Exelixis Provides Update on Oncologic Drugs Advisory Committee Meeting for Cabozantinib (CABOMETYX®) for the Treatment of Patients with Previously Treated Advanced Neuroendocrine Tumors

January 9, 2025

ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 9, 2025-- Exelixis, Inc. (Nasdaq: EXEL) today announced it has been notified by the U.S. Food and Drug Administration (FDA) that the supplemental New Drug Application (sNDA) for cabozantinib (CABOMETYX®) for the treatment of adults with previously treated advanced pancreatic neuroendocrine tumors (pNET) and advanced extra-pancreatic (epNET) will no longer be the subject of discussion at an Oncologic Drugs Advisory Committee meeting. The sNDA remains under consideration by FDA with a Prescription Drug User Fee Act action date of April 3, 2025.

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.

Exelixis Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, statements related to: the FDA's plans to discuss the sNDA for cabozantinib for the treatment of adults with previously treated advanced pNET and advanced epNET at an ODAC meeting; the therapeutic potential of cabozantinib as a treatment for patients with previously treated advanced pNET and advanced epNET; the regulatory review process with respect to Exelixis' sNDA for cabozantinib in previously treated advanced pNET and advanced epNET, including the Prescription Drug User Fee Act target action date assigned by the FDA; 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 cabozantinib as a treatment for pNET or epNET 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 cabozantinib; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of CABOMETYX; changes in economic and business conditions; and other factors affecting the ability of Exelixis to obtain regulatory approval for cabozantinib 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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