Erasca Announces IND Clearance for Potential First-in-Class and Best-in-Class Pan-KRAS Inhibitor ERAS-4001

06.02.2025

Both ERAS-4001 and potential best-in-class pan-RAS molecular glue ERAS-0015 received IND clearance in May ahead of company guidance

Initial Phase 1 monotherapy data for both RAS-targeting programs expected in 2026

SAN DIEGO, June 02, 2025 (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 clearance of an investigational new drug (IND) application by the United States Food and Drug Administration (FDA) for ERAS-4001, a potential first-in-class and best-in-class pan-KRAS inhibitor, for the treatment of patients with KRAS-mutant (KRASm) solid tumors.

“Our RAS-targeting franchise continues to meaningfully advance, and now with clearance of our IND for ERAS-4001, we are excited to advance both ERAS-4001 and ERAS-0015 into the clinic ahead of our guidance,” said Jonathan E. Lim, M.D., Erasca’s chairman, CEO, and co-founder. “ERAS-4001 targets multiple KRAS mutations as well as wildtype KRAS but spares HRAS and NRAS, potentially enabling a better therapeutic window relative to pan-RAS inhibitors. We believe these attributes offer a differentiated approach that can overcome treatment resistance to pan-RAS and mutant-selective KRAS inhibitors and address unmet needs for the 2.2 million people diagnosed annually worldwide with KRASm tumors. We look forward to continued efficient execution across our RAS-targeting programs and anticipate disclosing initial monotherapy data in 2026.”

The BOREALIS-1 Phase 1 trial will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of ERAS-4001 in patients with KRASm solid tumors. Erasca is also advancing ERAS-0015, a potential best-in-class pan-RAS molecular glue, which is being evaluated in the AURORAS-1 Phase 1 trial for the treatment of patients with RAS-mutant solid tumors.

About ERAS-0015
ERAS-0015 is an oral, highly potent pan-RAS molecular glue that is designed to inhibit RAS signaling with a potential best-in-class profile. In preclinical studies, ERAS-0015 demonstrated approximately 8-21 times higher binding affinity to cyclophilin A (CypA) versus the most-advanced pan-RAS molecular glue in development, approximately 5 times greater potency in RAS inhibition, and greater in vivo antitumor activity evidenced by achieving comparable or greater tumor growth inhibition or regression at doses that are as low as approximately one-tenth the dose of the most-advanced pan-RAS molecular glue. ERAS-0015 is also designed to prevent resistance against mutant-selective inhibitors through inhibition of RAS wildtype variants. In addition, ERAS-0015 has demonstrated favorable absorption, distribution, metabolism, and excretion (ADME) and pharmacokinetic (PK) properties in multiple animal species. Erasca is evaluating ERAS-0015 in the AURORAS-1 Phase 1 trial in patients with RAS-mutant solid tumors.

About ERAS-4001
ERAS-4001 is an oral, highly potent, and selective pan-KRAS inhibitor with a potential first-in-class and best-in-class profile. ERAS-4001 demonstrated good preclinical in vitro potency against KRAS G12X mutations, as well as KRAS wildtype amplifications, which may limit treatment resistance mediated through KRAS wildtype activation. No activity was observed for ERAS-4001 against HRAS or NRAS wildtype proteins, which may enable a better therapeutic window compared to pan-RAS inhibitors. It showed potent activity against both GTP-bound (active state) and GDP-bound (inactive state) KRAS with single digit nanomolar IC50s. In vivo, ERAS-4001 induced tumor regression in multiple KRASm models. In preclinical studies, ERAS-4001 showed encouraging absorption, distribution, metabolism, and excretion (ADME) and pharmacokinetic (PK) properties. Erasca is evaluating ERAS-4001 in the BOREALIS-1 Phase 1 trial in patients with KRAS-mutant solid tumors.

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 patients with cancer. 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, including ERAS-0015 and ERAS-4001; the planned advancement of our development pipeline, including the anticipated timing of data readouts for the AURORAS-1 and BOREALIS-1 trials; and our ability to successfully prioritize our pipeline portfolio to focus on existing programs that we believe have the highest probability of success. 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; our assumptions about the development potential of ERAS-0015 and ERAS-4001 are based in large part on the preclinical data generated by the licensors and we may observe materially and adversely different results as we conduct our planned studies and trials; results from preclinical studies or early clinical trials not necessarily being predictive of future results; our assumptions around which programs may have a higher probability of success may not be accurate, and we may expend our limited resources to pursue a particular product candidate and/or indication and fail to capitalize on product candidates or indications with greater development or commercial potential; potential delays in the commencement, enrollment, data readout, and completion of clinical trials and preclinical studies; 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; we may be unable to secure partnerships or other strategic collaborations for naporafenib on acceptable terms or at all; the inability to realize any benefits from our current licenses, acquisitions, and collaborations, 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; the sufficiency of our cash, cash equivalents, and marketable securities to fund operations; 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, 2024, 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.