ANI Pharmaceuticals Announces the FDA Approval and Launch of Prucalopride Tablets with 180-Day CGT Exclusivity

January 2, 2025

PRINCETON, N.J., Jan. 02, 2025 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced that following final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA), the Company has launched Prucalopride Tablets. ANI's Prucalopride Tablets is the generic version of the reference listed drug (RLD) Motegrity ®.

"We are delighted to build momentum early in 2025 with the approval of the first generic for Motegrity®, once again highlighting our superior R&D capabilities. The FDA has granted our Prucalopride Tablets a Competitive Generic Therapy (CGT) designation, with 180-day exclusivity. ANI continues to hold the second-highest number of CGT approvals in the U.S. Generics market," stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

U.S. annual sales for Prucalopride Tablets total approximately $168.0 million, based on October 2024 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 Established Brands business. For more information, visit www.anipharmaceuticals.com.

Forward-Looking Statements

This press release contains not only historical information, but also forward-looking statements made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements represent the Company's expectations or beliefs concerning future events, including statements regarding the benefits of the acquisition of Alimera Sciences. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "continue," "strategy," "future," "opportunity," "plan," "may," "should," "will," "shall," "would" other words of similar meaning, derivations of such words and the use of future dates. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties.

The following factors, among others, could cause actual results to differ materially from those described in these forward-looking statements: (i) the ability to implement business plans, forecasts, and other expectations in connection with the acquisition and integration of Alimera Sciences, Inc. ("Alimera") and identify and realize additional opportunities and, in particular, the possibility that the Company is unable to achieve anticipated synergies, (ii) costs and regulatory requirements relating to contract manufacturing arrangements, (iii) costs or delays associated with manufacturing (including the sources and any changes in sources thereof) of the Company's products, (iv) delays or failures in retaining and obtaining continuing and future product approvals from the FDA, and other regulatory issues relating to the Company's business and products, (v) market trends for the Company's products, , and the ability to achieve anticipated sales for such products, (vi) risks that the acquisition of Alimera may disrupt current plans and operations of the Company and potential difficulties of the Company in retaining employees of Alimera and/or maintaining business relationships of Alimera, (vii) the impact of any litigation to which the Company is, or may become, a party, including in connection with the acquisition and integration thereof, (viii) volatility in the Company's stock price, including as a result of the acquisition, (ix) changes in competitive and regulated industries in which the Company operates, variations in operating performance across competitors, changes in laws and regulations affecting the Company's business, and changes in the Company's capital structure as a result of the acquisition, (x) regulatory and other approvals relating to product development and manufacturing, (xi) 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 and/or the Company and its products, (xii) costs incurred in connection with the acquisition of Alimera and the possibility that the Company is unable to realize anticipated benefits of the acquisition or to realize estimated pro forma results and underlying assumptions, (xiii) delays in production, increased costs and potential loss of revenues if there is a change in manufacturers or manufacturing processes due to the limited number of suppliers for the Company's raw materials, active pharmaceutical ingredients, excipients and other materials, (xiv) the Company's reliance on single source third-party contract manufacturing supply for certain of its key products, , (xv) changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration, and other regulatory agencies, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions, (xvi) the impact of legislative or regulatory reform on the pricing for the Company's products, (xvii) the Company' ability to maintain the services of its key executives and other personnel, and (xviii) general business and economic conditions, such as inflationary pressures, geopolitical conditions including, but not limited to, the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies. 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, 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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