Corium Receives March 11, 2022 PDUFA Date for New Drug Application for ADLARITY® Patch (donepezil transdermal system) for Treatment of Patients with Alzheimer's Disease

Potential for company's second FDA approval in 12 months, affirming Corium 's strong CNS presence

Boston, MA, October 12, 2021 – Corium, Inc., a commercial-stage biopharmaceutical company leading the development and commercialization of novel central nervous system (CNS) therapies, announced today the U.S. Food and Drug Administration (FDA) set a Prescription Drug User Fee (PDUFA) target action date of March 11, 2022 for Corium's new drug application (NDA) for once-weekly ADLARITY (donepezil transdermal system), its lead investigational product and a patch formulation of donepezil for the treatment of patients with dementia due to mild, moderate, or severe Alzheimer's disease. If approved, ADLARITY would be Corium's second CNS product approved for the U.S. market in 12 months.

"Having ADLARITY under consideration by the FDA reflects the significant R&D expertise at Corium. With ADLARITY, Corium has leveraged our innovative Corplex technology to improve the most commonly used first-line treatment for patients with Alzheimer's," said Perry J. Sternberg, President and CEO of Corium. "Our team at Corium is committed to addressing the unmet treatment needs for the Alzheimer's community and others impacted by CNS diseases by developing innovative medicines. We look forward to the FDA's decision early next year."

ADLARITY is a transdermal formulation of donepezil made possible by Corium's proprietary Corplex™ technology. Corplex enables transdermal therapeutics that incorporate small molecule drugs previously thought incapable of delivery through the skin. The ADLARITY transdermal patch is constructed to be worn for seven days with consistent adhesion, a delivery method that avoids the difficulties associated with daily delivery of an oral medication for patients with significant memory problems. Corium also is developing Corplex for the delivery of drugs to treat patients with other CNS conditions, diseases in other therapeutic areas and consumer products beyond those for which it currently is used.

Donepezil, the most prescribed medication in a class of Alzheimer's drugs known as cholinesterase inhibitors, is the active ingredient in Aricept®. The FDA previously approved donepezil as a once-daily tablet and as an orally disintegrating tablet for the treatment of patients with mild, moderate, or severe forms of the disease. With the slow and steady releasing of donepezil, the ADLARITY transdermal system regularly delivers the drug through the skin, a design meant to avoid gastrointestinal tract absorption and associated side effects. Corium is seeking approval of two transdermal ADLARITY doses capable of delivering, respectively, 5 or 10 milligrams of donepezil daily.

Corium is pursuing the approval of ADLARITY via the FDA's 505(b)(2) regulatory pathway and referencing Aricept data. Corium resubmitted the ADLARITY NDA to address questions asked by

the FDA in a July 2020 complete response letter. The resubmitted NDA includes data from three clinical trials conducted following receipt of the FDA letter.

About Alzheimer's Disease

Alzheimer's disease is a progressive and irreversible brain disorder that lacks a cure. It involves changes in brain tissue including abnormal buildup of proteins as well as loss of neuron function.[1] The resulting damage leads to the loss of remembering, reasoning, and thinking abilities. The related behavioral changes include the loss of independence in activities of daily living and self-care.[2,3]

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.[4] In the United States, an estimated 6.2 million Americans aged 65 and older live with Alzheimer's disease in 2020, but by 2030, the number is projected to increase to 8.2 million, and in 2040, 11.1 million.[5,6] The U.S. Centers for Disease Control and Prevention estimates that in 2020, more than 11 million Americans provided an estimated 15.3 billion hours of unpaid care for patients with Alzheimer's disease, a contribution valued at $257 billion.[7] Alzheimer's disease is the sixth leading cause of death in U.S. adults.[8]

Other Recent Corium Developments

In July 2021, Corium commercially launched AZSTARYS® in the U.S. for the treatment of ADHD in patients 6 years of age and older, following FDA approval in March 2021. In September 2021, Corium closed on a $235 million term loan agreement with Hercules Capital, Inc., a leader in specialty financing for life science and technology companies.

About Corium

Corium, Inc. is a commercial-stage biopharmaceutical company that is leading the development and commercialization of central nervous system (CNS) therapies that provide clinicians with important treatment options for patients, their families, and their caregivers. Corium product AZSTARYS was approved by the FDA for the treatment of ADHD in patients 6 years of age and older in March 2021. In addition, Corium has a robust developmental pipeline focused on addressing other unmet needs in the treatment of CNS conditions. Corium also has a contract development and manufacturing operation in Grand Rapids, MI, that has expertise in the manufacture of transdermal applications of drugs and other products, and which manufactures ADLARITY, and prescription drug and consumer products for other companies. In November 2018, all of Corium's outstanding stock was acquired by an affiliate of Gurnet Point Capital. For further information, please visit www.corium.com

Corium President and CEO is Perry J. Sternberg, a biotechnology and pharmaceutical industry leader with more than 25 years of commercial experience across a wide range of therapeutic areas, including ADHD in diverse markets. Prior to joining Corium, Mr. Sternberg served a dual role at Shire Plc (Shire) as the Head of U.S. Commercial for seven therapeutic area business units, as well as the Chief Commercial Officer/Head of the Neuroscience Division, before the acquisition of Shire by Takeda Pharmaceutical Corporation Limited in early 2019.

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

Indication and Important Safety Information for AZSTARYS

AZSTARYS is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients aged 6 years and older.

WARNING: AZSTARYS is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep AZSTARYS in a safe place to prevent misuse and abuse. Selling or giving away AZSTARYS may harm others and is against the law.

Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Who should not take AZSTARYS?

Do not take AZSTARYS if you or your child are:

- allergic to serdexmethylphenidate, methylphenidate, or any of the ingredients in AZSTARYS.
- taking or have stopped taking within the past 14 days a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

Serious problems can occur while taking AZSTARYS. Tell your healthcare provider:

- if you or your child have heart problems, heart defects, high blood pressure, or a family history of these problems. Sudden death has occurred in people with heart problems or defects taking stimulant medicines. Sudden death, stroke and heart attack have happened in adults taking stimulant medicines. Your doctor should check you or your child carefully for heart problems before starting AZSTARYS. Since increases in blood pressure and heart rate may occur, the doctor should regularly check these during treatment. **Call your healthcare provider right away or go to the nearest hospital emergency room if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking AZSTARYS**.
- if you or your child have mental (psychiatric) problems, or a family history of suicide, bipolar illness, or depression. New or worse behavior and thought problems or new or

worse bipolar illness may occur. New psychotic symptoms (such as seeing or hearing things that are not real, believing things that are not true, being suspicious) or new manic symptoms may occur. **Call your healthcare provider right away if there are any new or worsening mental symptoms or problems** during treatment.

- if you or your child develop painful and prolonged erections (priapism), seek medical help right away. Priapism has occurred with methylphenidate (AZSTARYS). Because priapism can cause long-lasting damage, it should be checked by a healthcare professional right away
- if you or your child have circulation problems in fingers and toes (called peripheral vasculopathy, including Raynaud's phenomenon). Fingers or toes may feel numb, cool, painful, sensitive to temperature, and/or change color from pale, to blue, to red. **Call your healthcare provider right away if any signs of unexplained wounds appear on fingers or toes while taking AZSTARYS**.
- if your child is having slowing of growth (height and weight); Your child should have his or her height and weight checked often while taking AZSTARYS.
- if you or your child are pregnant or plan to become pregnant. It is not known if AZSTARYS may harm your unborn baby.
- if you or your child are breastfeeding or plan to breastfeed. AZSTARYS passes into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take AZSTARYS.

What are possible side effects of AZSTARYS?

The most common side effects of AZSTARYS include:

- decreased appetite
- nausea
- indigestion
- weight loss
- dizziness
- mood swings
- increased blood pressure
- trouble sleeping
- vomiting
- stomach pain
- anxiety
- irritability
- increased heart rate

These are not all the possible side effects of AZSTARYS. Call your doctor for medical advice about side effects.

What is AZSTARYS?

AZSTARYS is a central nervous system (CNS) stimulant prescription medicine for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. AZSTARYS may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

For additional safety information, click here for Prescribing Information and Medication Guide and discuss with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Contact:
Corium, Inc.
Heather Gartman
Gartmanpr@gmail.com
202-413-4226

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[1] National Institute on Aging. Alzheimer's Disease Fact Sheet. July 8, 2021. Accessed at https://www.nia.nih.gov/health/alzheimers-disease-fact-sheet.
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[3] Matthews KA, Xu W, Gaglioti AH, et al. Racial and ethnic estimates of Alzheimer's disease and related dementias in the United States (2015-2060) in adults aged ≥65 years. Alzheimers Dement. 2019;15(1):17-24. doi:10.1016/j.jalz.2018.06.3063.
[4] World Health Organization. Dementia. Sept 2, 2021. Accessed at https://www.who.int/news-room/fact-sheets/detail/dementia.
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