ANI Pharmaceuticals Announces the FDA Approval and Launch of Fluoxetine Oral Solution USP

November 28, 2022

BAUDETTE, Minn.--(BUSINESS WIRE)--Nov. 28, 2022-- ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (Nasdaq: ANIP) today announced that the Company received U.S. Food and Drug Administration (FDA) approval for the Abbreviated New Drug Application (ANDA) for Fluoxetine Oral Solution, USP 20 mg/5 mL.

ANI’s Fluoxetine Oral Solution is the generic version of the Reference Listed Drug (RLD) Prozac ®. The current annual U.S. market for Fluoxetine Oral Solution is approximately $14.6 million, according to IQVIA/IMS Health, a leading healthcare data and analytics provider.

"We continue to strengthen our generics business with new product launches, and laud the efforts of our R&D team in helping the Company fulfill its ongoing commitment to provide affordable generic alternatives to customers and patients in need,” stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

About ANI

ANI Pharmaceuticals, Inc. is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by building a successful Purified Cortrophin® Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release deal with 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, those relating to the commercialization and potential sales of the product and any additional product launches from the Company’s generic pipeline, other statements that are not historical in nature, particularly those that utilize terminology such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” 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 risk that the Company may face with respect to importing raw materials and other ingredients and supplies necessary for manufacture of our products; competition from other products; acquisitions; contract manufacturing arrangements; delays or failure in obtaining and maintaining product approval from the U.S. Food and Drug Administration; general business and economic conditions, including the ongoing impact of and uncertainties regarding the COVID-19 pandemic and inflationary pressures; market trends; products development; regulatory and other approvals and marketing.

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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