



Erasca Doses First Patient in SEACRAFT-1 Phase 1b Trial Evaluating Naporafenib Plus Trametinib in Patients with RAS Q61X Solid Tumors

08.29.2023

Anti-tumor activity in patients with NRAS Q61X melanoma and KRAS Q61X NSCLC supports tissue agnostic development in RAS Q61X solid tumors

Initial Phase 1b combination data from SEACRAFT-1 expected in Q2-Q4 2024

Dosing of first patient in pivotal SEACRAFT-2 trial in NRAS-mutant melanoma expected in H1 2024

SAN DIEGO, Aug. 29, 2023 (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 dosing of the first patient in the [SEACRAFT-1](#) Phase 1b trial evaluating pan-RAF inhibitor naporafenib in combination with MEK inhibitor trametinib (MEKINIST®) in patients with RAS Q61X solid tumors.

"Naporafenib has been dosed in over 500 patients to date, establishing its safety, tolerability, and preliminary proof-of-concept (PoC) in multiple indications," said Jonathan E. Lim, M.D., Erasca's chairman, CEO, and co-founder. "SEACRAFT-1 will explore the potential of naporafenib plus trametinib in patients with RAS Q61X solid tumors, which affects over 150,000 patients in the United States and Europe. This tissue agnostic approach is based on the encouraging anti-tumor activity generated by Novartis in patients with NRAS Q61X melanoma or KRAS Q61X non-small cell lung cancer (NSCLC). We look forward to sharing signal-seeking efficacy data in relevant tumor types from SEACRAFT-1 between the second and fourth quarters of 2024. In addition, we are on track to initiate SEACRAFT-2, a pivotal Phase 3 trial to evaluate naporafenib plus trametinib in patients with NRAS-mutant (NRASm) melanoma, in the first half of 2024."

About SEACRAFT-1

SEACRAFT-1 is an open-label Phase 1b trial that will examine the safety, tolerability, and preliminary efficacy of naporafenib in combination with trametinib (MEKINIST®) in previously treated patients aged 12 and older with locally advanced unresectable or metastatic RAS Q61X solid tumor malignancies including NRAS, HRAS, and KRAS mutations. Initial Phase 1b combination signal-seeking efficacy data in relevant tumor types is expected between Q2 and Q4 2024.

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 in certain 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 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.

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 our expectations regarding the size of the patient populations for our product candidates, including naporafenib; the planned advancement of our development pipeline, including the anticipated timing for the initial data readout for the SEACRAFT-1 trial and the first patient dosing in the SEACRAFT-2 trial, and other upcoming development milestones. 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, 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; results from preclinical studies or early clinical trials, including the clinical trial results discussed in this press release, not necessarily being predictive of future results; we have not conducted 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; the inability to realize any benefits from our current licenses, collaborations, and acquisitions and any future licenses, collaborations, or acquisitions, 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; 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 quarterly 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.

MEKINIST® is a registered trademark owned by or licensed to Novartis AG, its subsidiaries, or affiliates.

Contact:

Joyce Allaire

LifeSci Advisors, LLC

jallaire@lifesciadvisors.com

Source: Erasca, Inc.

ERASCA™

Source: Erasca, Inc.