Erasca Granted FDA Orphan Drug Designation for CNS-Penetrant EGFR Inhibitor ERAS-801 for the Treatment of Malignant Glioma

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ERAS-801 has now received ODD in addition to FDA Fast Track Designation

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

SAN DIEGO, June 22, 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 Orphan Drug Designation (ODD) to ERAS-801 for the treatment of malignant glioma, which includes glioblastoma (GBM). ERAS-801 is an orally bioavailable, small molecule EGFR inhibitor that exhibited substantial central nervous system (CNS) penetration in preclinical animal studies.

Per FDA regulations, ODD is granted by the FDA to investigational therapies addressing rare medical diseases or conditions affecting less than 200,000 people in the United States. Orphan drug status provides benefits to drug developers, including assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees, and the potential for seven years of post-approval marketing exclusivity.

"GBM is an aggressive malignancy afflicting approximately 37,000 patients annually in the United States and Europe. Currently approved EGFR inhibitors are limited by insufficient CNS penetration to treat GBM and minimal activity against GBM-specific EGFR amplifications, mutations, and other molecular alterations, which contribute to high rates of relapse and a five-year survival rate below 10%," said Jonathan E. Lim, M.D., Erasca's chairman, CEO, and co-founder. "Receiving ODD recognizes both the importance of innovation for patients with GBM and the therapeutic potential of ERAS-801 to provide a targeted treatment option for these patients, who have a poor prognosis. This ODD follows the earlier Fast Track Designation granted to ERAS-801 by the FDA and underscores the urgency of finding new treatments for this patient population. The broad activity against both oncogenic and wildtype EGFR, high CNS penetration, and demonstrated ability to improve outcomes in over 90% of diverse EGFR-driven patient-derived glioma models support the potential for ERAS-801 to overcome current challenges with existing therapies. We anticipate reporting initial monotherapy data for ERAS-801 from the Phase 1 THUNDERBBOLT-1 trial in patients with recurrent GBM 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 bioavailable 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 were 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 recurrent GBM (rGBM). In April 2023, the FDA granted Fast Track Designation (FTD) to ERAS-801 for the treatment of adult patients with GBM with EGFR gene alterations. In June 2023, the FDA granted ODD to ERAS-801 for the treatment of malignant glioma, which includes glioblastoma.

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 and/or ODD 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; 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; 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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