells was observed at day 8 following dosing with ATRC-101 among participants with evaluable baseline tumor biopsies and tumor H-scores ≥ 50 . Preliminary observations of serum cytokines appeared consistent with the proposed MOA of innate immune system activation leading to an adaptive immune response against tumor.

Next Steps

Phase 1b monotherapy dose expansion is ongoing at 30 mg/kg, a combination study evaluating ATRC-101 with pembrolizumab is active and another combination study with pegylated liposomal doxorubicin is expected to begin enrolling patients in 4Q21. Atreca expects to report additional monotherapy data by mid-2022, pembrolizumab combination data in mid-2022 and chemotherapy combination data in late 2022. Supported by data from the dose escalation portion of the trial, Atreca is developing a diagnostic to select patients based on target expression.

"We are very pleased with the results of the Phase 1b study presented today and look forward to the continued clinical development of ATRC-101 as both a monotherapy and in combination studies," said John Orwin, Chief Executive Officer of Atreca. "ATRC-101 is the first anti-cancer agent discovered via Atreca's platform to be tested in humans, and we believe that the activity observed in the trial provides a strong rationale for further investigation. Furthermore, we believe that these data provide validation for the ability of our discovery platform to identify novel, druggable tumor targets shared across groups of patients. We would like to thank all of the patients who enrolled, their families, and their caregivers for participating in this study."

ATRC-101 Conference Call and Webcast Information

Atreca will host a conference call/webcast today at 8:00 a.m. ET. The live webcast, including slides, can be accessed through the Events & Presentations section of the Company's website at <https://ir.atreca.com/news-and-events/event-calendar>. To access the conference call, please dial (800) 373-6606 (United States) or (409) 937-8918 (international) and reference the conference ID 2386207. An archived replay of the webcast will be available on the Company's website for 90 days following the live event.

About ATRC-101

ATRC-101 is a monoclonal antibody derived from an antibody identified using Atreca's discovery platform. ATRC-101 is believed to function through Driver Antigen Engagement, a novel mechanism of action in oncology. This mechanism involves systemic delivery of an antibody that, in preclinical models, engages the innate immune system to cause remodeling of the tumor microenvironment and drive T cell-mediated destruction of tumor cells. Atreca has identified the target of ATRC-101 as a tumor-specific ribonucleoprotein (RNP) complex. ATRC-101 has demonstrated robust anti-tumor activity as a single agent in multiple preclinical syngeneic tumor models, including one model in which PD-1 checkpoint inhibitors typically display limited activity. Further, ATRC-101 has been shown to react in vitro with a majority of human ovarian, non-small cell lung, colorectal, breast cancers and acral melanoma samples from multiple patients. Atreca initiated a Phase 1b first-in-human study of ATRC-101 in participants with select solid tumor cancers in early 2020. Clinical trials to evaluate ATRC-101 in combination with a PD-1 inhibitor and in combination with chemotherapy are planned for 2021, as well as in monotherapy dose expansion cohorts in the ongoing Phase 1b trial.

About Atreca, Inc.

Atreca is a biopharmaceutical company developing novel antibody-based immunotherapeutics generated by its differentiated discovery platform. Atreca's platform allows access to an unexplored landscape in oncology through the identification of unique antibody-target pairs generated by the human immune system during an active immune response against tumors. These antibodies provide the basis for first-in-class therapeutic candidates, such as our lead product candidate ATRC-101. A Phase 1b study evaluating ATRC-101 in multiple solid tumor cancers is currently enrolling participants. For more information on Atreca, please visit www.atreca.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and typically are identified by use of terms such as "continued," "anticipate," "potential," "expect," "believe," "planned," and similar words, although some forward-looking statements are expressed differently. These statements include those related to our strategy and future plans, including statements regarding the development of ATRC-101 and our preclinical, clinical and regulatory plans and the timing thereof, the availability and timing of data from monotherapy dose expansion cohorts in the Phase 1b trial and from combination cohorts evaluating ATRC-101 with pembrolizumab and with pegylated liposomal doxorubicin, initiating additional combination cohorts evaluating ATRC-101 with chemotherapy, trends consistent with the proposed MOA of innate immune system activation, and our development of a diagnostic to select patients based on target expression. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the initiation, timing, progress and results of our research and development programs, preclinical studies, clinical trials, regulatory submissions, and other matters that are described in our filings with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov, including in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of our most recently filed annual report on Form 10-K and quarterly report on Form 10-Q. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release, and we undertake no obligation to update any forward-looking statement in this press release, except as required by law.

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