Exelixis Announces U.S. FDA Accepts Investigational New Drug Application for XB002 in Patients with Advanced Solid Tumors

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– Promising preclinical data suggest best-in-class potential for XB002, a next-generation tissue factor-targeting antibody-drug conjugate –

– Phase 1 clinical trial expected to begin in Q2 2021 –

ALAMEDA, Calif.--(BUSINESS WIRE)--Apr. 5, 2021-- Exelixis, Inc. (Nasdaq: EXEL) today announced that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug Application (IND) to evaluate the safety, tolerability, pharmacokinetics and preliminary antitumor activity of XB002 in patients with advanced solid tumors. As a next-generation tissue factor-targeting antibody-drug conjugate (ADC), XB002 has the potential for an improved therapeutic index and may provide a favorable safety profile compared with earlier-generation tissue factor-targeting ADCs.

"The acceptance of our Investigational New Drug Application for XB002 gets us one step closer to our first biologic entering the clinic and learning more about its potential to help patients with difficult-to-treat cancers," said Gisela Schwab, M.D., President, Product Development and Medical Affairs and Chief Medical Officer, Exelixis. "Considering XB002's promising preclinical data and potential differentiation from other tissue factor-targeting antibody-drug conjugates, we look forward to initiating our phase 1 trial in patients with advanced solid tumors."

XB002 (formerly ICON-2) is an ADC composed of a human monoclonal antibody against tissue factor that is conjugated to a cytotoxic agent. After binding to tissue factor on tumor cells, XB002 is internalized, and the cytotoxic agent is released, resulting in targeted tumor cell death. XB002 is a rationally designed next-generation ADC that leverages proprietary linker-payload technology.

Preclinical data demonstrated that XB002 binds to tissue factor without affecting the coagulation cascade, in contrast with prior therapies in this class. The data also demonstrated encouraging activity of XB002 in multiple solid tumor cancer models and improved tolerability compared with other tissue factor-targeting ADCs. XB002 has shown significant tumor growth inhibition and, in some cases, complete regression. The rational design and preclinical profile of this novel tissue factor-targeting ADC suggest that, if born out in clinical evaluation, XB002 could have an improved therapeutic index and favorable safety profile compared with earlier tissue factor-targeting ADCs.

About Exelixis
Founded in 1994, Exelixis, Inc. (Nasdaq: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model system genetics, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. Our discovery efforts have resulted in four commercially available products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib), COTELLIC® (cobimetinib) and MINNEBRO® (esaxerenone), and we have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing our existing therapeutic assets with targeted business development activities and internal drug discovery – all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Exelixis is a member of the Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. In November 2020, the company was named to Fortune's 100 Fastest-Growing Companies list for the first time, ranking 17th overall and the third-highest biopharmaceutical company. For more information about Exelixis, please visit www.exelixis.com, follow @ExelixisInc on Twitter or like Exelixis, Inc. on Facebook.

Forward-looking Statements
This press release contains forward-looking statements, including, without limitation, statements related to: the clinical and therapeutic potential of XB002 to help patients with difficult-to-treat cancers and potential to provide a favorable safety profile compared with earlier tissue factor-targeting ADCs; Exelixis' plans to initiate a phase 1 clinical trial evaluating XB002 in patients with advanced solid tumors during the second quarter of 2021; and Exelixis' plans to reinvest in its business to maximize the potential of the company's pipeline, including through targeted business development activities and internal drug discovery. 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; Exelixis' continuing compliance with applicable legal and regulatory requirements; the potential failure of XB002 to demonstrate safety and/or efficacy in future trials; uncertainties inherent in the product development process; the continuing COVID-19 pandemic and its impact on Exelixis' research and development operations, including Exelixis' ability to initiate new clinical trials and clinical trial sites, enroll clinical trial patients, conduct trials per protocol, and conduct drug research and discovery operations and related activities; the costs of conducting clinical trials; Exelixis' dependence on third-party vendors for the development, manufacture and supply of XB002; 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 discussed under the caption "Risk Factors" in Exelixis' Annual Report on Form 10-K submitted to the Securities and Exchange Commission (SEC) on February 10, 2021, and in Exelixis' future filings with the SEC. 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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