Exelixis Announces Update on Patent Litigation with MSN Laboratories

January 19, 2023

ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 19, 2023-- Exelixis, Inc. (Nasdaq: EXEL) today announced that in the lawsuit *Exelixis, Inc. (Exelixis) v. MSN Laboratories Private Limited et al.* (*MSN*), Action No. 19-2017 (Consolidated), the U.S. District Court for the District of Delaware ruled in Exelixis' favor, rejecting MSN's challenge to the cabozantinib compound patent (U.S. 7,579,473). The District Court's decision follows an earlier Stipulation and Order of October 1, 2021, that MSN's proposed generic cabozantinib product (Abbreviated New Drug Application [ANDA] No. 213878) infringes the '473 patent.

Additionally, the District Court ruled that MSN's proposed ANDA product does not infringe Exelixis' N-2 polymorph patent (U.S. 8,877,776), which expires on October 8, 2030. The District Court's decision does not address the validity of the '776 patent, which was not contested by MSN.

"We are pleased the court upheld the validity of Exelixis' cabozantinib compound patent," said Jeffrey Hessekiel, J.D., Executive Vice President, General Counsel and Secretary, Exelixis. "While we are disappointed with the court's decision concerning infringement of the '776 patent, we remain confident in the strength of the cabozantinib patent estate. We will continue to vigorously defend our intellectual property, safeguarding the scientific innovation that drives Exelixis' ability to continue to discover, develop and ultimately bring new medicines to patients with difficult-to-treat cancers."

As a result of the ruling, Exelixis intends to request that the District Court order that the effective date of any potential U.S. regulatory approval of MSN's generic product, subject to any appeals or challenges, would be no earlier than August 14, 2026, which is the expiration date of Exelixis' '473 patent.

This ruling does not impact Exelixis' separate and ongoing suit against MSN, *Exelixis, Inc. vs. MSN Laboratories Private Limited et al.*, Civil Action No. 22-00228 (Consolidated) (MSN II), concerning four different Orange Book-listed patents related to cabozantinib, including U.S. Patents No. 11,091,439 (crystalline salt forms); 11,091,440 (pharmaceutical compositions); 11,098,015 (methods of treatment); and 11,298,349 (pharmaceutical composition). MSN has already stipulated to infringement of the '439, '440, and '015 patents, which expire on January 15, 2030. The remaining '349 patent expires on February 10, 2032. Trial in MSN II is scheduled to begin in October 2023 in the U.S. District Court for the District of Delaware.

About Exelixis

Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by bi-coastal centers of 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 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' confidence in the strength of the cabozantinib patent estate and plans to pursue every available legal action to defend its intellectual property; Exelixis' ability to continue to discover, develop and ultimately bring new medicines to patients with difficult-to-treat cancers; the anticipated schedule for the trial in MSN II; Exelixis' plans to request a specific effective date from the District Court for any potential U.S. regulatory approval of MSN's generic product; 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: Exelixis' ability to protect its intellectual property rights; the degree of market acceptance of CABOMETYX in the indications for which it is approved and in the territories where it is approved, and Exelixis' and its partners' ability to obtain or maintain coverage and reimbursement for this product; the effectiveness of CABOMETYX in comparison to competing products; market competition, including the potential for competitors to obtain approval for generic versions of CABOMETYX; Exelixis' and its partners' ability to maintain and scale adequate sales, marketing, market access and product distribution capabilities for its products or to enter into and maintain agreements with third parties to do so; Exelixis' and its partners' continuing compliance with applicable legal and regulatory requirements; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products and product candidates; changes in economic and business conditions, including as a result of the COVID-19 pandemic and other global events; and other factors 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, 2022, 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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