ANI Pharmaceuticals Announces Launch of Authorized Generic of Lithobid® Extended Release Tablets

December 21, 2016

BAUDETTE, Minnesota (December 21, 2016) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced the launch of Lithium Carbonate Extended Release Tablets, 300mg, an authorized generic of Lithobid®, which is used in the treatment of manic episodes of Bipolar Disorder. The annual US market for lithium carbonate is approximately $19 million, per IMS Health.

Arthur S. Przybyl, ANI’s President and Chief Executive Officer said, "We are pleased to announce the launch of an authorized generic of our mature brand product Lithobid®. This generic launch represents ANI’s 11th new product introduction in 2016 capping a substantial commercial portfolio expansion for the company this year. We look to continued commercial portfolio growth in 2017.”

About Lithium Carbonate Extended Release Tablets

Lithium Carbonate Extended Release Tablets are indicated in the treatment of manic episodes of Bipolar Disorder. Bipolar Disorder, Manic (DSM-IV) is equivalent to Manic Depressive illness, Manic, in the older DSM-II terminology. Lithium Carbonate Extended Release Tablets are also indicated as a maintenance treatment for individuals with a diagnosis of Bipolar Disorder. Maintenance therapy reduces the frequency of manic episodes and diminishes the intensity of those episodes which may occur.

About ANI

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ANI Pharmaceuticals, Inc. (the “Company” or “ANI”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. 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, statements about price increases, the Company’s future operations, products financial position, operating results and prospects, the Company’s pipeline or potential markets therefor, 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,” 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; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; 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, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. 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.

For more information about ANI, please contact:

Investor Relations
IR@anipharmaceuticals.com