Corium To Present at Academy of Managed Care Pharmacy: Fast-Acting AZSTARYS® (serdexmethylphenidate and dexmethylphenidate) Significantly Improves Attention and Behavior in Children Aged 6 to 12 Years With ADHD

First and only product containing prodrug of dexmethylphenidate

Provides 30-minute onset and 13-hour duration of effect

Boston, MA, March 28, 2022 – Corium, Inc., a commercial-stage biopharmaceutical company leading the development and commercialization of novel central nervous system (CNS) therapies, announced that its poster, "Serdexmethylphenidate/d-Methylphenidate Capsules for Children With ADHD: Effects on SKAMP-C Evaluated Over 13 Hours in a Randomized, Double-blind, Placebo-controlled Laboratory Classroom Study," will be presented at the Academy of Managed Care Pharmacy (AMCP) on March 30, 2022, in Chicago, IL. Corium's once-daily oral capsule AZSTARYS (serdexmethylphenidate (SDX) and dexmethylphenidate (d-MPH)), significantly improved both attention and behavior with a 30-minute onset and up to 13 hours of duration in children ages 6 to 12 years diagnosed with attention deficit hyperactivity disorder (ADHD), compared to a placebo. An author will report the findings (poster # F21), from a *post hoc* analysis of a pivotal Phase 3 study, at the AMCP.

The U.S. Food and Drug Administration (FDA) approved AZSTARYS 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. Once-daily AZSTARYS is available nationally in the U.S. in 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.

"This analysis of data previously collected in a pivotal trial demonstrates that the fast onset and long duration of AZSTARYS delivers early and prolonged efficacy to manage attention and behavior throughout the treatment day of patients with ADHD. These results offer patients, parents, and healthcare professionals valuable information to consider when choosing among proven ADHD treatments. We appreciate the opportunity to share this data at the AMCP," said Charles Oh, MD, Chief Medical Officer of Corium.

The findings are from an evaluation of the participants in a placebo-controlled laboratory classroom study (NCT03292952), based on their scores on the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) Rating Scale – Combined (SKAMP-C). The SKAMP-C is a validated measure of classroom behaviors in children with ADHD, with lower scores representing improvement and a reduction of ADHD symptoms. The children, whose

average age was 9.6 years, took the SKAMP-C before receiving AZSTARYS or the placebo and then eight times after dosing, starting at 30 minutes and then at hours 1, 2, 4, 8, 10, 12 and 13.

The primary efficacy measure in the trial was the average change in the SKAMP-C score from before dosing and then at multiple times during the classroom day. The *post hoc* analysis was conducted to align the data with other MPH clinical trial designs, which have used the morning of the classroom day, or an analogous study visit, as the baseline for pre-medication SKAMP-C scores.

The average changes in SKAMP-C scores averaged across all time measures were significantly improved by -5.41 points ($p<0.001$) for participants receiving AZSTARYS compared to those receiving the placebo, with respective score changes of -4.87 vs. 0.54. Similarly, the SKAMP-C scores in the *post hoc* analysis showed significant improvement for children treated with AZSTARYS compared with the placebo group. The onset of treatment effect began at 30 minutes after dosing, with a significant score difference of -3.97 between groups ($P<0.001$), and continued for 13 hours after dosing, with a significant score difference of -3.49 ($P=0.004$).

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).

The trial enrolled 155 children aged 6 to 12 years in a three-week, open-label dose optimization phase. Of those children, 150 were randomized to a seven-day, double-blind, placebo-controlled treatment period.

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 (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.

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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