FOR IMMEDIATE RELEASE

Corium, Inc. Announces FDA Filing Acceptance of New Drug Application for ADLARITY® (donepezil transdermal system) for the Treatment of Alzheimer’s Disease

MENLO PARK, Calif., January 27, 2020 (GLOBE NEWSWIRE) – Corium, Inc., a commercial-stage biopharmaceutical company leading the development of novel transdermal healthcare products that are intended to provide alternative treatment options for patients and their families, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the company’s New Drug Application (NDA) for ADLARITY (donepezil transdermal system), its lead investigational agent for the treatment of dementia of the Alzheimer’s type in patients with mild, moderate, and severe Alzheimer’s disease. FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of July 30th, 2020.

“We are thrilled with FDA’s acceptance of Corium’s NDA filing for ADLARITY,” said Perry J. Sternberg, President and CEO of Corium. “If approved, this product could represent the first once-weekly transdermal formulation of donepezil for the treatment of Alzheimer’s disease.”

“Unfortunately, very few treatments are currently available for Alzheimer’s disease. ADLARITY could provide a meaningful new option for patients living with this devastating disease, as well as their caregivers,” said Richard Isaacson, M.D., associate professor of neurology and director of the Alzheimer’s Prevention Clinic at Weill Cornell Medicine, who has also served on an advisory board at Corium.

About ADLARITY

ADLARITY (donepezil transdermal system) is an investigational, once-weekly transdermal formulation of Pfizer’s Aricept® (donepezil HCL) that leverages Corium’s proprietary Corplex™ technology platform. Corplex technology enables the development of new transdermal therapeutics incorporating small molecule drugs previously thought to have been incapable of delivery through the skin. The active ingredient, donepezil, is the most widely prescribed medication in a class of Alzheimer’s drugs known as cholinesterase inhibitors and is currently approved by FDA for the treatment of mild, moderate and severe forms of the disease. Donepezil is currently only available in tablet or orally disintegrating tablet form, each administered once daily, and is known to cause gastrointestinal side effects.

Corium is seeking approval of ADLARITY under the 505(b)(2) regulatory pathway, referencing Aricept data, for both a 5mg/day and 10mg/day transdermal patch that would be applied to the skin once weekly. Corium believes that ADLARITY has the potential to improve the quality of life of patients and their caregivers by promoting adherence to prescribed therapy with a less frequent once a week dosing regimen. In clinical trials, ADLARITY also demonstrated the potential to reduce gastrointestinal side effects compared to the daily dosing of oral donepezil.
About Alzheimer’s Disease

Alzheimer’s disease is a progressive brain disorder in which brain cells degenerate and die, causing a steady decline in memory and mental function. According to the Alzheimer’s Association, an estimated 5.8 million Americans were living with Alzheimer’s disease in 2019; by 2050, this number is projected to rise to 13.8 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.

About Corium

Corium, 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 including Mayne Pharma 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. In November 2018, all of Corium’s outstanding stock was acquired by an affiliate of Gurnet Point Capital. For further information, please visit www.coriumintl.com.

About Gurnet Point Capital

Gurnet Point Capital is a unique healthcare fund founded by Ernesto Bertarelli and led by Chris Viehbacher, who, together, have decades of expertise in an industry for which they share a passion, both as Chief Executives and as investors. With an initial allocation of $2 billion, GPC is investing long-term capital and supporting entrepreneurs in building a new generation of companies. Based in Cambridge, MA, its remit is global, encompassing life sciences and medical technologies. The fund invests across all stages of product development through to commercialization and does so with an approach that is a hybrid of venture and private equity investing strategies. www.gurnetpointcapital.com

ADLARITY®, Corplex™ and MicroCor® are registered trademarks of Corium, Inc.
Aricept® is a registered trademark of Eisai Inc.

###

Contact:
Corium, Inc.
Christina Dickerson
christina@coriumtech.com
(650) 298-8257