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Corium Announces Streamlined Bioequivalence Development Path for Transdermal Corplex™ Donepezil Following Positive Pre-IND Communication from FDA

Reports Positive PK Results from Clinical Study of Optimized Once-weekly Corplex Donepezil for Alzheimer's Disease

MENLO PARK, Calif., May 02, 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 submission for once-weekly transdermal Corplex Donepezil.

Following review of Corium's pre-IND submission, which included summary results from the initial Phase 1 pharmacokinetic (PK) study, the FDA provided clear guidance on the company's development plans and registration pathway. The agency advised Corium that if the company can adequately demonstrate bioequivalence between Corplex Donepezil Transdermal Delivery System (TDS) and oral Aricept® (donepezil hydrochloride) in its planned PK bioequivalence studies, additional clinical efficacy studies will not be required.

"We are pleased that the FDA has concurred with our clinical development plan, which is intended to demonstrate bioequivalence between transdermal Corplex Donepezil and oral Aricept," said Peter D. Staple, President and Chief Executive Officer of Corium. "Preparations are underway for a pilot bioequivalence study, which we look forward to starting later this year. Our objective is to use the results from this pilot study to finalize the design of a pivotal bioequivalence study that we expect to commence by mid-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.

Positive PK Results for Optimized Once-weekly Corplex Donepezil

Corium also announced positive findings from a new Phase 1 PK study evaluating optimized proprietary formulations of the once-weekly Corplex Donepezil product candidate. Two formulations achieved comparable dosing to oral Aricept with PK profiles that demonstrate the potential for bioequivalence. The company has selected a lead formulation based on these results.

Parminder "Bobby" Singh, Ph.D., Corium's Chief Technology Officer and Vice President, R&D added, "Our optimized Corplex Donepezil patches achieved the targeted sustained delivery of donepezil and skin tolerability requirements for a once-weekly treatment, while also demonstrating enhanced reproducibility. We look forward to advancing our lead formulation into a pilot bioequivalence study, followed by the pivotal bioequivalence study."

Bioequivalence clinical studies are designed to assess the biological equivalence of pharmaceutical products based on their PK profiles, and are generally performed in healthy subjects. These studies are relatively short in duration and provide a development path that is substantially less costly and more streamlined than typical clinical development programs, which require studies demonstrating safety and efficacy.

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

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, with symptoms typically first appearing in people age 65 and older. By 2025, the number of Americans age 65 and older with Alzheimer's disease 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 developed and is the sole commercial manufacturer of seven prescription drug and consumer products with partners Teva Pharmaceuticals, Par Pharmaceutical 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. Corium has multiple proprietary programs in preclinical and clinical development for the treatment of osteoporosis, and neurodegenerative and neurological disorders. 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 business strategy, 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, 2015, filed with the Securities and Exchange Commission on February 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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