Exelixis Announces U.S. FDA Accepted the New Drug Application for Zanzalintinib in Combination with an Immune Checkpoint Inhibitor for Patients with Metastatic Colorectal Cancer

February 2, 2026

– The FDA assigned a Prescription Drug User Fee Act target action date of December 3, 2026 –

– Application is based on results from the phase 3 STELLAR-303 pivotal trial, in which zanzalintinib in combination with atezolizumab improved median overall survival and significantly reduced the risk of death versus regorafenib in the intention-to-treat population –

ALAMEDA, Calif.--(BUSINESS WIRE)--Feb. 2, 2026-- Exelixis, Inc. (Nasdaq: EXEL) today announced that its New Drug Application (NDA) for zanzalintinib, in combination with atezolizumab (Tecentriq®), has been accepted for review in the U.S. for the treatment of adult patients with metastatic colorectal cancer (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 Food and Drug Administration (FDA) assigned a standard review with a Prescription Drug User Fee Act target action date of December 3, 2026.

"We are encouraged by this meaningful progress toward addressing the needs of patients with previously treated metastatic colorectal cancer, for whom effective therapies have been limited and treatment outcomes remain poor," said Dana T. Aftab, Ph.D., Executive Vice President, Research and Development, Exelixis. "Zanzalintinib has the potential to become an important advancement in a challenging treatment landscape, and if approved, zanzalintinib in combination with atezolizumab would provide a novel mechanism of action for patients with previously treated metastatic colorectal cancer. We are deeply grateful to the patients, caregivers and investigators contributing to the clinical research in support of this application, and we look forward to collaborating with the FDA during the review process for our first NDA for zanzalintinib."

The NDA is based on the results of the phase 3 STELLAR-303 pivotal trial, in which zanzalintinib in combination with atezolizumab demonstrated a statistically significant improvement in overall survival (OS) versus regorafenib in the intention-to-treat (ITT) population of patients with previously treated CRC. Detailed results, including OS and progression-free survival (PFS) in the ITT population and in the subset of patients without liver metastases (non-liver metastases, NLM), were presented at the 2025 European Society for Medical Oncology (ESMO) Congress and published in *The Lancet*. Data pertaining to the other dual primary endpoint, OS in patients without active liver metastases, were immature at the data cutoff, and the trial is proceeding to the planned final analysis for this endpoint, which is expected in mid-2026, based on current event rates.

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 metastatic CRC. 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 PFS, 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. With zanzalintinib, Exelixis sought to build upon its extensive experience with the target profile of cabozantinib, the company's flagship medicine, while improving key characteristics, including pharmacokinetic half-life. Zanzalintinib is currently being developed for the treatment of advanced solid tumors, including colorectal cancer, kidney cancer and neuroendocrine tumors.

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 therapeutic potential of zanzalintinib, in

combination with atezolizumab, as a treatment for patients with previously treated mCRC; the regulatory review process, including the PDUFA target action date assigned by the FDA, and Exelixis' plans to collaborate with the FDA while the application is reviewed; and Exelixis' scientific pursuit to create transformational treatments that give patients more 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: complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere, including the risk that the FDA may not approve the combination of zanzalintinib with atezolizumab as a treatment for patients with previously treated mCRC in a timely fashion, if at all; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating zanzalintinib and/or atezolizumab; Exelixis' ability to protect its intellectual property rights; market competition; changes in economic and business conditions; and other factors affecting the ability of Exelixis to obtain regulatory approval for zanzalintinib in new indications 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 February 2026.

[2] Cancer Stat Facts: Colorectal Cancer. SEER website. Available at: https://seer.cancer.gov/statfacts/html/colorect.html. Accessed February 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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Investors Contact:
Andrew Peters
SVP, Strategy and Investor Relations
Exelixis, Inc.
650-837-7248
apeters@exelixis.com

Media Contact:
Stekki Millman
Senior Director, Public Affairs
Exelixis, Inc.
650-837-7187
smillman@exelixis.com

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