ANI Pharmaceuticals Announces the FDA Approval of Everolimus Tablets for Oral Suspension

September 23, 2026

PRINCETON, N.J., Sept. 23, 2026 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced that it received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA), for Everolimus Tablets for Oral Suspension 2mg, 3mg and 5mg. ANI's Everolimus Tablets for Oral Suspension are the generic version of the reference listed drug (RLD) Afinitor Disperz®.

"The FDA approval of Everolimus Tablets for Suspension is another example of our R&D team's continued execution on technically demanding formulations, and the launch adds further momentum to our commercial portfolio. Our U.S. focused generics business continues to produce outstanding results, and we remain on track to launch at least 15 new generics this year," stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

U.S. annual sales for Everolimus Tablet for Oral Suspension totaled approximately $123 million, based on July 2026 moving annual total (MAT) IQVIA data.

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified biopharmaceutical company committed to its mission of "Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high-quality therapeutics. The Company is focused on delivering sustainable growth through its Rare Disease business, which markets novel products in the areas of ophthalmology, rheumatology, nephrology, neurology, and pulmonology; its Generics business, which leverages R&D expertise, operational excellence, and U.S.-based manufacturing; and its Brands business. For more information, visit https://www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release relate to information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the Company's strategy; its plans with respect to the commercialization and potential sales of the Company's products, including the launch of Everolimus; its efforts to bring limited-competition products to market and ensure that is high-quality products are readily accessible to its customers and patients in need; expansion plans for the Company's Rare Disease, Generics and Brands businesses; and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," the negatives thereof, or other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to: the ability of the Company's approved products to achieve commercialization at levels of market acceptance that will allow the Company to maintain profitability; delays and disruptions in the production of the Company's approved products; delays or failure to obtain or maintain approvals by the FDA of the Company's products; changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration and other regulatory agencies; risks that the Company may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of the Company's products from both domestic and overseas sources due to supply chain disruptions or for any other reason; the limited number of suppliers for active pharmaceuticals ingredients for our products; the ability of the Company's manufacturing partners to meet its product demands and timelines; the level of competition the Company faces and the legal, regulatory and/or legislative strategies employed by its competitors to prevent or delay competition from generic alternatives to branded products; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the Company's ability, and that of its suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; legal proceedings and product liability claims relating to our products and our business; and general business and economic conditions, such as inflationary pressures and geopolitical conditions.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, and other periodic reports, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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