Exelixis Announces Update on Patent Litigation Trial Appeal with MSN Laboratories

August 31, 2026

ALAMEDA, Calif.--(BUSINESS WIRE)--Aug. 31, 2026-- 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. Court of Appeals for the Federal Circuit (Appeal No. 25-1236) has affirmed a key portion of the 2024 judgment of the U.S. District Court for the District of Delaware in Exelixis' favor. The appellate court upheld the District Court's decision that three patents covering the crystalline malate salt of cabozantinib (No. 11,091,439 [crystalline salt]; 11,091,440 [pharmaceutical compositions]; and 11,098,015 [methods of treatment]) are not invalid. Concurrently, the appellate court dismissed the appeal regarding the validity dispute over one of Exelixis' patents covering low-impurity cabozantinib formulations (U.S. Patent No. 11,298,349), ruling the matter moot.

The Federal Circuit's decision upholds the validity of the '439, '440 and '015 crystalline salt patents, preserving market exclusivity of Exelixis' cabozantinib (marketed under the brand name CABOMETYX®). While the appellate court issued a procedural ruling dismissing the '349 formulation patent appeal as moot, this decision does not impact the broader strength or integrity of the cabozantinib patent estate.

Exelixis will continue to pursue all necessary legal actions to defend its intellectual property portfolio, which is essential to safeguarding the scientific innovation that drives the company's mission to help cancer patients recover stronger and live longer.

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 additional appeals or regulatory exclusivity. MSN's ability to commercially launch would depend on the outcome of litigation involving another low-impurity formulation patent (U.S. Pat. No. 12,128,039) that expires in February 2032, with a trial scheduled to begin in November 2026.

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 and biotherapeutics. This comprehensive approach harnesses decades of robust investment in our science and partnerships to advance our pipeline of franchise molecules, including our novel oral kinase inhibitor zanzalintinib, and to 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' plans to pursue all necessary legal action to defend its intellectual property portfolio; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20260831878873/en/

Investors Contact:
Andrew Peters
SVP, Strategy and Investor Relations
Exelixis, Inc.
650-837-7248
apeters@exelixis.com

Media Contact:
Claire McConnaughey
Senior Director, Public Affairs
Exelixis, Inc.
650-837-7052
cmcconn@exelixis.com

Source: Exelixis, Inc.