Exelixis Announces Clinical Development Collaboration with Merck for Phase 3 STELLAR-316 Pivotal Trial for Patients with Colorectal Cancer

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– Merck to supply KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph), the company's subcutaneous anti-PD-1 therapy,for planned STELLAR-316 trial –

ALAMEDA, Calif.--(BUSINESS WIRE)--May 19, 2026-- Exelixis, Inc. (Nasdaq: EXEL) today announced that the company has entered into a clinical development collaboration with Merck, known as MSD outside of the United States and Canada, to supply KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph) injection for subcutaneous administration in combination with zanzalintinib in STELLAR-316, a planned phase 3 pivotal trial in patients with resected stage II/III colorectal cancer (CRC). Under the terms of the clinical development collaboration with Merck, Exelixis is sponsoring the STELLAR-316 pivotal trial, and Merck will supply KEYTRUDA QLEX.

"This collaboration with Merck for the STELLAR-316 trial reflects the continued progress of the zanzalintinib clinical development program and is an important step forward in our efforts to advance a potentially new treatment option that may help prevent or delay metastatic progression for patients with resected colorectal cancer," said Dana T. Aftab, Ph.D., Executive Vice President, Research and Development, Exelixis. "We look forward to initiating the clinical trial to evaluate this novel combination, with the goal of enhancing treatment strategies and meaningfully improving clinical outcomes for patients with this form of cancer who face a high risk of recurrence."

STELLAR-316 is a planned phase 3 pivotal trial that will evaluate zanzalintinib with and without KEYTRUDA QLEX in patients with resected stage II/III CRC who, following definitive therapy, have tested positive for molecular residual disease (MRD+) and have no radiographic evidence of disease. The primary endpoint of the trial will be disease-free survival, with key secondary endpoints including circulating tumor DNA clearance. In January 2026, Exelixis announced a collaboration with Natera, a global leader in cell-free DNA and precision medicine, for STELLAR-316. Natera will provide its Signatera™ assay to identify MRD+ patients for trial enrollmentExelixis expects to initiate STELLAR-316 in mid-2026.

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 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.

In February 2026, Exelixis announced that the U.S. Food and Drug Administration (FDA) accepted the company's New Drug Application for zanzalintinib, in combination with atezolizumab (Tecentriq®), for the treatment of adult patients with metastatic CRC 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.

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

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.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' clinical development plans for zanzalintinib, including pursuant to the clinical development collaboration with Merck for the phase 3 pivotal trial STELLAR-316; Exelixis's belief in the therapeutic potential of zanzalintinib, including the potential to be a new treatment option that may help prevent or delay metastatic progression for patients with resected colorectal cancer; Exelixis' goal of enhancing treatment strategies and meaningfully improving clinical outcomes for patients

with CRC who face a high risk of recurrence; 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 potential failure of zanzalintinib to demonstrate safety and/or efficacy in clinical trials; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' and Merck's continuing compliance with applicable legal and regulatory requirements; the costs of conducting clinical trials; Exelixis' dependence on third-party vendors for the development, manufacture and supply of zanzalintinib; Exelixis' and Merck's 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 April 2026.

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