



February 22, 2016

## Corium Announces Positive Topline Results From Phase 1 Clinical Study of Transdermal Corplex™ Memantine as a Potential Treatment of Alzheimer's Disease

**Demonstrates Pharmacokinetic Profile Supporting the Feasibility of Sustained Transdermal Delivery**

**Webcast and Conference Call Today at 5:00 p.m. ET (2:00 p.m. PT)**

MENLO PARK, Calif., Feb. 22, 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 positive topline interim results from a Phase 1 clinical study designed to evaluate the pharmacokinetics (PK), safety and tolerability of the Corplex™ Memantine transdermal delivery system for the treatment of Alzheimer's disease. Memantine (the active ingredient in Namenda® and Namenda XR®) is an NMDA receptor antagonist approved by the U.S. Food and Drug Administration for use in once- and twice-daily oral dosage forms for the treatment of moderate to severe dementia of the Alzheimer's type. In designing the memantine product candidate to achieve sustained delivery in a convenient multi-day transdermal dosage form, Corium applied its proprietary Corplex technology, which was developed to enable the controlled transdermal delivery of a wide range of drugs.

The purpose of this Phase 1 clinical study was to evaluate the PK, safety and tolerability of the Corplex Memantine transdermal product in eleven healthy volunteers aged 50-80, compared to Actavis' Namenda XR oral capsule.

Key Topline Results from the Phase 1 Study:

- | After a single application of the once-weekly Corplex Memantine product candidate, plasma concentrations approached steady state at day 7, and were comparable to the plasma concentrations of 28 mg oral Namenda XR at day 7. The Corplex Memantine candidate was also tested over a three-day duration and, as expected, the average plasma concentrations overlapped with the plasma concentrations observed over the first three to four days of the once-weekly application.
- | PK and statistical projections for subsequent weeks of therapy at steady state predict similar exposure between Corplex Memantine and continued daily oral administration of Namenda XR.
- | Sustained and controlled delivery of memantine was demonstrated in the plasma concentrations of all subjects, supporting the feasibility of a convenient multi-day dosing regimen, as compared to daily oral administration.
- | No systemic adverse events unique to transdermal delivery were observed with Corplex Memantine. Although some subjects experienced significant skin irritation in the PK study, acceptable skin tolerability was observed in a follow-on wear study for a three-day patch, using a modified application procedure and configuration.
- | Results support advancing Corplex Memantine into further clinical development for the three-day patch, and following further optimization, evaluating a once-weekly dosing regimen.

"These Phase 1 pharmacokinetic results provide a strong foundation for taking Corplex Memantine into further clinical development," said Parminder "Bobby" Singh, Ph.D., Chief Technology Officer and Vice President, Research and Development at Corium. "We are very encouraged by the outcome of this study, especially combined with our recently announced successful Phase 1 results for Corplex Donepezil. Corium is making rapid progress in developing transdermal product candidates for the two most-prescribed Alzheimer's disease therapeutics with the potential to offer important benefits for patients and their caregivers across all stages of the disease."

### Study Design

The Phase 1 PK study was performed at a single trial site in Australia in healthy volunteers aged 50 to 80 (average age 65 years).

The study evaluated three treatments in a partial crossover design: a once-weekly Corplex patch targeted to deliver 28 mg/day of memantine, a three-day Corplex patch targeted to deliver 28 mg/day of memantine and a once-daily Namenda XR 28 mg capsule administered consecutively for seven days. The primary objective was to assess the pharmacokinetics of single-dose Corplex Memantine compared to daily oral administration of Namenda XR. The secondary objectives were

assessment of safety and skin tolerability. As part of the Phase 1 protocol, a separate clinical wear study was conducted to evaluate the effects of a modified patch application procedure and configuration on skin tolerability and adhesion for a three-day Corplex patch. The patch formulation used in the wear study was identical to the formulation used in the PK study.

Corium plans to submit the full results of this Phase 1 clinical study for presentation at a future scientific meeting.

### **Conference Call and Webcast Details**

Corium will host a live webcast and conference call to discuss topline results from the Phase 1 PK clinical study of Corplex Memantine on Monday, February 22, 2016 at 5:00 p.m. Eastern time (2:00 p.m. Pacific time).

Investors and analysts can access the conference call toll-free by dialing (844) 831-3024 (United States) or +1 (315) 625-6887 (international). The conference ID# is 56128832. The live webcast with slides can be accessed under "Events and Presentations" on the Investors section of Corium's website at <http://ir.coriumgroup.com/events.cfm>. Please access the website 10 minutes prior to the start of the call to ensure adequate time for any software downloads that may be necessary. A replay of the conference call and webcast will be available for two weeks and may be accessed by dialing toll-free (855) 859-2056 (United States) or +1 (404) 537-3406 (international) and entering the conference ID# 56128832, or by visiting Corium's website.

### **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 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<sup>1</sup> 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.<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.

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, and is known to cause gastrointestinal side effects.

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. Corium recently announced topline interim results of its successful Phase 1 clinical study of Corplex™ Donepezil, a once-weekly transdermal formulation of donepezil.

### **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](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 timing and plans, the achievement of clinical and commercial milestones, and the advancement of our technologies and our proprietary, co-developed 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 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.

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

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