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## **Corium Initiates Phase 1 Clinical Trial of Corplex(TM) Donepezil Transdermal System for the Treatment of Alzheimer's Disease**

MENLO PARK, Calif., Aug. 25, 2015 (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 commencement of dosing in a Phase 1 clinical trial to evaluate the safety, pharmacokinetics and pharmacodynamics of Corplex™ Donepezil Transdermal System for the sustained and controlled delivery of a treatment for Alzheimer's disease. The product, which is based on Corium's proprietary transdermal formulation and adhesive technology, is designed to deliver donepezil (the active ingredient in Aricept®) for up to seven days in a single-patch application. Donepezil, an anticholinesterase inhibitor, is a leading Alzheimer's drug approved for the treatment of mild, moderate, and severe disease as a daily tablet.

"We believe there is a significant need for a multi-day transdermal donepezil product for patients diagnosed with Alzheimer's disease, offering the potential to improve therapeutic compliance and convenience for patients and their caregivers," said Parminder "Bobby" Singh, Ph.D., Corium's Chief Technology Officer and Vice President, Research and Development.

"Initiation of this Phase 1 pharmacokinetics clinical trial is a major milestone for Corium, and for the advancement of our Corplex technology platform in neurology product applications. We look forward to moving additional neurology candidates into the clinic in the coming months."

The Phase 1 study is a single-dose, crossover study of 12 subjects in the age group representative of Alzheimer's disease (50-80 years of age). The primary objective of the study is to assess the pharmacokinetic profile of two Corplex Donepezil formulations over seven days, compared to the Aricept tablet. The secondary objectives are assessment of safety and skin tolerability, and evaluation of pharmacodynamics by measuring changes in concentrations of a well-characterized biomarker. The trial, which is expected to be completed in late 2015, follows extensive preclinical evaluation in predictive human skin and animal models that demonstrated sustained delivery over a seven-day period.

Corium is also developing a second Alzheimer's disease product candidate, a transdermal patch delivering memantine (the active ingredient in Namenda® and Namenda XR®), which is expected to enter Phase 1 clinical trials during the fourth calendar quarter of 2015.

### **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 advantage of using reduced quantities of active ingredient. Additionally, Corplex transdermal patches can be smaller in size while achieving the same or better therapeutic effect, and can adhere to either wet or dry surfaces. Corium's Corplex technology has been successfully commercialized in Procter & Gamble's Crest® Whitestrips products, and utilized in several proprietary therapeutic products in development.

### **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<sup>1</sup> people have Alzheimer's disease in 2015 with symptoms typically first appearing in people age 65 and older. By 2025, the number of people age 65 and older with Alzheimer's disease is estimated to reach 7.1 million.<sup>2</sup> 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 taken once daily as a tablet. The oral dosage form of this product presents compliance challenges for family members and caregivers who cannot rely on patients to consistently take their daily tablets, in addition to causing gastrointestinal side effects, including nausea, vomiting and loss of appetite.

## 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 advanced transdermal and transmucosal delivery systems. Corium has developed and is the sole commercial manufacturer of six 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 co-developed with Teva. Corium has multiple proprietary programs in preclinical and clinical development for the treatment of osteoporosis and neurological disorders. For further information, please visit [www.coriumgroup.com](http://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 plans and the advancement of our technologies and our proprietary and partnered 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 financial results are detailed in Corium's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the Securities and Exchange Commission on July 30, 2015, 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 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.

<sup>1,2</sup>2015 ALZHEIMER'S DISEASE FACTS AND FIGURES, Alzheimer's Association

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