ANI Pharmaceuticals Announces the Launch of Nitazoxanide Tablets

March 19, 2025

PRINCETON, N.J., March 19, 2025 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced the launch of Nitazoxanide Tablets, 500 mg. ANI's Nitazoxanide Tablets are the generic version of the reference listed drug (RLD) Alinia ®.

"The market launch of Nitazoxanide Tablets, another niche limited competition product, underscores our purpose of 'Serving Patients, Improving Lives'," stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

"We share ANI's commitment to providing affordable, high-quality medicines for the patients who depend on them and are pleased to partner on the launch of this limited competition product," stated Dr. Jagadeesh Rangisetty, Chief Executive Officer of Biophore.

U.S. annual sales for Nitazoxanide Tablets total approximately $36.1 million, based on December 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 Brands business. For more information, visit www.anipharmaceuticals.com.

About Biophore India Pharmaceuticals Pvt. Ltd.
Biophore, an established pharmaceutical company, is engaged in the development and manufacturing of niche, high quality pharmaceutical products for the generic industry. Since its inception in 2007, Biophore has emerged as a trusted partner for niche and complex products in the generic industry across US, Europe and other regulated markets. For more information, please visit our website, http://www.biophore.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: the ability of our approved products, including Cortrophin Gel, ILUVIEN and YUTIQ, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, including the acquisition of Alimera, in a timely manner or at all; the limitation of our cash flow as a result of the indebtedness and liabilities incurred from the recent acquisition of Alimera; the risks that our acquisitions and investments, including the recent acquisition of Alimera, could disrupt our business and harm our financial position and operating results; delays and disruptions in production of our approved products, increased costs and potential loss of revenues if we need to change suppliers due to the limited number of suppliers for our raw materials, active pharmaceutical ingredients, expedients, and other materials; delays and disruptions in production of our approved products as a result of our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel, ILUVIEN and YUTIQ; delays or failure in obtaining and maintaining approvals by the FDA of the products we sell; changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration and other regulatory agencies, and the focus of the current U.S. presidential administration, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions; risks that we 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 our products from both domestic and overseas sources due to supply chain disruptions or for any other reason; the ability of our manufacturing partners to meet our product demands and timelines; the impact of changes or fluctuations in exchange rates; our ability to develop, license or acquire, and commercialize new products; our obligations in agreements under which we license, develop or commercialize rights to products or technology from third parties and our ability to maintain such licenses; the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products; our ability to protect our intellectual property rights; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the impact of any litigation to which we are, or may become, a party; our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; our ability to maintain the services of our key executives and other personnel; and 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 in the Middle East, 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.

Investor Relations:

Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Source: ANI Pharmaceuticals, Inc.