ANI Pharmaceuticals and Dexcel Announce FDA Approval of Donepezil Hydrochloride 23mg Tablets

February 24, 2016

Baudette, Minnesota (February 24, 2016) - ANI Pharmaceuticals, Inc. (“ANI”) (NASDAQ: ANIP) today announced that its collaboration partner Dexcel Pharma Technologies Ltd. (“Dexcel”) has received approval from the U.S. Food and Drug Administration (“FDA”) of the Abbreviated New Drug Application (“ANDA”) for Donepezil HCl 23mg Tablets. Sales of the product for calendar year 2015 were $44 million, according to IMS Health, with five current generic competitors. ANI and Dexcel expect to begin shipping to customers shortly.

Arthur S. Przybyl, President and CEO of ANI Pharmaceuticals stated, “We are excited to have achieved this milestone with Dexcel and look forward to a successful launch.”

About Donepezil 23mg Tablets

Donepezil is an acetylcholinesterase inhibitor indicated for the treatment of dementia of the Alzheimer’s type. Efficacy has been demonstrated in patients with mild, moderate, and severe Alzheimer’s Disease.

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.

About Dexcel

Dexcel Pharma is a private international specialty pharmaceutical group, dedicated to the development, manufacturing and commercialization of novel drug formulations and complex generics. Dexcel Pharma has a broad portfolio of branded and generic products, sold in more than 30 countries worldwide. Dexcel Pharma was established in 1968 and is headquartered in Israel.

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 therefore, 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 risks that the Company may face with respect to importing raw materials; increased competition; acquisitions; 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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