ANI Pharmaceuticals Announces FDA Approval of Oxycodone Hydrochloride Oral Solution 5mg/5mL

June 2, 2015

Baudette, Minnesota (June 2, 2015) – ANI Pharmaceuticals, Inc. (“ANI”) (NASDAQ: ANIP) today announced that it has received approval from the U.S. Food and Drug Administration (FDA) of its Abbreviated New Drug Application (ANDA) for Oxycodone Hydrochloride Oral Solution 5mg/5mL. Trailing twelve-month sales for the product are $30 million, according to IMS, with three current competitors. ANI expects to begin shipping to its customers shortly.

Arthur S. Przybyl, President and CEO of ANI Pharmaceuticals, stated, “This ANDA represents ANI’s first in the area of pain management and our first internally-developed product to receive approval. Pain management represents a strategic focus for the Company and ANI’s development pipeline includes several other products in that category.”

ANI has forty-six generic drug products under development addressing a total annual market size of approximately $3.3 billion, based on data from IMS Health.

About Oxycodone Hydrochloride Oral Solution

Oxycodone Hydrochloride Oral Solution 5mg/5mL is an opioid agonist indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate.

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 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; 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
(218) 634-3608
IR@anipharmaceuticals.com