Erasca Announces Two Clinical Trial Collaboration and Supply Agreements for Trametinib to Evaluate Naporafenib Combination in SEACRAFT-1 and SEACRAFT-2 Trials

02.14.2024

Naporafenib is a potential first-in-class and best-in-class pan-RAF inhibitor in multiple RAS/MAPK pathway-driven tumors

Initial SEACRAFT-1 Phase 1b combination data in RAS Q61X solid tumors expected between Q2-Q4 2024

Initiation of pivotal SEACRAFT-2 in NRASm melanoma expected in H1 2024

SAN DIEGO, Feb. 14, 2024 (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 two clinical trial collaboration and supply agreements (CTCSAs) with Novartis (NYSE: NVS) for the MEK inhibitor trametinib (MEKINIST®).

The agreements will support the clinical development of the pan-RAF inhibitor naporafenib in combination with trametinib for the treatment of patients with RAS Q61X solid tumors in the Phase 1b SEACRAFT-1 trial and in patients with previously treated NRAS-mutant (NRASm) unresectable or metastatic melanoma in the randomized, pivotal Phase 3 SEACRAFT-2 trial. Erasca is sponsoring the trials, and Novartis is supplying trametinib at no cost.

“We are excited to work with Novartis to further evaluate the promising clinical development of naporafenib in combination with trametinib in our SEACRAFT trials as part of our two lead indications: NRASm melanoma and RAS Q61X solid tumors,” said Jonathan E. Lim, M.D., Erasca’s chairman, CEO, and co-founder. “Both trials are supported by compelling anti-tumor activity with a tolerable and manageable adverse event profile demonstrated in clinical data generated by Novartis. We expect to initiate our SEACRAFT-2 Phase 3 trial in the first half of 2024 and report initial SEACRAFT-1 Phase 1b combination data in RAS Q61X solid tumors between the second and fourth quarters of 2024.”

In the United States and Europe, approximately 150,000 patients with RAS Q61X solid tumors are diagnosed annually, particularly in melanoma, non-small cell lung cancer (NSCLC), thyroid cancer, colorectal cancer, pancreatic cancer, and other tumor types. Approximately 20-30% of patients with melanoma have NRAS mutations, which is an aggressive form that accounts for approximately 50,000 new cancer cases annually in the United States and Europe. Both RAS Q61X solid tumors and NRASm melanoma represent high unmet needs with no approved targeted therapies for these respective mutation types. Erasca is exploring whether naporafenib in combination with trametinib can improve outcomes and help provide meaningful therapeutic benefit for these advanced solid tumor indications.

About Naporafenib

Naporafenib (formerly LXH254) is a potent and selective pan-RAF inhibitor, with a potential first-in-class and best-in-class profile. Naporafenib has been dosed in over 500 patients to date, whereby safety, tolerability, pharmacokinetics, and pharmacodynamics have been established in both monotherapy and select combinations. Clinical proof-of-concept (PoC) has been established for the combination with trametinib for patients with NRAS-mutant (NRASm) melanoma, which includes NRAS Q61X melanoma, and preliminary clinical PoC has been established for the combination with trametinib for patients with RAS Q61X in non-small cell lung cancer (NSCLC). Erasca plans to focus initially on advancing and securing regulatory approval for naporafenib plus trametinib in NRASm melanoma as part of the planned pivotal Phase 3 SEACRAFT-2 trial and in RAS Q61X tissue agnostic solid tumors as part of the Phase 1b SEACRAFT-1 trial, respectively. Erasca is also exploring additional combinations of naporafenib with other proprietary therapeutic agents in our pipeline. Naporafenib has received FDA Fast Track Designation for patients with unresectable or metastatic NRASm melanoma who have progressed on, or are intolerant to, an anti-PD(L)-1 based regimen.

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 one of the deepest RAS/MAPK pathway-focused pipelines 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 naporafenib; the planned advancement of our development pipeline, including the development plan and anticipated timing of the data readout and dosing of the first patient in the SEACRAFT-1 and SEACRAFT-2 clinical trials, respectively; and our ability to realize the benefits of the CTCSA described in this press release. 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; potential delays in the commencement, enrollment, data readouts, and completion of clinical trials and our preclinical studies; our dependence on third parties in connection with manufacturing, the supply of third-party drugs, 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; 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 become available; we have not completed any clinical trials of naporafenib and are reliant on data generated by Novartis in prior clinical trials conducted by it; our planned SEACRAFT trials may not support the registration of naporafenib; our assumptions regarding 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; regulatory developments in the United States and foreign countries; a FDA Fast Track Designation (FTD) may not result in a more expedited development or regulatory review process, and such a designation does not increase the likelihood that naporafenib in combination with trametinib will receive marketing approval in the United States; the FDA may later decide that naporafenib in combination with trametinib no longer meets the conditions for FTD; our dependence on third parties in connection with our existing collaboration and supply agreements (including the CTCSA described in this press release); our ability to obtain and maintain intellectual property protection for our product candidates and maintain our rights under intellectual property licenses; the impact of global geopolitical events and war on our business; our ability to fund our operating plans with our current cash, cash equivalents, and marketable securities; and other risks described in our prior filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our most recent 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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