Erasca Announces FDA Clearance of IND Application for CNS-Penetrant KRAS G12C Inhibitor ERAS-3490 in KRAS G12C-Mutated Advanced or Metastatic Solid Tumors

December 13, 2022

ERAS-3490, an orally available small molecule KRAS G12C inhibitor, has demonstrated robust nonclinical CNS and systemic activity

SAN DIEGO, Dec. 13, 2022 (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-3490, an orally available small molecule KRAS G12C inhibitor designed to have high central nervous system (CNS) penetration for the treatment of KRAS G12C-mutated solid tumors, including non-small cell lung cancer (NSCLC).

“KRAS G12C is a prevalent oncogenic mutation that was historically considered undruggable. While first generation inhibitors have made great progress against this mutation, we believe that they do not sufficiently penetrate the blood-brain barrier which can lead to poor disease control, particularly in NSCLC, where up to 40% of patients may develop CNS metastases,” said Jonathan E. Lim, M.D., Erasca’s chairman, CEO, and co-founder. “ERAS-3490, our first homegrown development candidate, was selected for its robust CNS and systemic activity. We are pleased the FDA has cleared our IND for ERAS-3490.”

In April, Erasca presented nonclinical data for ERAS-3490 at the American Association for Cancer Research (AACR) Annual Meeting showing robust anti-tumor activity in KRAS G12C mutant MIA PaCa-2, NCI-H1373, and NCI-H2122 CDX subcutaneous models. ERAS-3490 also demonstrated robust anti-tumor activity and dose-dependent survival benefit in the KRAS G12C NSCLC intracranial model NCI-H1373-luc, a nonclinical model of NSCLC CNS metastases.

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 development programs, including ERAS-3490; our beliefs regarding market sizes and opportunities; and the planned advancement of our development pipeline. 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 in connection with 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 and acquisitions and any future licenses, acquisitions, or collaborations, and our ability to fulfill our obligations under such arrangements; 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 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 having serious adverse consequences on our business, financial condition and stock price; 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, 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.

Contact:
Joyce Allaire
LifeSci Advisors, LLC
jallaire@lifesciadvisors.com

Source: Erasca, Inc.

Source: Erasca, Inc.