ANI Pharmaceuticals Announces FDA Approval of Oxcarbazepine Tablets

June 13, 2016

BAUDETTE, Minnesota (June 13, 2016) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that it has received approval from the U.S. Food and Drug Administration (“FDA”) of the Prior Approval Supplement (“PAS”) for Oxcarbazepine Tablets, 150mg, 300mg and 600mg. The current annual U.S. market for this product, based on trailing twelve months sales, is $145 million according to IMS Health.

Arthur S. Przybyl, ANI’s President and CEO stated, “This approval is the result of ANI’s ongoing effort to re-activate the discontinued ANDAs that we have acquired in recent years. The PAS included the successful qualification of a new API source for the drug substance as well as the addition of manufacturing and packaging at ANI’s Baudette site.”

About Oxcarbazepine tablets

Oxcarbazepine is an antiepileptic drug indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults and as monotherapy in the treatment of partial seizures in children aged 4 years and above with epilepsy, and as adjunctive therapy in children aged 2 years and above with partial seizures.

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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