eFFECTOR Therapeutics Announces Topline Results of Phase 2 KICKSTART Trial of Tomivosertib Combined with Pembrolizumab in Non-Small Cell Lung Cancer

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SOLANA BEACH, Calif. and REDWOOD CITY, Calif., April 04, 2024 (GLOBE NEWSWIRE) -- eFFECTOR Therapeutics, Inc. (NASDAQ: EFTR), a leader in the development of selective translation regulator inhibitors (STRIs) for the treatment of cancer, today announced topline results from the primary analysis of the randomized Phase 2 KICKSTART trial which tested tomivosertib or placebo, each combined with pembrolizumab, as frontline treatment for patients with non-small cell lung cancer (NSCLC) with PD-L1 ≥50%. Based on 36 events, the hazard ratio for progression free survival (PFS, the primary endpoint of the study) using a stratified Cox proportional hazards model was 0.62 (95% confidence intervals 0.3 to 1.3) in favor of tomivosertib. The two-sided p value for PFS, based on a stratified log rank test, was 0.21, which did not meet the pre-specified threshold of p≤0.2. The median PFS was 13.0 weeks in the tomivosertib plus pembrolizumab arm and 11.7 weeks in the placebo plus pembrolizumab arm, respectively. Overall survival results remain immature, however no trend favoring tomivosertib was observed. There were 67% Grade 3 or higher treatment emergent adverse events in the tomivosertib plus pembrolizumab arm versus 37% in the placebo plus pembrolizumab arm.

“While there was evidence of modest tomivosertib activity in the trial, based on the totality of the data currently available we do not see an obvious path forward to continue developing tomivosertib in frontline NSCLC,” said Steve Worland, Ph.D., president and chief executive officer of eFFECTOR. “We sincerely appreciate the contributions of all the patients, their families, and trial site professionals who contributed to the execution of the trial. We will continue to analyze trial data and hope to present our findings at a future medical conference.”

Dr. Worland continued: “While we’re disappointed that tomivosertib won’t be moving forward in frontline NSCLC, our strategy to maximize the value of all assets in our pipeline remains unchanged. Zotatifin, with its novel mechanism distinct from that of tomivosertib’s, is a drug candidate that is poised to enter a randomized, potentially registrational trial in estrogen receptor positive (ER+) breast cancer later this year. Our focus is now further sharpened towards advancing zotatifin through development as efficiently as possible, building on the recent positive updates of median PFS (mPFS) and safety data at last year’s San Antonio Breast Cancer Symposium (SABCS®). As a next step for the zotatifin program, we expect to report additional data, including the recommended phase 2 dose (RP2D), for zotatifin combined with fulvestrant and abemaciclib in the second half of 2024. In addition, as part of our strategy to leverage investigator-sponsored trials to conserve capital, a separate, investigator-sponsored trial of tomivosertib in acute myeloid leukemia (AML) will continue unchanged. The mechanistic rationale to test tomivosertib in AML is entirely distinct from the rationale in NSCLC and relies on tomivosertib’s potential to inhibit production of survival proteins Mcl-1 and Bcl-2, which are required for leukemia cell survival.”

About eFFECTOR Therapeutics

eFFECTOR is a clinical-stage biopharmaceutical company pioneering the development of a new class of oncology drugs referred to as STRIs. eFFECTOR’s STRI product candidates target the eIF4F complex and its activating kinase, mitogen-activated protein kinase interacting kinase (MNK). The eIF4F complex is a central node where two of the most frequently mutated signaling pathways in cancer, the PI3K-AKT and RAS-MEK pathways, converge to activate the translation of select mRNA into proteins that are frequent culprits in key disease-driving processes. Each of eFFECTOR’s product candidates is designed to act on a single protein that drives the expression of a network of functionally related proteins, including oncoproteins and immunosuppressive proteins in T cells, that together control tumor growth, survival and immune evasion. Zotatifin, eFFECTOR’s inhibitor of eIF4A, is currently being evaluated in a Phase 2a expansion cohort in combination with fulvestrant and abemaciclib in ER+ breast cancer. Tomivosertib, eFFECTOR’s MNK inhibitor, is currently being evaluated in an investigator-sponsored trial in AML. eFFECTOR has a global collaboration with Pfizer to develop inhibitors of a third target, eIF4E.

Forward-Looking Statements

eFFECTOR cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to: the potential therapeutic benefits of our product candidates; our plans to focus our development efforts on, and advance the development of, zotatifin in ER+ breast cancer, including the potential for additional data, determination of an RP2D and to enter a registrational trial, the timing thereof; our expectations for the continuation of the investigator initiated study of tomivosertib in AML; our strategy to maximize the value of all assets in our pipeline; and our plans regarding the presentation of data findings at a future medical conference. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: interim results previously reported for the zotatifin clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data and as more patient data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; topline results that we report is based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; we may be unable to identify a path forward for zotatifin or tomivosertib based on our limited capital resources, which we may use sooner than expected and may be insufficient to allow clinical trial readouts or further clinical development or for us to continue our operations; our lender may seek to declare a default under our loan and security agreement to the extent that a material adverse change in our business is deemed to have occurred or otherwise and accelerate immediate repayment of all outstanding obligations under our loan agreement; our dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; the success of our clinical trials and preclinical studies for our product candidates is uncertain; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; and other risks described in our prior filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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