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Corium Reports Positive Progress in Pilot Bioequivalence Study of Once-Weekly Corplex™ Donepezil Patch

Second Period Interim Results with Partial Crossover Data Consistent with First Period Results

MENLO PARK, Calif., March 20, 2017 (GLOBE NEWSWIRE) -- Corium International, Inc. (Nasdaq:CORI), a commercial-stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty transdermal products, today reported on positive progress in the pilot bioequivalence (BE) study of its Corplex Donepezil candidate, a once-weekly transdermal patch for delivery of the most commonly prescribed treatment for the symptoms of Alzheimer's disease.

The pilot BE study is a three-period, randomized crossover study comparing the steady-state pharmacokinetic (PK) profiles of once-daily oral Aricept® (donepezil hydrochloride) with two Corplex Donepezil transdermal patches that differ only in surface area. Corium reported that the steady-state PK profiles of the transdermal dosage forms measured in the second treatment period, which includes partial crossover data, continue to exhibit a close similarity with the oral PK results and were indicative of bioequivalence. The Corplex transdermal systems continued to be well tolerated, with favorable skin safety and gastrointestinal side effect profiles.

The company reported that the pilot study is on track for completion of the third and final treatment period in April and expects to report on results from the entire study in May.

The objective of the pilot study is to enable the company to finalize key parameters, including patch surface area and number of subjects, for a successful pivotal BE study. The primary objective of the pivotal study will be the demonstration of statistically similar PK profiles between the final transdermal candidate and the oral dosage form. Corium is pursuing the BE development and regulatory pathway based on written feedback provided by the FDA in 2016.

"We are very encouraged with the positive progress in the crossover clinical study of our lead Alzheimer's program and the continued low attrition rates," said Peter D. Staple, President and Chief Executive Officer of Corium. "With our extensive experience in successfully conducting pilot and pivotal bioequivalence studies, we are well-positioned for the upcoming pivotal BE study. Preparations for the pivotal study, expected to commence later in 2017, are well underway, and we look forward to advancing this candidate towards an NDA filing in 2018. We believe Corplex Donepezil will provide an important new treatment option to improve the lives of Alzheimer's patients and their caregivers."

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. An estimated 5.5 million Americans are living with Alzheimer's disease in 2017; by 2025, this number is expected to exceed 7 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. Corplex advanced transdermal and transmucosal systems are broadly adaptable for use in multiple drug categories and indications, and have the potential to reduce quantities of active ingredient utilized in transdermal products. Additionally, Corplex transdermal patches can enable efficient drug delivery, and adhere to either wet or dry surfaces for an extended period of time.

Corium's Corplex technology has been successfully commercialized in Procter & Gamble's Crest® Whitestrips products, and is being utilized in several proprietary 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. 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.coriumgroup.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 clinical trial and regulatory timing and plans, the achievement of clinical and commercial milestones, and the advancement of our technologies and our 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 December 31, 2016, filed with the Securities and Exchange Commission on February 14, 2017, and other reports as filed from time to time with the Securities and Exchange Commission. 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.

Source: Corium

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Source: Corium International, Inc.