

## **Corium Launches ADLARITY® (donepezil transdermal system) for Patients with Alzheimer's Dementia**

***First once-weekly transdermal system offering continuous delivery of donepezil, most-commonly prescribed Alzheimer's dementia drug***

### ***Broadens Corium's CNS drug portfolio***

Boston, MA, September 29, 2022 – Corium, Inc., a fully-integrated biopharmaceutical company leading the development and commercialization of novel central nervous system (CNS) therapies, announced today that ADLARITY (donepezil transdermal system) is now available for prescription in the U.S. for the treatment of patients with mild, moderate, or severe dementia of the Alzheimer's type.

ADLARITY, approved by the U.S. Food and Drug Administration in March 2022, is the first and only once-weekly patch to continuously deliver consistent doses of donepezil through the skin, enabling a favorable overall gastrointestinal (GI) side effect profile. Donepezil, an acetylcholinesterase inhibitor and the active ingredient in the oral medication Aricept®, is the most prescribed Alzheimer's dementia medication. Patients may be switched by their prescriber from a daily 5 mg or 10 mg dose of oral donepezil directly to the once-weekly ADLARITY, which is available in daily 5 mg or 10 mg transdermal formulations.

"We are thrilled to be launching ADLARITY and feel fortunate for the opportunity to provide patients living with Alzheimer's dementia, their families, and their caregivers a new, innovative way to deliver donepezil in a consistent and well-tolerated option," said Perry Sternberg, President and Chief Executive Officer of Corium. "The launch of ADLARITY demonstrates the value of Corium's innovative CORPLEX™ technology and our commitment to providing treatment options that address unmet needs for CNS conditions. I want to thank our people, whose tireless commitment made the possibility of helping millions of people in the U.S. living with Alzheimer's disease a reality."

"I can see this weekly patch helping patients and caregivers by providing the ease of a once-weekly treatment with continuous donepezil delivery through the skin," said Lori La Bey, founder of Alzheimer's Speaks, a patient advocacy organization, and caregiver of a family member with Alzheimer's.

ADLARITY became available through wholesalers as of September 19, 2022, and has received first-line formulary coverage for patients with some commercial insurances, with more expected as the year progresses. Corium is working with the U.S. Centers for Medicare and Medicaid Services toward greater patient accessibility through government-sponsored programs, including Medicare Part D, with coverage expected to begin in 2023. Corium is taking a phased approach to launching ADLARITY. As Medicare becomes available, Corium will broaden launch efforts, with a nationwide launch planned for 2023.

Physicians interested in receiving more information or resources can request field representative support via <http://www.adlarityhcp.com/>. Corium also is supporting patient access to ADLARITY under CoriumCares™, a patient access and support program offering information about access and reimbursement as well as copay assistance for eligible commercially-insured patients. More information is available at <http://www.adlarity.com/savings-and-support> or (800) 433-4893.

## **About Alzheimer's Disease**

Alzheimer's disease is a progressive and irreversible brain disorder. It involves changes in brain tissue including abnormal buildup of proteins as well as loss of neuron function. The resulting damage leads to the loss of remembering, reasoning, and thinking abilities. Dementia ranges in severity from mild, when it is just beginning to affect a person's functioning, to moderate, to severe, when the person must depend on others for the basic activities of day-to-day life. Patients with Alzheimer's disease also develop changes to their swallowing during early to mid-stage disease that can progress to dysphagia, or swallowing impairment, in later stages. Dysphagia increases their risk of dehydration, or aspiration, which frequently leads to aspiration pneumonia, a common cause of death among these patients. The related behavioral changes also include the loss of independence in activities of daily living and self-care.

An estimated 6.5 million Americans older than 65 were living with Alzheimer's disease in 2022, with a possible rise to 14 million by 2060. Globally, more than 55 million people have dementia, and Alzheimer's disease may account for 60 to 70 percent of patients, according to the World Health Organization. The U.S. Centers for Disease Control and Prevention estimates that in 2021 more than 11 million Americans provided an estimated 16 billion hours of unpaid care for patients with Alzheimer's disease.

## **About CORPLEX**

Corium has deep expertise in transdermal technology and an industry-leading track record of developing and manufacturing transdermal products. ADLARITY's approval and launch represent important milestones for Corium's proprietary CORPLEX transdermal technology in the prescription market, which builds on the success of CORPLEX use in leading consumer health products for over a decade. CORPLEX was developed with the goal of optimizing clinical benefits for patients by delivering continuous, controlled, and sustained release of a drug over a defined time. Corium's pipeline portfolio includes a focus on developing other CNS therapies that leverage its CORPLEX technology.

## **About Corium**

Corium, Inc., is a fully-integrated biopharmaceutical company that is leading the development and commercialization of CNS therapies that provide physicians with innovative treatment options for patients, their families, and their caregivers. Corium is commercializing two U.S. FDA approved products, ADLARITY and AZSTARIS. For

further information, please visit <http://www.corium.com>.

## About Gurnet Point Capital

Gurnet Point Capital is a unique healthcare investment platform within the B-Flexion group and led by a team with deep expertise in an industry for which they share a passion, both as investors and senior executives. GPC invests long-term capital and supports entrepreneurs in building a new generation of companies that deliver outsized returns through active ownership. Based in Cambridge, MA, its remit encompasses life sciences and health care focused businesses, with a particular emphasis on businesses that have high growth potential in the product development and commercialization stages of their evolution. With its strategy of driving best in class operational transformation for these businesses, to create social impact while generating significant economic value, GPC is able to deliver differentiated results for its investors and partners. For more, go to <http://www.gurnetpointcapital.com>.

## INDICATION

ADLARITY is indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type.

**IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS** ADLARITY is contraindicated in patients with known hypersensitivity to donepezil or to piperidine derivatives or with a history of allergic contact dermatitis with use of ADLARITY.

## WARNINGS AND PRECAUTIONS

- **Application site skin reactions:** ADLARITY may cause skin application-site reactions. These reactions are not necessarily indicative of sensitization; however, allergic contact dermatitis may occur and should be suspected if application-site reactions spread beyond the size of the transdermal system, there is evidence of a more intense local reaction, and symptoms do not significantly improve within 48 hours of transdermal system removal.
- **Anesthesia:** ADLARITY is likely to exaggerate succinylcholine-type muscle relaxation during anesthesia.
- **Cardiovascular conditions:** ADLARITY may have vagotonic effects on the sinoatrial and atrioventricular nodes. These effects may manifest as bradycardia or heart block in patients both with and without known underlying cardiac conduction abnormalities. Syncopal episodes have been reported in association with the use of donepezil.
- **Nausea and vomiting:** ADLARITY may cause diarrhea, nausea, and vomiting. Although in most cases these effects have been transient, some cases lasted 1 to 3 weeks. Patients should be monitored closely during initiation and titration of ADLARITY.
- **Peptic ulcer disease and gastrointestinal bleeding:** ADLARITY may increase gastric acid secretion. Patients should be monitored closely for active or occult gastrointestinal bleeding, especially those with a history of ulcer disease or those receiving concurrent nonsteroidal anti-inflammatory drugs (NSAIDs).
- **Genitourinary conditions:** Although not observed in clinical trials of ADLARITY, bladder outflow obstruction may occur.

- **Seizures:** ADLARITY is believed to have some potential to cause generalized convulsions; however, seizure activity may also be a manifestation of Alzheimer's disease.
- **Pulmonary conditions:** ADLARITY should be prescribed with care to patients with a history of asthma or obstructive pulmonary disease.

### **ADVERSE REACTIONS**

The most common side effects of ADLARITY (>3%) were headache (15%), application site pruritus (9%), muscle spasms (9%), insomnia (7%), abdominal pain (6%), application site dermatitis (6%), constipation (6%), diarrhea (4%), application site pain (4%), dizziness (4%), abnormal dreams (4%) and skin laceration (4%).

### **DRUG INTERACTIONS**

Cholinesterase inhibitors, including donepezil, have the potential to interfere with the activity of anticholinergic medications. A synergistic effect may be expected when cholinesterase inhibitors are given concurrently with succinylcholine, similar neuromuscular blocking agents, or cholinergic agonists such as bethanechol.

***For additional safety information, click here for the [Prescribing Information](#) and [Patient Information](#).***

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

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