Erasca Granted FDA Fast Track Designation for CNS-Penetrant EGFR Inhibitor ERAS-801 in Patients with Glioblastoma

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ERAS-801 has demonstrated broad preclinical activity against oncogenic EGFR variants and wildtype alterations

Initial THUNDERBBOLT-1 Phase 1 data in patients with recurrent GBM expected in H2 2023

SAN DIEGO, May 01, 2023 (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 granted Fast Track Designation (FTD) to ERAS-801 for the treatment of adult patients with glioblastoma (GBM) with epidermal growth factor receptor (EGFR) gene alterations. ERAS-801 is an orally bioavailable, small molecule EGFR inhibitor that exhibited substantial central nervous system (CNS) penetration in animal studies.

FTD is designed to help drugs reach patients faster by facilitating the development and expediting the review of drugs with the potential to fill an unmet medical need by treating a serious or life-threatening condition. Programs that receive FTD benefit from early and frequent interactions with the FDA during the clinical development process and, if relevant criteria are met, the FDA may consider reviewing portions of a marketing application before the sponsor submits the complete application.

“Receiving FTD from the FDA underscores the serious unmet medical need in patients with GBM and reinforces the promise that ERAS-801 may offer as a differentiated treatment option,” said Jonathan E. Lim, M.D., Erasca’s chairman, CEO, and co-founder. “GBM is an aggressive malignancy with high rates of relapse and a five-year survival rate below 10%. While over half of GBM cases are driven by EGFR alterations and/or amplifications, there are no approved EGFR inhibitors for the treatment of GBM due to the lack of sufficient brain penetration to treat primary brain tumors as well as lack of activity against EGFR alterations observed in GBM, such as EGFRvIII. To help overcome these limitations, ERAS-801 was specifically designed to have high CNS penetration and broad activity against both oncogenic and wildtype EGFR. We look forward to working closely with the FDA to expedite clinical development of ERAS-801 for these patients and anticipate reporting initial monotherapy data from the Phase 1 THUNDERBBOLT-1 trial in recurrent GBM (rGBM) in the second half of 2023.”

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

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 brain-to-plasma partition coefficient, K_p, of 3.7 and a corresponding unbound partition coefficient, $K_{p,uu}$, of 1.2, which was up to four times higher than approved EGFR inhibitors, suggesting that approximately 100% of the free drug in plasma is able to cross the blood-brain barrier (BBB). At clinically relevant exposures across 30 patient-derived GBM models that are intended to represent the heterogeneity of GBM, ERAS-801 demonstrated a survival benefit in 13 out of 14 (93%) EGFR mutant and/or amplified models and had statistically significantly higher brain penetrance and prolonged survival compared to approved EGFR tyrosine kinase inhibitors, including osimertinib, lapatinib, and erlotinib. ERAS-801 is currently being evaluated as a monotherapy in THUNDERBBOLT-1, an ongoing Phase 1 trial in patients with rGBM.

About THUNDERBBOLT-1
THUNDERBBOLT-1 is evaluating the safety, tolerability, and preliminary efficacy of ERAS-801 as a monotherapy in patients with rGBM. 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 may potentially explore ERAS-801 in combination with other agents and in broader patient types. Initial Phase 1 data from THUNDERBBOLT-1 are anticipated in the second half of 2023.

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; our ability to realize the benefits from ERAS-801 receiving FTD from the FDA; and the planned advancement of our development pipeline, including the development plan and anticipated timing of data readouts for the THUNDERBBOLT-1 clinical 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; the inability to realize any benefits from our current licenses, collaborations, or acquisitions and any future licenses, collaborations, or acquisitions, and our ability to fulfill our obligations under such arrangements; regulatory developments in the United States and foreign countries; our dependence on third parties in connection with our existing collaboration and supply agreements; 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 marketable securities; our ability to maintain undisrupted business operations due to the COVID-19 pandemic and global geopolitical events, such as the ongoing conflict between Russia and Ukraine; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may adversely affect our business, financial condition and stock price, and the broader economy and biotechnology industry; we may use our capital resources sooner than we expect; and other risks described in our prior filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our annual report on Form 10-K for the year ended December 31, 2022, 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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Source: Erasca, Inc.

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