# Erasca Granted FDA Fast Track Designation for Pan-RAS Molecular Glue ERAS-0015 in Patients with Metastatic Pancreatic Adenocarcinoma

08.24.2026

*Designation follows encouraging Phase 1 activity across multiple tumor types including 2L+ KRAS G12X pancreatic cancer*

*Three potentially registration-enabling trials planned across pancreatic and lung cancers*

*Additional Phase 1 monotherapy and combination data expected in H1 2027*

SAN DIEGO, Aug. 24, 2026 (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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) to ERAS-0015 for the treatment of patients with metastatic pancreatic adenocarcinoma. ERAS-0015 is an oral, highly potent pan-RAS molecular glue designed to inhibit RAS signaling with a potential best-in-class profile.

"Receiving FTD is an important milestone for ERAS-0015 and reflects the urgent need for new therapies for patients with metastatic pancreatic cancer," said Jonathan E. Lim, M.D., Erasca's chairman, CEO, and co-founder. "Together with the encouraging clinical activity and favorable tolerability observed to date, this FTD helps to position us to rapidly advance the clinical development of ERAS-0015, including working closely with FDA on a planned Phase 3 trial in pancreatic cancer, alongside two additional potentially pivotal trials in lung cancer. We look forward to reporting additional monotherapy and combination data in the first half of 2027."

FTD is intended to facilitate development and expedite the review of therapies for serious conditions with unmet medical needs. Designated programs may benefit from more frequent interactions with the FDA and, if relevant criteria are met, may be eligible for benefits such as accelerated approval, priority review, and rolling review.

In July 2026, Erasca reported updated preliminary data from the AURORAS-1 Phase 1 trial in the U.S. demonstrating encouraging clinical activity, including a 57% $uORR_{8wk}$ in patients with second-line or later (2L+) KRAS G12X pancreatic ductal adenocarcinoma (PDAC) receiving ERAS-0015 monotherapy at the recommended dose for expansion (RDE) of 32 mg once daily.[1] All responding patients across doses remained on treatment as of the data cutoff, and ERAS-0015 continued to demonstrate favorable tolerability.[2] Additional data from the monotherapy expansion and combination dose escalation cohorts, including the panitumumab combination, are expected in the first half of 2027.

[1] The $uORR_{8wk}$ is the overall response rate (ORR) (confirmed and unconfirmed responses) for patients who received first dose of ERAS-0015 at least 8 weeks prior to the May 25, 2026 data cut off.
[2] May 25, 2026 data cut off

**About ERAS-0015**
ERAS-0015 is an investigational, oral, highly potent pan-RAS molecular glue designed to inhibit RAS signaling with a potential best-in-class profile. Erasca is evaluating ERAS-0015 in the AURORAS-1 Phase 1 trial in patients with RAS-mutant solid tumors. Early dose escalation data in AURORAS-1 demonstrated favorable safety and tolerability results, well-behaved, linear PK, and confirmed and unconfirmed partial responses in multiple patients across multiple tumor types with different RAS mutations, including confirmed partial responses at doses as low as 8 mg once daily (QD). 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.

**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: FTD may not result in a more expedited development or regulatory review process, and such a designation does not increase the likelihood that ERAS-0015 will receive marketing approval in the United States; FTD does not change the standards for regulatory approval; the FDA may later decide that ERAS-0015 no longer meets the conditions for FTD qualification or decide that the time period for FDA review or approval will not be shortened; whether FTD helps to position us to rapidly advance the clinical development of ERAS-0015, including our plan to initiate a Phase 3 trial in pancreatic cancer, and two potentially registration-enabling trials in lung cancer; our expectations regarding the potential therapeutic benefits of our product candidates, including ERAS-0015; and the planned advancement of our development pipeline, including the anticipated timing of data readouts for the AURORAS-1 trial, and the initiation of the clinical trials of ERAS-0015 described in this press release; our expectations that our planned clinical trials will serve as registrational-enabling studies; characterizations of the clinical profile of ERAS-0015; and the potential for ERAS-0015 to be best-in-class. 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: the timing of our clinical data readouts, including for the AURORAS-1 trial may be delayed; our product candidates, including ERAS-0015, may not

demonstrate therapeutic benefits that we expect; interim, topline and preliminary results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data and as more patient data becomes available, including the risk that an unconfirmed partial response to treatment may not ultimately result in a confirmed partial response to treatment after follow-up evaluations; observations regarding the first dosage level at which a clinical response is detected are based on data generated within an individual clinical trial, and comparisons of clinical observations across different trials involve data from separate trials with distinct designs, patient populations, and methodologies, and therefore may not be directly comparable; 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; results from preclinical studies 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; our planned potentially registration-enabling trials may be delayed based on FDA feedback or requirements, as the FDA retains broad discretion to require additional clinical data prior to the conduct of a registrational trial or submission for regulatory approval; even if our planned trials are successful, they may not support regulatory approval; unfavorable results from preclinical studies or clinical trials; 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, including our ability to successfully defend against allegations raised by, or any litigation initiated by, Revolution Medicines (RevMed) that ERAS-0015 infringes patents held by RevMed or was derived from RevMed trade secrets; 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, 2025, 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

**Media Contact:**
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Source: Erasca, Inc.