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Corium Presents Full Clinical Results from Phase 1 Pharmacokinetic Study of Once-weekly Corplex™ Donepezil Transdermal System

Positive Data Supporting Once-weekly Corplex Donepezil as Therapeutic Alternative to Daily Oral Aricept® Presented at Alzheimer's Association International Conference® 2016

MENLO PARK, Calif., July 27, 2016 (GLOBE NEWSWIRE) -- Corium International, Inc. (Nasdaq:CORI), a commercial-stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty transdermal products, today announced the presentation of full clinical trial results demonstrating sustained and controlled delivery of donepezil in the plasma concentrations of all subjects treated with Corium's once-weekly Corplex Donepezil patch. Consistent with topline interim data, the average plasma concentration with Corplex Donepezil was comparable to oral Aricept (donepezil hydrochloride), and indicative of bioequivalence. These pharmacokinetic results enabled Corium to select an optimized formulation for further clinical development and support an expedited development pathway for Corplex Donepezil.

The data were presented today by Parminder "Bobby" Singh, Ph.D., Corium's Chief Technology Officer and Vice President, Research and Development at the Alzheimer's Association International Conference 2016 (AAIC) in Toronto, Ontario.

"We are pleased to present our positive clinical data for Corium's once-weekly Corplex Donepezil transdermal product at this year's AAIC," said Dr. Singh. "A seven-day patch that reliably delivers a sustained dose of donepezil has the potential to simplify administration, improve adherence to treatment, and improve the lives of Alzheimer's patients and their caregivers."

Corium's product candidate is designed for sustained and controlled delivery of the drug in a convenient, weekly dosage form. This Alzheimer's disease product incorporates the company's proprietary Corplex technology, which Corium developed to enable transdermal delivery of a wide range of drugs. Sustained delivery of a therapeutic agent in a transdermal system can improve clinical adherence and potentially reduce adverse effects that may be associated with the oral route of administration.

The Phase 1 clinical study was conducted in healthy female volunteers aged 50-80, and involved the administration of a single dose of seven-day Corplex Donepezil targeted to deliver 5 mg/day of the drug, followed by once-daily Aricept 5 mg tablets administered consecutively for seven days. The primary objective was to assess the pharmacokinetics of single-dose once-weekly Corplex Donepezil formulations, compared to daily oral Aricept. The secondary objectives were assessment of safety and skin tolerability.

As presented in the study results, after a single application of the Corplex Donepezil patch, plasma concentrations of the selected lead formulation approached steady state at Day 7, achieving comparable dosing to oral Aricept. Pharmacokinetic and statistical projections for subsequent weeks of therapy at steady state predict a highly similar exposure between transdermal Corplex Donepezil and continued daily oral administration of Aricept, with excellent skin tolerability. The results support the feasibility of a convenient once-weekly dosing regimen.

On May 2, 2016, Corium announced that, following review of Corium's pre-IND submission, the U.S. Food and Drug Administration (FDA) advised Corium that if the company can adequately demonstrate bioequivalence between Corplex Donepezil Transdermal Delivery System (TDS) and oral Aricept in its planned PK bioequivalence studies, additional clinical efficacy studies will not be required. Corium plans to initiate a pilot bioequivalence study later this year and expects to commence a pivotal bioequivalence study in 2017. If the results from the pivotal study supports bioequivalence, Corium expects to be able to submit a 505(b)(2) New Drug Application (NDA) as early as mid-2018.

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 5.1 million Americans suffered from Alzheimer's disease in 2015; by 2025, this number is estimated to reach 7.1 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 Teva Pharmaceuticals, Endo Pharmaceuticals 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 that is currently in Phase 3 trials, 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 March 31, 2016, filed with the Securities and Exchange Commission on May 13, 2016, 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.

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