Exelixis Announces Settlement of CABOMETYX® (cabozantinib) Patent Litigation with Cipla Limited and Cipla USA

May 20, 2024

ALAMEDA, Calif.--(BUSINESS WIRE)--May 20, 2024-- Exelixis, Inc. (Nasdaq: EXEL) today announced that it has entered into a Settlement and License Agreement (Agreement) with Cipla Ltd. and Cipla USA, Inc. (collectively Cipla). This settlement resolves two patent litigations brought by Exelixis in response to Cipla's Abbreviated New Drug Application (ANDA) seeking approval to market generic versions of CABOMETYX® (cabozantinib) tablets prior to the expiration of the applicable patents. The first case (Civil Action No. 23-287), filed on March 16, 2023, relates to Cipla's ANDA for a 60 mg cabozantinib dosage strength. The second case (Civil Action No. 24-565-RGA), filed on May 9, 2024, relates to a recent amendment to Cipla's ANDA, for the primary purpose of seeking additional approval for 20 mg and 40 mg cabozantinib dosage strengths.

Pursuant to the terms of the Agreement, Exelixis will grant Cipla a license to market generic versions of CABOMETYX in the United States beginning on January 1, 2031, if approved by the U.S. Food and Drug Administration and subject to conditions and exceptions common to agreements of this type.

Additionally, in accordance with the Agreement, the parties will terminate all ongoing Hatch-Waxman litigation between Exelixis and Cipla regarding CABOMETYX patents pending in the U.S. District Court for the District of Delaware.

The Agreement is confidential and subject to review by the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice. The lawsuits will be dismissed after a period of time to allow for FTC review.

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: Exelixis' obligations under the Agreement, including Exelixis' granting of a license to Cipla to market generic versions of CABOMETYX in the United States beginning on January 1, 2031 and termination by the parties of all ongoing Hatch-Waxman litigation regarding CABOMETYX patents; and the expectation that the lawsuits will be dismissed after a period of time following FTC review. 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: Exelixis' ability to effect its obligations under the Agreement; and other factors 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' other 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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