ANI Announces Launch of Authorized Generic of Brethine®

October 16, 2018

BAUDETTE, Minnesota (October 16, 2018) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq:ANIP) today announced the launch of Terbutaline Sulfate Tablets USP, 2.5mg and 5mg, an authorized generic of Brethine®. The current annual U.S. market for this product is approximately $11 million, according to Iqvia. Prior to ANI’s launch there was only one supplier of the product in the U.S. market.

ANI acquired the NDA for Brethine® (terbutaline sulfate) tablets in December 2016.

Arthur S. Przybyl, ANI’s President and CEO stated, "ANI continues to successfully execute on our strategy of re-commercializing products from our portfolio of acquired discontinued ANDAs and NDAs. Terbutaline sulfate is our seventh generic product introduction in 2018.”

About Terbutaline Sulfate Tablets USP

Terbutaline sulfate is indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema.

About ANI

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 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.

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