Exelixis Announces Update on Second Patent Litigation Trial with MSN Laboratories

October 15, 2024

ALAMEDA, Calif.--(BUSINESS WIRE)--Oct. 15, 2024-- Exelixis, Inc. (Nasdaq: EXEL) today announced that in the lawsuit *Exelixis, Inc. (Exelixis) vs. MSN Laboratories Private Limited et al. (MSN)*, Civil Action No. 22-00228 (Consolidated), the U.S. District Court for the District of Delaware ruled in Exelixis' favor, rejecting MSN's challenge to three Orange Book-listed patents related to cabozantinib, including U.S. Patents No. 11,091,439 (crystalline salt); 11,091,440 (pharmaceutical compositions); and 11,098,015 (methods of treatment). The District Court's decision in Exelixis' favor on the validity of these patents follows an earlier Stipulation entered on June 21, 2022, that MSN's proposed generic cabozantinib product (Abbreviated New Drug Application [ANDA] No. 213878) infringes the '439, '440, and '015 patents, which expire on January 15, 2030.

Additionally, the court ruled that Exelixis' pharmaceutical composition patent (U.S. 11,298,349) is not invalid and not infringed by MSN's proposed ANDA product.

"We are pleased with the court's ruling, which upheld the validity of Exelixis' '439, '440, '015 and '349 patents," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "We remain confident in the strength of the current and emerging cabozantinib patent estate. We will continue to pursue every available legal action to defend our intellectual property rights, which are crucial to safeguarding the scientific innovation that drives our mission to help cancer patients recover stronger and live longer."

MSN is seeking approval for a product containing a different polymorphic form of cabozantinib (l)-malate than the form contained in Exelixis' breakthrough CABOMETYX ® (cabozantinib) product. To Exelixis' knowledge, the U.S. Food and Drug Administration (FDA) has not yet granted tentative approval of that potential product. If the FDA ultimately approves MSN's ANDA, given today's decision, the earliest that MSN may be permitted to commercially launch its proposed generic product in the U.S. is January 15, 2030, subject to any appeals or additional regulatory exclusivity.

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' confidence in the strength of the cabozantinib patent estate and plans to pursue every available legal action to defend its intellectual property rights; the potential timing for MSN to commercially launch its proposed generic product in the U.S.; Exelixis' and Exelixis' scientific pursuit to create transformational treatments that give more patients 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: Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of CABOMETYX; 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; 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 cabozantinib; changes in economic and business conditions; 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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