Significant ADHD Symptom Improvement with 30-Minute Onset and 13-Hour Duration of Efficacy Delivered by Once-Daily Corium Product AZSTARYS® (serdexmethylphenidate and dexmethylphenidate) in Children Ages 6 to 12 Years

First and Only Product Containing Prodrug of Dexmethylphenidate

Complete Phase 3 Trial Data Reported in Journal of Child and Adolescent Psychopharmacology

Boston, MA, October 29, 2021 – Corium, Inc., a commercial-stage biopharmaceutical company leading the development and commercialization of novel central nervous system (CNS) therapies, announced publication of results from its Phase 3 pivotal efficacy study in the November 2021 *Journal of Child and Adolescent Psychopharmacology*. The study showed that Corium's first-in-class, once-daily oral capsule AZSTARYS (serdexmethylphenidate [SDX] and dexmethylphenidate [d-MPH]) significantly improved attention deficit hyperactivity disorder (ADHD) symptoms compared to placebo in children ages 6 to 12 years with a 30-minute onset, 13-hour duration of efficacy, and well-tolerated safety profile comparable to that observed with other stimulant medications. Data from this study will be presented at CHADD's *Virtual International Conference on ADHD.*

"The complete results of the pivotal classroom trial in our peer-reviewed publication show how the novel SDX/d-MPH medication AZSTARYS delivers early and prolonged efficacy throughout the treatment day in children and adolescents with ADHD. These findings are clinically meaningful for parents and health care professionals to aid in evaluating and selecting proven ADHD therapies for their children," said co-author Andrew Cutler, MD, Chief Medical Officer at Neuroscience Education Institute and a Clinical Associate Professor of Psychiatry at SUNY Upstate Medical University.

Corium received approval to market AZSTARYS from the U.S. Food and Drug Administration (FDA) as a once-daily treatment of ADHD symptoms in patients aged 6 years and older on March 2, 2021. AZSTARYS is the first and only medicine containing SDX, a prodrug of d-MPH which provides for an extended duration of d-MPH release throughout the day. Corium launched once-daily AZSTARYS in July 2021 with three SDX/immediate-release d-MPH dose strengths of 26.1/5.2 mg, 39.2/7.8 mg, and 52.3/10.4 mg to meet a wide variety of patients' needs.

"We believe the proven fast onset and prolonged efficacy of AZSTARYS provides patients with ADHD and caregivers an alternative to existing products that can take too long to alleviate symptoms or wear off in the afternoon or early evening," said Charles Oh, MD, Chief Medical Officer of Corium. "We want to thank the trial participants and their families for their contributions in helping develop this first-in-class treatment."

For the pivotal Phase 3 trial (NCT03292952), investigators enrolled 155 children 6 to 12 years of age in a three-week, open-label Dose Optimization Phase. 150 of those children were subsequently randomized to a seven-day, double-blind, placebo-controlled treatment period. Efficacy was established for primary and secondary endpoints.

Primary Efficacy Assessment Shows Significant Reduction of ADHD Symptoms
The primary efficacy assessment was the evaluation of classroom behaviors using the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) Rating Scale – Combined (SKAMP-C). The SKAMP scale is a validated measure of subjective impairment of classroom behaviors in children with ADHD, with lower scores representing reduction of symptoms. The mean change from baseline in SKAMP-C scores collected during the laboratory classroom day was significantly better for AZSTARYS compared to placebo, with respective scores of -4.87 vs. 0.54 and a treatment difference of 5.41 ($p<0.001$).

Rapid Onset with Extended Duration of Action for Significant ADHD Symptom Control
To provide clinicians with data comparable to that from studies of other once-daily methylphenidate products, the investigators conducted a *post hoc* analysis of the mean change from pre-dose baseline to each post-dose assessment conducted at 0.5, 1, 2, 4, 8, 10, 12, and 13 hours during the laboratory classroom day. The post-hoc analysis showed AZSTARYS was statistically superior to placebo starting at 30 minutes after dosing and continuing through 13 hours ($p<0.001$ for 0.5 to 10 hours and $p\leq.02$ for hours 12 and 13).

A secondary endpoint, the Permanent Product Measure of Performance (PERMP), corroborated the early onset at 30 minutes and extended duration of efficacy through 13 hours. The PERMP is a skill-adjusted, 10-minute math test used to assess attention in children with ADHD at various times during the day. The PERMP results in children receiving AZSTARYS were significantly superior to the scores in children receiving placebo ($p<0.001$) averaged across the classroom day.

Well Tolerated ADHD Symptom Management
Investigators reported no serious adverse events (AEs) in the study. Reported AEs were typical of methylphenidate treatment, and the majority were rated as mild to moderate in severity. Those AEs occurring more frequently in the ASZTARYS group (in 2 percent or more of the participants) compared to the placebo group were headache (5.4 vs. 1.3 percent, AZSTARYS and placebo respectively), upper abdominal pain (4.1 vs. 1.3 percent), insomnia (2.7 vs. 1.3 percent), and pharyngitis (sore throat) (2.7 vs. 0 percent).

About AZSTARYS
As a prodrug, SDX is specifically designed to be pharmacologically inactive until reaching the lower gastrointestinal tract, where, by design, SDX is gradually converted to d-MPH throughout the day. The result is a treatment that provides symptom control both rapidly with the immediate-release d-MPH component and for an extended duration with the SDX component.

AZSTARYS, a Schedule II therapy, includes a combination of 70 percent SDX (Schedule IV) and 30 percent immediate-release d-MPH (Schedule II). Based on an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of SDX, the U.S. Department of Health and Human Services (HHS) concluded that "SDX is related in action and effect to the schedule IV substance phentermine and can therefore be expected to have a similar potential for abuse." HHS also affirmed that "in clinical studies, SDX demonstrated a lower potential for abuse when compared to d-MPH."

About ADHD

Attention-deficit hyperactivity disorder (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.

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.

Other Recent Corium Developments

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. In addition, Corium announced in October, that it has received an FDA PDUFA date of March 11, 2022, with respect to its NDA for Adlarity®, a novel patch treatment for Alzheimer's disease.

About Corium

Corium, Inc., is a commercial-stage biopharmaceutical company that is leading the development and commercialization of novel CNS therapies that provide clinicians with important new treatment options for patients, their families, and their caregivers. 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's 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, Massachusetts, 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. For further information, please visit www.gurnetpointcapital.com.

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