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Corium Announces Streamlined Bioequivalence Development Path for Transdermal Corplex™ Memantine

Second Alzheimer's Candidate to Follow Shortened Clinical Timeline

MENLO PARK, Calif., Aug. 24, 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 receiving favorable written feedback from the U.S. Food and Drug Administration (FDA) on the company's Pre-Investigational New Drug Application (PIND) submission for once-weekly transdermal Corplex Memantine.

Following review of Corium's pre-IND submission, which included summary results from a Phase 1 pharmacokinetic (PK) study of the product candidate, the FDA concurred with the company's development plans, including its proposal for pivotal studies based on the demonstration of bioequivalence, or BE, between the Corplex Memantine Transdermal Delivery System (TDS) and oral Namenda XR® (memantine HCl) extended release capsules.

"We are pleased with the FDA's positive feedback on our bioequivalence-based clinical development plan," said Peter D. Staple, President and Chief Executive Officer of Corium. "This guidance parallels the feedback that we received from the FDA for Corplex Donepezil, and was well-supported by our clinical study data. The bioequivalence approach enables the development of these important new treatments with reduced risk, time, and cost, compared to typical transdermal development programs."

"We look forward to advancing our once-weekly Alzheimer's products through clinical trials, and pursuing a streamlined regulatory pathway. These new transdermal therapeutics are designed to deliver drugs that collectively address an estimated 90% of the current market, and have the potential to improve the lives of patients and their caregivers."

Corium recently reported results of studies on its optimized formulation of Corplex Memantine, which demonstrated delivery of the required dose of memantine over seven days in a pig study while also indicating acceptable skin tolerability. In preparation for a pilot BE trial, the company next plans to conduct a human PK study of this optimized formulation in healthy subjects to confirm skin tolerability and sustained delivery over one week.

Bioequivalence clinical studies are designed to assess the biological equivalence of pharmaceutical products based on the similarity of their PK profiles to those of already-approved drugs, and are generally performed in healthy subjects. These studies are relatively short in duration of treatment, and provide a development path that is substantially less costly and more streamlined compared to standard clinical development programs.

A Section 505(b)(2) NDA is a new drug application in which the FDA and applicant may rely on certain investigations of safety and effectiveness that were previously conducted by someone other than the applicant, and is applicable to an active drug substance that has previously been approved in a different dosage form.

About Alzheimer's Disease and Memantine

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.

Memantine (the active ingredient in Namenda®) is one of the most widely prescribed medications for the treatment of moderate to severe dementia of the Alzheimer's type. Memantine is the only FDA-approved N-methyl-D-aspartate (NMDA)-receptor antagonist for use in Alzheimer's and works by regulating the activity of glutamate, a neurotransmitter in the brain involved in learning and memory. Memantine is currently only available in once- and twice-daily oral dosage forms, presenting compliance challenges for family members and caregivers who cannot rely on patients to consistently take their daily tablets.

Memantine and donepezil (the active ingredient in Aricept®) together represent approximately 90% of the units sold for the

treatment of Alzheimer's disease in the United States.

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 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 June 30, 2016, filed with the Securities and Exchange Commission on August 12, 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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