# Erasca Presents Promising Preliminary Phase 1/1b Monotherapy Data for ERAS-007 ERK and ERAS-601 SHP2 Inhibitors Supporting Ongoing and Future Combination Trials

September 7, 2022

*23% (6/26) of patients with RAS/MAPK-altered non-CRC solid tumors and 44% (4/9) with BRAF-driven non-CRC solid tumors responded (confirmed and unconfirmed PR) to single agent ERAS-007 or ERAS-601*

*ERAS-007 and ERAS-601 had favorable safety and tolerability profiles with largely non-overlapping treatment-related adverse events that support combination development*

*Initiation of ERAS-007 plus ERAS-601 MAPKlamp trial in RAS/MAPK-altered, including BRAF-driven, solid tumors anticipated to begin in first half of 2023*

*Erasca to host R&D Day today at 4:30 pm ET*

SAN DIEGO, Sept. 07, 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 promising preliminary Phase 1/1b monotherapy data for ERK1/2 inhibitor ERAS-007 and SHP2 inhibitor ERAS-601 in BRAF-driven and RAS/MAPK-altered solid tumors.

A retrospective pooled analysis of all trials evaluating ERAS-007 or ERAS-601 in advanced solid tumors was performed that included Erasca's ongoing HERKULES-1 and FLAGSHP-1 trials and Asana BioSciences' previously completed ASN007-101 trial. The analysis was designed to identify responsive subsets that were particularly sensitive to ERAS-007 or ERAS-601 for prioritized combination development within indications of high unmet medical need where no approved targeted therapies are available. Patients with solid tumors with RAS/MAPK alterations were segmented into two groups based on differing levels of responsiveness to monotherapy inhibition and differences in RAS/MAPK pathway reactivation: (1) patients with colorectal cancer (CRC) and (2) patients with non-CRC.

"Worldwide, an estimated 5.5 million lives are at stake annually due to RAS/MAPK pathway alterations, with over 70% of unmet needs lacking approved targeted therapies. We believe the promising single agent responses and favorable safety and tolerability profiles for ERAS-007 and ERAS-601 in patient subsets are highly encouraging and further support our prioritized combination development strategy," said Jonathan E. Lim, M.D., Erasca's chairman, CEO, and co-founder. "These early data suggest combining ERAS-007 with the cell cycle inhibitor palbociclib may synergistically achieve tumor cell killing and overcome compensatory responses to RAS/MAPK inhibition in RAS mutant CRC, which represents half of all patients with CRC, and KRAS mutant pancreatic cancer, which accounts for over 90% of patients with pancreatic cancer. Moreover, these preliminary efficacy signals heighten our conviction regarding the therapeutic potential of our first MAPKlamp, combining ERAS-007 with ERAS-601 in specific patient populations with RAS/MAPK alterations such as certain BRAF-driven malignancies. We anticipate initiating a dose escalation trial for ERAS-007 in combination with ERAS-601 in the first half of 2023."

Key findings from the retrospective pooled interim analysis of ERAS-007 and ERAS-601 include*:

- 23% (6/26) of patients with RAS/MAPK-altered non-CRC solid tumors responded (2 confirmed and 4 unconfirmed PRs) to single agent ERAS-007 or ERAS-601
- 44% (4/9) with a subset of BRAF-driven non-CRC solid tumors responded (1 confirmed and 3 unconfirmed PRs) to single agent ERAS-007 or ERAS-601
- ERAS-007 and ERAS-601 had favorable safety and tolerability monotherapy profiles with largely non-overlapping treatment-related adverse events that are expected to be monitorable and manageable at the likely recommended combination doses

Wei Lin, M.D., Erasca's chief medical officer, added, "What we have learned from other targeted therapies is that combinations are the best approach to provide durable treatment responses in patients with RAS/MAPK alterations. These early data demonstrating monotherapy activity with ERAS-007 or ERAS-601 and favorable safety profiles are highly encouraging and support the potential of ERAS-007 and ERAS-601 to be foundational combination agents for the treatment of solid tumors with RAS/MAPK alterations. We look forward to further exploring the therapeutic potential of combinations involving ERAS-007 and ERAS-601, including with each other as part of Erasca's first MAPKlamp combination, across different patient types."

* Data cutoff dates of 11/6/20, 7/11/22, and 5/16/22 for ASN007-101, FLAGSHP-1, and HERKULES-1 trials, respectively.

**About ERAS-007**
ERAS-007 is a potential best-in-class oral, selective ERK1/2 inhibitor being investigated alone or in combination with different inhibitors targeting upstream nodes of the RAS/MAPK pathway as part of Erasca's MAPKlamp strategy. The extracellular signal-regulated kinases (ERK), ERK1 and ERK2, belong to a family of serine-threonine kinases that regulate cellular signaling and comprise the terminal node of the RAS/MAPK pathway. ERAS-007 is being investigated across a series of HERKULES clinical trials that span multiple tumor types and includes both monotherapy and combinations with approved and investigational agents, such as receptor tyrosine kinase (RTK), RAS, RAF, and/or cell cycle inhibitors. HERKULES-1

is a Phase 1b/2 clinical trial for ERAS-007 as a single agent and will include a combination with the SHP2 inhibitor ERAS-601 (together, Erasca's first MAPKlamp) in advanced solid tumors. HERKULES-2 is a Phase 1b/2 master protocol for ERAS-007 in combination with various agents in patients with non-small cell lung cancer (NSCLC). HERKULES-3 is a Phase 1b/2 master protocol for ERAS-007 in combination with various agents in patients with gastrointestinal cancers.

**About ERAS-601**
ERAS-601 is a potential best-in-class oral, selective SHP2 inhibitor being investigated alone or in combination. SHP2 acts as a convergent node for RTK signaling, relaying growth and survival signals from RTKs to intracellular signaling pathways. ERAS-601 combined with the ERK1/2 inhibitor ERAS-007 makes up Erasca's first innovative MAPKlamp strategy. ERAS-601 is being investigated across a series of clinical trials that span multiple tumor types and include both monotherapy and combinations with approved and investigational agents. FLAGSHP-1 is a Phase 1/1b clinical trial evaluating ERAS-601 as a monotherapy in advanced solid tumors and in combination in triple wildtype (KRAS/NRAS/BRAF wildtype) CRC and human papillomavirus (HPV)-negative head and neck squamous cell carcinoma (HNSCC). HERKULES-1 is a Phase 1b/2 clinical trial that will include evaluation of ERAS-601 in combination with ERAS-007 in advanced solid tumors. HERKULES-2 is a Phase 1b/2 master protocol that includes evaluation of ERAS-601 in combination with various agents in patients with NSCLC.

**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, including ERAS-007 and ERAS-601, and their combination as part of our first MAPKlamp strategy; our expectations regarding the monotherapy data for ERAS-007 and ERAS-601 described in this press release being indicative of future clinical results; our beliefs regarding market sizes and opportunities; the planned advancement of our development pipeline; and the anticipated date for the initiation of the ERAS-007 and ERAS-601 combination 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: the retrospective analysis of pooled data covers multiple clinical trials with different designs, inclusion criteria, and dosing regimens, which cannot be directly compared, and therefore may not be a reliable indicator of efficacy and safety data; interim results of clinical trials 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 more patient data become available; 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 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.

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Source: Erasca, Inc.


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