Corium to Present Positive Data on ADHD Medication AZSTARYS® (serdexmethylphenidate and dexmethylphenidate) and Alzheimer's Disease Medication ADLARITY® (donepezil transdermal system) at Psych Congress 2022

Debut of sleep effects, disorder severity reduction and real-world analysis data on AZSTARYS, first and only ADHD medication with novel prodrug of dexmethylphenidate

Report of comparison with oral donepezil and skin effects data on ADLARITY, first and only once-weekly patch for patients with mild, moderate, or severe dementia of the Alzheimer's type

BOSTON, September 13, 2022 /PRNewswire/ -- Corium, Inc., a commercial-stage biopharmaceutical company leading the development and commercialization of novel central nervous system (CNS) therapies, announces the debut of positive data on September 18, 2022, at the upcoming Psych Congress 2022 in New Orleans about its two FDA-approved medicines, AZSTARYS (serdexmethylphenidate [SDX] and dexmethylphenidate [d-MPH]) for patients six and older with ADHD, and ADLARITY (donepezil transdermal system) for patients with mild, moderate, or severe dementia of the Alzheimer's type.

The five poster presentations affirm Corium's progress in developing transformative medicines that improve the health of patients with CNS disorders. Among the three posters reporting new AZSTARYS findings are the debut of analysis of the medicine's effects on children's sleep, disorder severity reduction, and real-world usage. The two ADLARITY posters will report bioequivalence and safety comparisons with oral donepezil and new skin tolerability results of the transdermal formulation.

"The positive data from Corium that will be featured at Psych Congress 2022 deliver meaningful knowledge about our two CNS treatments, AZSTARYS for ADHD and ADLARITY for dementia due to Alzheimer's disease," said Charles Oh, M.D., Chief Medical Officer of Corium. "Our broad participation at Psych Congress is also a significant milestone highlighting Corium's ongoing commitment and leadership in the CNS therapeutic space."

Corium's Psych Congress 2022 posters will be presented on Sunday, September 18, and Monday, September 19, from 1:30 to 3:00 pm CDT (2:30 to 4:00 pm EDT) in Hall D of the New Orleans Convention Center:

Poster #	Title	Authors (presenting author in bold)
AZSTARYS		
Poster 52	Serdexmethylphenidate/Dexmethylphenidate Effects on Sleep in Children With Attention-Deficit Hyperactivity Disorder.	**Greg Mattingly, MD;** Ann C. Childress, MD; Andrew J. Cutler, MD; Jose Estrada, PhD; and Meg Corliss, PhD
Poster 109	Serdexmethylphenidate/Dexmethylphenidate for Children With Attention-Deficit Hyperactivity Disorder: Reduction in Disorder Severity From a Laboratory Classroom Study	Ann C. Childress, MD; Scott Kollins, PhD; Andrew C. Barrett, PhD; Rene Braeckman, PhD; Sven Guenther, PhD; Travis C. Mickle, PhD; Charles Oh, MD; and **Matthew Brams, MD**
Poster 112	A Retrospective Real-World Analysis Demonstrating the Value of Azstarys for Patients With Attention-Deficit Hyperactivity Disorder	Steve Faraone, PhD; Mara Lenco, MS; **Meg Corliss, PhD; and** Charles Oh, MD
ADLARITY		
Poster 21	Bioequivalence and Safety Comparison of Once-Weekly Donepezil Transdermal System With Oral Donepezil: Results of a Phase 1 Pharmacokinetic Study in Healthy Volunteers	Pierre Tariot, MD; Rene Braeckman, PhD; and **Charles Oh, MD**
Poster 22	Evaluation of Skin Adhesion and Local Skin Tolerability of Once-Weekly Donepezil Transdermal System: Results of a Phase 1 Trial in Healthy Volunteers	Pierre Tariot, MD; Rene Braeckman, PhD; and **Charles Oh, MD**

About AZSTARYS

AZSTARYS, approved for patients aged 6 years and older, is the first and only once daily treatment for ADHD symptoms containing SDX, the prodrug of d-MPH. SDX is designed specifically to be pharmacologically inactive until reaching a patient's lower gastrointestinal (GI) tract, where, by design, the prodrug gradually converts to d-MPH throughout the day. This formulation provides control of ADHD symptoms both rapidly with the immediate-release d-MPH and for an extended duration with SDX. Once-daily AZSTARYS is available in the U.S. in three SDX/d-MPH dose strengths of 26.1/5.2 mg, 39.2/7.8 mg, and 52.3/10.4 mg.

About ADLARITY

ADLARITY is the first and only once-weekly patch to continuously deliver consistent doses of donepezil through the skin, resulting in a low likelihood of the adverse GI side effects and fluctuations in drug concentrations associated with oral donepezil. Donepezil is the most prescribed medication in a class of Alzheimer's drugs known as acetylcholinesterase inhibitors and is the active ingredient in the oral medication Aricept®. ADLARITY is the first approved prescription drug product using Corium's proprietary CORPLEX™ transdermal technology,

which has been used for years in consumer products.

About ADHD
ADHD is a common neurodevelopment disorder marked by an ongoing pattern of inability to pay attention or hyperactivity with impulsive behaviors, or both, which interferes with functioning or development. ADHD usually is diagnosed during childhood but often continues into adulthood. Children with ADHD may have trouble paying attention, controlling impulsive behaviors (may act without thinking about what the result will be), or be overly active. In the United States, an estimated 6.1 million children have received an ADHD diagnosis, including 2.4 million aged 6 to 11 years.

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. The related behavioral changes include the loss of independence in activities of daily living and self-care. Dementia ranges in severity from mild, when it is just beginning to affect a person's functioning, to severe, when the person must depend on others for the basic activities of day-to-day life.

An estimated 6.2 million Americans were living with Alzheimer's disease in 2021, with a possible rise to 13.8 million by 2060. Globally, more than 55 million people have dementia, and Alzheimer's disease may account for 60 to 70 percent of patients with dementia, according to the World Health Organization. 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.

Indication and Important Safety Information for AZSTARYS (serdexmethylphenidate and dexmethylphenidate)

INDICATION
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.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE
• CNS stimulants, including AZSTARYS, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy

CONTRAINDICATIONS
• Known hypersensitivity to serdexmethylphenidate, methylphenidate, or other product components. Bronchospasm, rash, and pruritus have occurred with AZSTARYS.

Hypersensitivity reactions such as angioedema and anaphylactic reactions have occurred with other methylphenidate products.
• Concomitant treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days, because of the risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS
• Sudden death has been reported in association with CNS stimulant treatment at recommended doses in pediatric patients with structural cardiac abnormalities or other serious heart problems. In adults, sudden death, stroke, and myocardial infarction have been reported at recommended doses. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmias, coronary artery disease, or other serious heart problems.
• CNS stimulants cause an increase in blood pressure and heart rate. Monitor all patients for hypertension and tachycardia.
• *Exacerbation of Pre-existing Psychosis*: May exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. *Induction of a Manic Episode in Patients with Bipolar Disorder*: May induce a mixed/manic episode in patients with bipolar disorder. Prior to initiating treatment, screen for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms, or a family history of suicide, bipolar disorder, or depression). *New Psychotic or Manic Symptoms*: At recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a history of psychotic illness or mania. Discontinue if symptoms occur.
• Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed.
• CNS stimulants, including AZSTARYS, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; very rare sequelae include digital ulceration and/or soft tissue breakdown. Carefully observe patients during treatment for digital
changes. Further evaluation may be required, including referral.
• CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Monitor height and weight at appropriate intervals in pediatric patients. Treatment may need to be interrupted in children not growing or gaining weight as expected.

ADVERSE REACTIONS
• Based on accumulated data from other methylphenidate products, the most common (>5% and twice the rate of placebo) adverse reactions are appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased.

DRUG INTERACTIONS
• Adjust dosage of antihypertensive drug as needed. Monitor blood pressure.
• Avoid use of AZSTARYS on the day of surgery if halogenated anesthetics will be used.

For additional safety information, click here for Prescribing Information and Medication Guide, including BOXED WARNING.

Indication and Important Safety Information for ADLARITY (donepezil transdermal system)

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**: Skin application-site reactions have occurred with ADLARITY. 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, as a cholinesterase inhibitor, is likely to exaggerate succinylcholine-type muscle relaxation during anesthesia.
• **Cardiovascular conditions**: Cholinesterase inhibitors, including 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**: Donepezil has been shown to produce diarrhea, nausea, and vomiting. Although in most cases these effects have been transient, some cases lasted 1 to 3 weeks. Patients should be observed closely during initiation and titration of ADLARITY.
• **Peptic ulcer disease and gastrointestinal bleeding**: Cholinesterase inhibitors, including ADLARITY, may increase gastric acid secretion. Patients should be monitored closely for symptoms of active or occult gastrointestinal bleeding, especially those with a history of ulcer disease or those receiving concurrent nonsteroidal anti-inflammatory drugs (NSAIDs). Clinical studies of donepezil tablets in a dose of 5 mg/day to 10 mg/day have shown no increase, relative to placebo, in the incidence of either peptic ulcer disease or gastrointestinal bleeding.
• **Genitourinary conditions**: Although not observed in clinical trials of ADLARITY, cholinomimetics, including ADLARITY, may cause bladder outflow obstruction.
• **Seizures**: Cholinomimetics, including ADLARITY, are believed to have some potential to cause generalized convulsions; however, seizure activity may also be a manifestation of Alzheimer's disease.
• **Pulmonary conditions**: Cholinesterase inhibitors, including ADLARITY, should be prescribed with caution to patients with a history of asthma or obstructive pulmonary disease.

ADVERSE REACTIONS
The most common side effects (>3%) of ADLARITY 10 mg/day TDS 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 ADLARITY, 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, or call 1-800-FDA-1088.

About Corium
Corium, Inc., is a commercial-stage biopharmaceutical company that is leading the development and commercialization of CNS therapies that provide clinicians with important new treatment options for patients, their families, and their caregivers. Corium is commercializing two U.S. FDA approved products, ADLARITY and AZSTARYS. Corium has a robust development pipeline focused on addressing unmet needs in the treatment of patients with CNS conditions. In November 2018, all of Corium's outstanding stock was acquired by an affiliate of Gurnet Point Capital. 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.

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