



Corium Announces Issuance of Key U.S. Patent Covering Corplex™ Donepezil Transdermal System for Alzheimer's Disease

June 13, 2018

Provides Composition of Matter Coverage to 2037

MENLO PARK, Calif., June 13, 2018 (GLOBE NEWSWIRE) -- Corium International, Inc. (NASDAQ:CORI), a commercial stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty transdermal products, announced today that the United States Patent and Trademark Office (PTO) has issued a cornerstone patent related to the company's Corplex Donepezil Transdermal Delivery System (TDS), a once-weekly patch that delivers the most commonly prescribed medication for Alzheimer's patients. U.S. Patent No. 9,993,466 provides coverage of the drug product and its unique design features, including composition elements that achieve a sustained, controlled and effective delivery of donepezil across the skin for the 7-day wear period. In addition, the PTO recently issued a notice of allowance on another patent related to methods of transdermal delivery of donepezil using the product described in U.S. Patent No. 9,993,466. As previously announced, the Corplex Donepezil TDS has achieved positive results in clinical bioequivalence testing, and Corium is preparing to file a New Drug Application for the product based on these results.

"Our novel Corplex TDS design and formulation technologies were enabling for the once-weekly transdermal delivery of Donepezil," said Parminder "Bobby" Singh, Ph.D., Chief Technology Officer and Vice President, R&D at Corium, and a co-inventor on the patent. "The issuance of this patent highlights our innovation in the transdermal delivery of molecules such as donepezil that have previously been very challenging to transport across the skin with traditional patch technologies."

The new patent is eligible for listing in the U.S. FDA Orange Book, and its life extends at least to July 2037. It is the first to issue of a series of pending Corium patent applications relating to various aspects of Corplex Donepezil, as well as similar products.

About Alzheimer's Disease and Donepezil

Alzheimer's disease is a progressive brain disorder in which the brain cells degenerate and die, causing a steady decline in memory and mental function. According to the Alzheimer's Association, an estimated 5.7 million Americans are living with Alzheimer's disease in 2018; by 2050, this number is projected to rise to 13.8 million. Alzheimer's disease is the most common cause of dementia among older adults. Dementia ranges in severity from mild, when it is just beginning to affect a person's functioning, to moderate, and severe, when the person must depend on others for the basic activities of day-to-day life.

Donepezil (the active ingredient in Aricept®) is the most widely prescribed medication in a class of Alzheimer's drugs known as cholinesterase inhibitors, and is approved for the treatment of mild, moderate and severe disease. Donepezil is currently only available in tablet or orally disintegrating tablet form, each administered once daily, presenting compliance challenges for family members and caregivers who cannot rely on patients to consistently take their daily tablets, and is known to cause gastrointestinal side effects, including nausea, vomiting and loss of appetite.

About Corplex

Corium's Corplex system is a novel commercial-stage platform technology designed to broadly enable the transdermal delivery of small molecules, many of which have not previously been amenable to transdermal delivery. Corium's Corplex technology has been successfully commercialized in Procter & Gamble's Crest® Whitestrips products, and is being utilized in therapeutic products under development.

About Corium

Corium International, Inc. is a commercial-stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products that leverage the company's broad experience with advanced transdermal and transmucosal delivery systems. Corium has multiple proprietary programs in preclinical and clinical development, focusing primarily on the treatment of neurological disorders, with lead programs in Alzheimer's disease. Corium has developed and is the sole commercial manufacturer of seven prescription drug and consumer products with partners Mayne Pharma and Procter & Gamble. The company has two proprietary transdermal platforms: Corplex™ for small molecules and MicroCor®, a biodegradable microstructure technology for small molecules and biologics, including vaccines, peptides and proteins. In addition to its proprietary Alzheimer's program, the company's late-stage pipeline includes a contraceptive patch co-developed with Agile Therapeutics and additional transdermal products that are being developed with other partners. For further information, please visit www.coriumintl.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding our products, intellectual property rights and portfolio, regulatory pathway, timing and plans, and the advancement of our technologies, proprietary products and product candidates. Forward-looking statements are based on management's current expectations and projections and are subject to risks and uncertainties, which may cause Corium's actual results to differ materially from the statements contained herein. Further information on potential risk factors that could affect Corium's business and its results are detailed in Corium's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the Securities and Exchange Commission (SEC) on May 15, 2018, and other reports as filed from time to time with the SEC. Undue reliance should not be placed on forward-looking statements, especially guidance on future financial or operating performance, which speaks only as of the date they are made. Corium undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made or to reflect the occurrence of unanticipated events.

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