



Exelixis Announces Zanzalintinib in Combination with an Immune Checkpoint Inhibitor Improved Overall Survival in STELLAR-303 Phase 3 Pivotal Trial in Patients with Metastatic Colorectal Cancer

June 22, 2025

– Zanzalintinib in combination with atezolizumab demonstrated a statistically significant reduction in risk of death versus regorafenib in intent-to-treat population –

ALAMEDA, Calif.--(BUSINESS WIRE)--Jun. 22, 2025-- [Exelixis, Inc.](#) (Nasdaq: EXEL) today announced positive topline results from the STELLAR-303 phase 3 pivotal trial in which zanzalintinib in combination with atezolizumab (Tecentriq®) demonstrated a statistically significant improvement in overall survival (OS) versus regorafenib in the intent-to-treat (ITT) population of patients with previously treated non-microsatellite instability (MSI)-high metastatic colorectal cancer (CRC). These topline findings are from the final analysis conducted by the Independent Data Monitoring Committee of one of the dual primary endpoints of the STELLAR-303 phase 3 trial. The trial will proceed to the planned final analysis for the other dual primary endpoint of OS in patients without liver metastases (non-liver metastases, NLM).

The safety profiles of zanzalintinib in combination with atezolizumab and of regorafenib were generally consistent with what has been previously observed, and no new safety signals were identified.

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.

"The STELLAR-303 results, which showed a survival benefit with the combination of zanzalintinib and atezolizumab versus regorafenib across all randomized patients with previously treated metastatic colorectal cancer, marks an important first milestone for our zanzalintinib pivotal development program," said Amy Peterson, M.D., Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer, Exelixis. "We look forward to discussing the findings with regulatory authorities and presenting the detailed results at an upcoming medical conference."

Secondary endpoints of STELLAR-303 include progression-free survival, objective response rate and duration of response in the ITT population and in the NLM subgroup of patients. Exelixis plans to submit detailed results of STELLAR-303 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 901 patients 1:1 to either zanzalintinib (100 mg) in combination with atezolizumab or regorafenib. 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. Presence of liver metastases at baseline for all enrolled patients was 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 third-generation oral tyrosine kinase inhibitor that inhibits the activity of receptor tyrosine kinases implicated in cancer growth and spread, including VEGF receptors, MET, AXL and MER. These receptor tyrosine kinases are involved in both normal cellular function and in pathologic processes such as oncogenesis, metastasis, tumor angiogenesis and resistance to multiple therapies, including immune checkpoint inhibitors. 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, head and neck 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 the second leading cause of cancer-related deaths in the U.S.¹ Approximately 154,000 new cases will be diagnosed in the U.S. with around 53,000 expected deaths from the disease in 2025.¹ 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 just 16.2%.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, antibody-drug conjugates and other biotherapeutics. This comprehensive approach harnesses decades of robust investment in our science and partnerships to advance our investigational programs and 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 the combination of zanzalintinib in combination with atezolizumab to improve overall survival in patients with metastatic CRC; Exelixis' plans to discuss the trial data from STELLAR-303 with regulatory authorities and to present detailed findings 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; 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 Key Statistics for Colorectal Cancer. ACS website. Available at: <https://www.cancer.org/cancer/types/colon-rectal-cancer/about/key-statistics.html>. Accessed June 2025.

² Cancer Stat Facts: Colorectal Cancer. SEER website. Available at: <https://seer.cancer.gov/statfacts/html/colorect.html>. Accessed June 2025.

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:

Susan Hubbard
EVP, Public Affairs and
Investor Relations
Exelixis, Inc.
650-837-8194
shubbard@exelixis.com

Media Contact:

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

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