Atreca Announces FDA Clearance of Investigational New Drug Application for ATRC-101

December 3, 2019

First IND clearance of a clinical candidate derived from Atreca's differentiated drug discovery platform

Phase 1b clinical trial in patients with solid tumors to begin in early 2020

REDWOOD CITY, Calif., Dec. 03, 2019 (GLOBE NEWSWIRE) -- Atreca, Inc. (Atreca) (NASDAQ: BCEL), a biotechnology company focused on the development of novel cancer therapeutics generated through a unique discovery platform based on interrogation of the active human immune response, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application. Atreca expects to initiate a first-in-human Phase 1b clinical trial of ATRC-101 in patients with solid tumors in early 2020.

"The FDA's clearance of our IND application for ATRC-101 is a significant milestone for Atreca and validates the ability of our differentiated drug discovery platform to generate novel clinical candidates against cancer," said John Orwin, Chief Executive Officer. "We believe that ATRC-101, with both its unique target and mechanism of action, represents an exciting approach in oncology, and we look forward to the initiation of our Phase 1b clinical trial in early 2020."

The Phase 1b trial will be an open-label, dose escalation, monotherapy trial with an adaptive 3+3 design and will enroll patients with a variety of solid tumor cancers, including ovarian, non-small cell lung, colorectal, breast and acral melanoma. The antigenic target of ATRC-101, a ribonucleoprotein complex, is expressed on over 50% of patient samples for each of these tumor types. Major objectives for the trial are to characterize the safety of ATRC-101 and determine a recommended dose for future studies. The trial will also evaluate potential biomarkers and the initial clinical activity of ATRC-101.

About ATRC-101
ATRC-101 is a monoclonal antibody derived from an antibody identified using Atreca's discovery platform. ATRC-101 functions through Driver Antigen Engagement, a novel mechanism of action in oncology. This mechanism involves systemic delivery of an antibody that has been shown in preclinical models to engage the innate immune system, 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 ribonucleoprotein (RNP) complex. Underlining the rationale for human testing, 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 cancer and acral melanoma samples from multiple patients.

About Atreca, Inc.
Atreca is a biopharmaceutical company developing novel antibody-based cancer 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 tumor. These antibodies provide the basis for first-in-class therapeutic candidates, such as ATRC-101, with the potential to address unmet need in large groups of cancer patients. The company expects to commence a Phase 1b study evaluating ATRC-101, its lead product candidate, in multiple solid tumor cancers in early 2020. For more information on Atreca, please visit www.atreca.com.

Forward-Looking Statements
This release contains forward-looking statements regarding our strategy and future plans, including statements regarding the development of ATRC-101 and our clinical and regulatory plans, and the timing thereof. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "will", "expect," "believe," "potential," "continue," and similar words, although some forward-looking statements are expressed differently. 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, any clinical trials and Investigational New Drug application and other regulatory submissions, and other matters that are described in our prospectus, dated June 19, 2019, as filed with the Securities and Exchange Commission (SEC) pursuant to Rule 424(b) under the Securities Act of 1933, as amended, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, which are available on the SEC's website at www.sec.gov, including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this 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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