February 3, 2016

Corium Announces Positive Topline Results From Phase 1 PK Clinical Study of Once-Weekly Transdermal Corplex™ Donepezil as a Potential Treatment of Alzheimer's Disease

Demonstrates Sustained Delivery, Acceptable Skin Tolerability, and Pharmacokinetic Profile to Support the Feasibility of Once-Weekly Dosing

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

MENLO PARK, Calif., Feb. 03, 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™ Donepezil transdermal delivery system for the treatment of mild, moderate and severe dementia of the Alzheimer's type. Donepezil (the active ingredient in Aricept®) is the leading acetylcholinesterase inhibitor approved by the U.S. Food and Drug Administration for daily use in oral tablets and disintegrating tablets for the treatment of Alzheimer's disease. Corium's product candidate is designed for sustained and controlled delivery of the drug in a convenient, once-weekly dosage form, and incorporates its Corplex technology, which Corium developed to enable sustained transdermal delivery of a wide range of drugs.

The purpose of the Phase 1 study was to evaluate the pharmacokinetics, safety and tolerability of once-weekly, single-dose Corplex Donepezil in healthy volunteers aged 50-80, compared to Eisai's Aricept once-daily oral tablet taken for seven consecutive days.

Key Topline Results from the Phase 1 Study:

- After a single application of the once-weekly Corplex Donepezil patch, plasma concentrations approached steady state at day 7. The average plasma concentration on day 7 with Corplex Donepezil was higher than the comparator, 5 mg oral Aricept, and was approximately 70% of the expected plasma concentration of 10 mg oral Aricept.
- PK and statistical projections for subsequent weeks of therapy at steady state predict a highly similar exposure between once-weekly Corplex Donepezil and continued daily oral administration of Aricept.
- Sustained and controlled delivery of donepezil was demonstrated in the plasma concentrations of all subjects treated with once-weekly Corplex Donepezil, supporting the feasibility of a convenient once-weekly dosing regimen, as compared to daily oral administration.
- Active metabolite formation was minimal and similar for both the transdermal and oral routes of administration, indicating that there were no changes in metabolite concentration in plasma associated with drug absorption through the skin.
- Subjects treated with once-weekly Corplex Donepezil experienced acceptable skin tolerability and no systemic adverse events unique to transdermal delivery.
- Results support advancing Corplex Donepezil into further clinical development, which will include optimizing the patch for a once-weekly administration delivering 10 mg/day.

"We are very pleased with the Phase 1 pharmacokinetic results, which provide a solid basis for advancing Corplex Donepezil into further clinical development," said Parminder "Bobby" Singh, Ph.D., Chief Technology Officer and Vice President, Research and Development at Corium. "The clinical data demonstrate the potential for a once-weekly donepezil patch that reliably delivers sustained and controlled pharmacokinetics comparable to the daily oral administration of Aricept. These results further validate the ability of Corium's Corplex platform to administer difficult to deliver drugs across the skin, and to advance the breadth of our transdermal pipeline."

Study Design

The study was performed at a single trial site in Australia in healthy volunteers aged 50 to 80 (average age 69 years).

Early in the study, subjects starting on a 10 mg oral dose experienced adverse events consistent with the oral product labeling. The intensity of these events led to discontinuation of the 10 mg oral dosing, and the 5 mg oral dose was used as the sole comparator.

The study was subsequently conducted as a single-dose, two-period crossover study of nine subjects, with each subject receiving two treatments: a once-weekly Corplex patch targeted to deliver 5 mg/day of donepezil; and a once-daily Aricept 5 mg tablet administered consecutively for seven days. The primary objective was to assess the pharmacokinetics of single-dose once-weekly Corplex Donepezil compared to daily oral Aricept. The secondary objectives were assessment of safety and skin tolerability.

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 Donepezil on Wednesday, February 3, 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 45051957. 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 # 45051957, 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 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[1] 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.[2] 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 as a once-daily tablet, 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 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 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 Annual Report on Form 10-K for the year ended September 30, 2015, filed with the Securities and Exchange Commission on December 16, 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 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.

[1,2]2015 ALZHEIMER'S DISEASE FACTS AND FIGURES, Alzheimer's Association

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