Exelixis Provides Update on the Phase 3 STELLAR-303 Trial Evaluating Zanzalintinib in Combination with an Immune Checkpoint Inhibitor in Patients with Metastatic Colorectal Cancer

June 22, 2026

ALAMEDA, Calif.--(BUSINESS WIRE)--Jun. 22, 2026-- Exelixis, Inc. (Nasdaq: EXEL) today announced results from the final analysis of the dual primary endpoint of overall survival (OS) in the subset of patients without active liver metastases (non-liver metastases, NLM) in the phase 3 STELLAR-303 pivotal trial evaluating zanzalintinib in combination with atezolizumab (Tecentriq®) versus regorafenib in previously treated non-microsatellite instability (MSI)-high metastatic colorectal cancer (mCRC). The results showed a non-statistically significant trend in OS favoring the combination in the NLM subpopulation (stratified hazard ratio: 0.83; 95% confidence interval: 0.66–1.05; P=0.1185), with median OS values of 15.9 months with zanzalintinib in combination with atezolizumab, and 12.7 months with regorafenib.

The safety profile of zanzalintinib in combination with atezolizumab in the NLM subgroup was consistent with that previously reported in the intention-to-treat (ITT) population, and no new safety signals were identified.

Exelixis previously announced that STELLAR-303 met its other dual primary endpoint, demonstrating a statistically significant improvement in OS in the ITT population, which included all randomized patients regardless of the presence of active liver metastases. Detailed results demonstrating the statistically significant improvement in OS in the ITT population were presented at the 2025 European Society for Medical Oncology Congress and published in *The Lancet*.

In February 2026, Exelixis announced that the U.S. Food and Drug Administration (FDA) accepted the company's New Drug Application (NDA) for zanzalintinib, in combination with atezolizumab, for the treatment of patients with mCRC who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, and, if RAS wild-type, an anti-epidermal growth factor receptor (EGFR) therapy. The FDA assigned a Prescription Drug User Fee Act target action date of December 3, 2026.

Detailed findings from the NLM subgroup analysis will be submitted for presentation at an upcoming medical conference.

About STELLAR-303
STELLAR-303 (NCT05425940) is a global, multicenter, randomized, phase 3, open-label study that randomized patients 1:1 to either zanzalintinib in combination with atezolizumab (n=451) or regorafenib (n=450). The study includes patients with previously treated non-MSI-high mCRC. The dual primary endpoints of the study are OS in the ITT population and in the NLM subgroup of patients. The ITT population consisted of all randomized patients, regardless of the presence of liver metastases. The NLM subgroup consisted of patients who did not have active liver metastases at baseline as determined by investigator assessment. Secondary endpoints include progression-free survival, objective response rate and duration of response in the ITT population and in the NLM subgroup of patients. More information about the trial is available at ClinicalTrials.gov.

About Zanzalintinib
Zanzalintinib is a novel oral kinase inhibitor that inhibits the activity of the TAM kinases (TYRO3, AXL, MER), MET and VEGF receptors. These kinases play important roles in oncogenic processes, including tumor cell proliferation, metastasis, angiogenesis, drug resistance and evasion of antitumor immunity. The zanzalintinib development program includes a series of ongoing and planned pivotal trials to explore its therapeutic potential in CRC, clear cell and non-clear cell renal cell carcinoma, and neuroendocrine tumors, as well as earlier-stage trials in meningioma, lung cancer and castration-resistant prostate cancer.

Zanzalintinib is an investigational agent that is not approved for any use and is the subject of ongoing clinical trials.

About CRC
CRC is the third most common cancer and a leading cause of cancer-related deaths in the U.S.[1] Approximately 159,000 new cases will be diagnosed in the U.S. in 2026, with around 55,000 expected deaths from the disease.[1] CRC is most frequently diagnosed among people aged 65-74 and is more common in men and in people of non-Hispanic American Indian/Alaska Native descent.[2] Nearly a quarter of CRC cases are diagnosed at the metastatic stage, at which point the five-year survival rate is around just 15%.[1,2] The liver is the most common site for CRC metastasis. Liver metastases significantly impact survival, with a median five-year survival rate of less than 14% when treated with palliative chemotherapy.[3]

About Exelixis
Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by drug discovery and development excellence, we are rapidly evolving our product portfolio to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules and biotherapeutics. This comprehensive approach harnesses decades of robust investment in our science and partnerships to advance our pipeline of franchise molecules, including our novel oral kinase inhibitor zanzalintinib, and to extend the impact of our flagship commercial product, CABOMETYX® (cabozantinib). Exelixis is driven by a bold scientific pursuit to create transformational treatments that give more patients hope for the future. For information about the company and its mission to help cancer patients recover stronger and live longer, visit www.exelixis.com, follow @ExelixisInc on X (Twitter), like Exelixis, Inc. on Facebook and follow Exelixis on LinkedIn.

Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, statements related to: the presentation of detailed results from the STELLAR-303 NLM subgroup analysis at an upcoming medical conference and Exelixis' scientific pursuit to create transformational treatments that give more patients hope for the future. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and

projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the availability of data at the referenced times; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere, including with respect to Exelixis' NDA for zanzalintinib for the treatment of patients with previously treated metastatic CRC, when used in combination with atezolizumab, including the risk that the FDA may not approve zanzalintinib as a treatment for metastatic CRC in a timely fashion, if at all; Exelixis' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating zanzalintinib; Exelixis' dependence on third-party vendors for the development, manufacture and supply of zanzalintinib; Exelixis' ability to protect its intellectual property rights; market competition; changes in economic and business conditions; and other factors affecting Exelixis and its development programs detailed from time to time under the caption "Risk Factors" in Exelixis' most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and in Exelixis' future filings with the Securities and Exchange Commission. All forward-looking statements in this press release are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein, except as required by law.

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[1] Cancer Facts & Figures 2026. ACS website. Available at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2026/2026-cancer-facts-and-figures.pdf. Accessed June 2026.

[2] Cancer Stat Facts: Colorectal Cancer. SEER website. Available at: https://seer.cancer.gov/statfacts/html/colorect.html. Accessed June 2026.

[3] Ros J, Salva F, Dopazo C, et al. Liver transplantation in metastatic colorectal cancer: are we ready for it? *Br J Cancer.* May 2023;128(10):1797-1806.

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