



Exelixis to Initiate Phase 1 Clinical Development of XL092, First New Compound to Enter the Clinic from Reinitiated Discovery Efforts

February 12, 2019

– Phase 1 dose-escalation trial follows filing of IND in December 2018 –

ALAMEDA, Calif.--(BUSINESS WIRE)--Feb. 12, 2019-- Exelixis, Inc. (Nasdaq: EXEL) today announced it is initiating phase 1 clinical development for XL092, the first internally-discovered Exelixis compound to enter the clinic following the company's reinitiation of drug discovery activities. XL092 is a next-generation oral tyrosine kinase inhibitor that targets VEGF receptors, MET, and other kinases implicated in cancer's growth and spread. The molecule is the subject of an active Investigational New Drug (IND) application Exelixis submitted to the U.S. Food and Drug Administration in December 2018.

"Exelixis is building a pipeline of diverse investigational medicines behind cabozantinib through in-house drug discovery activities and targeted in-licensing," said Peter Lamb, Ph.D., Executive Vice President of Scientific Strategy and Chief Scientific Officer of Exelixis. "XL092 is a novel compound that targets key signal transduction pathways in tumors, while potentially addressing tumor-induced immune suppression. Data from the upcoming phase 1 clinical trial will be used to determine the potential for further development of XL092."

The multi-center phase 1 clinical trial is designed to evaluate the pharmacokinetics, safety and tolerability of XL092. The trial is divided into dose-escalation and expansion phases. The dose-escalation phase of the trial will enroll patients with advanced solid tumors, with the primary objective of determining a dose for daily oral administration of XL092 suitable for further evaluation. Assuming positive data from the initial phase of the trial, the expansion phase is designed to further explore the selected dose of XL092 in individual tumor cohorts, where safety, tolerability, and initial clinical activity would be evaluated.

"Supported by revenues from the global cabozantinib franchise, Exelixis is building on our prolific drug discovery history to advance a new generation of Exelixis medicines," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "As the first molecule to enter clinical development from our new laboratories here in Alameda, XL092 represents an important milestone for our company and highlights our commitment to the patients we serve. We look forward to the clinical progress of XL092 and the continued maturation of other earlier-stage molecules currently in development."

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 genetic systems, 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 approved 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 Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. For more information about Exelixis, please visit www.exelixis.com, follow [@ExelixisInc](https://twitter.com/ExelixisInc) on Twitter or like [Exelixis, Inc.](https://www.facebook.com/Exelixis) on Facebook.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the potential of XL092 to address tumor-induced immunosuppression; Exelixis' plan to use data from the upcoming phase 1 clinical trial to determine the potential for further development of XL092; Exelixis' expectations for the clinical progress of XL092 and continued maturation of other earlier-stage molecules currently in development; 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: risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; the potential failure of XL092 to demonstrate safety and/or efficacy in a phase 1 clinical trial and be deemed suitable for future evaluation; uncertainties inherent in the drug discovery and product development process, including evolving regulatory requirements, slower than anticipated patient enrollment or inability to identify a sufficient number of clinical trial sites; the costs of conducting clinical trials; Exelixis' dependence on third-party vendors for the development, manufacture and supply of XL092; 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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 1, 2018, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Annual Report on Form 10-K expected to be filed with the SEC on February 22, 2019. 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.

Exelixis, the Exelixis logo, CABOMETYX, COMETRIQ and COTELLIC are registered U.S. trademarks. MINNEBRO is a Japanese trademark.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20190212005852/en/>

Source: Exelixis, Inc.

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

Hal Mackins
For Exelixis, Inc.
415-994-0040
hal@torchcomllc.com