Erasca Announces FDA Clearance of IND Application for ERAS-801 in Glioblastoma Multiforme and Collaboration with GCAR for Potential Inclusion in GBM AGILE Clinical Trial

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IND filing achieved ahead of schedule; dosing of first patient in THUNDERBBOLT-1 Phase 1 clinical trial in recurrent GBM anticipated in Q1 2022

Early collaboration with GCAR could support potential registrational path in GBM

ERAS-801 is a highly CNS-penetrant EGFR inhibitor with broad activity against oncogenic EGFR variants

SAN DIEGO, Dec. 17, 2021 (GLOBE NEWSWIRE) -- Erasca, Inc. (Nasdaq: ERAS), a clinical-stage precision oncology company singularly focused on discovering, developing, and commercializing therapies for patients with RAS/MAPK pathway-driven cancers, today announced the United States Food and Drug Administration (FDA) has cleared an investigational new drug (IND) application for ERAS-801, an orally available small molecule epidermal growth factor receptor (EGFR) inhibitor specifically designed to have high central nervous system (CNS) penetration for the treatment of recurrent glioblastoma multiforme (rGBM). The company has also entered into a collaboration with the Global Coalition for Adaptive Research (GCAR) to determine the feasibility of the evaluation of ERAS-801 as part of the Glioblastoma Adaptive Global Innovative Learning Environment (GBM AGILE) trial.

"We are pleased with the pace at which our ERAS-801 program is advancing. Filing this IND a quarter ahead of schedule and receiving FDA clearance allows us to begin potentially helping patients sooner," said Jonathan E. Lim, M.D., Erasca's chairman, CEO, and co-founder. "GBM is a rapid and aggressive malignancy for which patients have limited treatment options and a median overall survival of 17 months after diagnosis. Aberrant EGFR signaling is implicated in approximately 125,000 patients with GBM worldwide annually. ERAS-801's profile of strong CNS penetrance and broad activity against EGFR amplifications driven by both oncogenic EGFR variants and wildtype EGFR has the potential to address significant unmet need in this patient population. We look forward to initiating our THUNDERBBOLT-1 Phase 1 trial evaluating ERAS-801 in patients with recurrent GBM in the first quarter of 2022."

Dr. Lim continued, "We are honored to enter into an early collaboration with GCAR, a leading nonprofit sponsoring the innovative GBM AGILE trial, which uses a streamlined, patient-centric approach to identify and advance the most effective treatment options for GBM more rapidly. GBM AGILE, an adaptive clinical trial that evaluates multiple drugs against a common comparator, is a seamless, international Phase 2/3 trial that we believe supports a clear registrational path in the United States and other key markets. Our early involvement with GCAR and the GBM Knowledge Network made up of industry leaders further reinforces the therapeutic promise of ERAS-801. We look forward to working together with GCAR and the GBM AGILE team to explore the robust potential of ERAS-801 in patients with GBM who are in much need of better treatment options."

ERAS-801 was designed and developed by a renowned team of cancer researchers—David Nathanson, Ph.D., Michael Jung, Ph.D., and Timothy Cloughesy, M.D. ERAS-801 was licensed from Katmai Pharmaceuticals, Inc.

About GBM AGILE
GBM AGILE is an international, innovative, long-standing platform trial designed to identify and advance effective therapies more rapidly through response adaptive randomization, data connectivity, and a seamless Phase 2/3 design. Conducted under a master protocol, the trial design allows simultaneous evaluation of multiple candidates as monotherapy or in combination against common controls. The operational infrastructure enables a more efficient and expedited approach to testing new therapies for GBM with the intent of lowering the cost, time, and number of patients required to evaluate potentially effective therapies. Data from the GBM AGILE trial has the potential to be used as the foundation for a new drug application (NDA) with the FDA and/or any comparable submission with other health authorities.

About ERAS-801
ERAS-801 is a highly potent, selective, reversible, and orally available small molecule EGFR inhibitor with significantly enhanced CNS penetration. In animal models, ERAS-801 had a 3.7:1 brain-to-plasma ratio and a $K_{p,uu}$ (partition coefficient that measures unbound drug concentration) that was up to four times higher than approved EGFR inhibitors, indicating a higher concentration of unbound drug in the brain compared to the blood. At clinically relevant exposures, ERAS-801 demonstrated a survival benefit in nine out of 10 (90%) EGFR amplified glioblastoma patient-derived models tested and had statistically significantly higher brain penetrance and prolonged survival compared to approved EGFR tyrosine kinase inhibitors.

About THUNDERBBOLT-1
THUNDERBBOLT-1 will evaluate the safety, tolerability, and preliminary efficacy of ERAS-801 as a monotherapy in patients with recurrent GBM. The dose escalation portion will determine the recommended dose, which will then be used during the dose expansion portion to further evaluate the efficacy and safety of ERAS-801. Future sub-studies of THUNDERBBOLT-1 will potentially explore ERAS-801 in combination with other agents and in broader patient types. Dosing of the first patient in THUNDERBBOLT-1 is anticipated in the first quarter of 2022.

About Erasca
At Erasca, our name is our mission: To erase cancer. We are a clinical-stage precision oncology company singularly focused on discovering, developing, and commercializing therapies for patients with RAS/MAPK pathway-driven cancers. Our company was co-founded by leading pioneers in precision oncology and RAS targeting to create novel therapies and combination regimens designed to comprehensively shut down the RAS/MAPK pathway for the treatment of cancer. We have assembled what we believe to be the deepest RAS/MAPK pathway-focused pipeline in the industry. We believe our team's capabilities and experience, further guided by our scientific advisory board which includes the world's leading experts in the RAS/MAPK pathway, uniquely position us to achieve our bold mission of erasing cancer.

Cautionary Note Regarding Forward-Looking Statements

Erasca 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: our expectations regarding the potential therapeutic benefits of our product candidates and the potential patient populations for our product candidates, including ERAS-801; the planned advancement of our development pipeline, including the development plan and anticipated date of the dosing of the first patient in the THUNDERBBOLT-1 clinical trial; and statements related to the anticipated benefits from our early collaboration with GCAR regarding the potential to evaluate ERAS-801 as part of the GBM AGILE trial. 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: our approach to the discovery and development of product candidates based on our singular focus on shutting down the RAS/MAPK pathway, a novel and unproven approach; delays in our preclinical and clinical development programs; our dependence on third parties to conduct manufacturing, research, and preclinical and clinical testing; 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; unfavorable results from preclinical studies or clinical trials; results from preclinical studies or early clinical trials not necessarily being predictive of future results; regulatory developments in the United States and foreign countries; our ability to obtain and maintain intellectual property protection for our product candidates and maintain our rights under intellectual property licenses; our ability to fund our operating plans with our current cash, cash equivalents, and investments; our ability to maintain undisrupted business operations due to the COVID-19 pandemic; and other risks described in our prior filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our quarterly report on Form 10-Q for the three months ended June 30, 2021, and any subsequent filings with the SEC. 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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