

Once-Daily AZSTARYS® (serdexmethylphenidate and dexamethylphenidate), First and Only Product Containing Dexamethylphenidate Prodrug for ADHD in Patients Aged 6 Years and Older, Significantly Reduces ADHD Symptoms

Data Presented at American Psychiatric Nurses Association Annual Meeting

Boston, MA, October 14, 2021 – Corium, Inc., a commercial-stage biopharmaceutical company leading the development and commercialization of novel central nervous system (CNS) therapies, announced today its first-in-class once-daily oral capsule AZSTARYS (serdexmethylphenidate [SDX] and dexamethylphenidate [d-MPH]), which was approved by the U.S. Food and Drug Administration (FDA) in March 2021, significantly reduced attention deficit hyperactivity disorder (ADHD) symptoms in children ages 6 to 12 years during a phase 3 controlled classroom clinical trial. The results are being presented in a poster and a Meet the Presenter session on October 15, 2021, during the American Psychiatric Nurses Association (APNA) 35th Annual Conference, held virtually on October 13-16. AZSTARYS is the first and only medicine to add the innovative SDX prodrug with d-MPH.

“The clinical data from the classroom study demonstrate that the first medicine to combine the innovative d-MPH prodrug with d-MPH can safely and effectively improve ADHD symptoms in children. AZSTARYS gives parents and clinicians another option when seeking an ADHD therapy for children” said Ann Childress, M.D., president of the Center for Psychiatry and Behavioral Medicine and an investigator in the AZSTARYS clinical trial.

Data from the trial (NCT03292952) presented at APNA documented AZSTARYS is an effective treatment for ADHD symptoms in children as demonstrated through improvements in both primary and secondary efficacy endpoints. The investigators randomized 150 children to receive AZSTARYS or placebo during a seven-day double-blind treatment period that followed a three-week dose-optimization phase.

The primary efficacy endpoint was the mean change in the Swanson, Kotkin, Agler, M-Flynn, and Pelham Rating Scale – Combined (SKAMP-C) during the classroom day. The mean change from baseline in the SKAMP-C was significantly lower (indicating improvement) with AZSTARYS compared to placebo, -4.87 vs. 0.54, respectively, $p < 0.001$. The validated SKAMP scale rates impairments children may exhibit in classroom behaviors using 13 items and uses a seven-point scale from 0 = normal to 6 = maximal impairment for each item.

AZSTARYS also produced significant improvements in ADHD symptoms as measured by a secondary efficacy endpoint, the Weekly Rating of Evening and Morning Behavior – Revised (WREMB-R). The mean change from baseline in the overall WREMB-R scores for AZSTARYS and placebo were -11.7 vs. -7.2; $p = 0.003$. The validated WREMB-R scale measures 11 behaviors as reported by parents to the study investigators. The scale rates three morning and eight evening behaviors, on a scale of 0 = no difficulty to 3 = a lot of difficulty.

There were no serious Adverse Events, deaths, or overdoses in the study. The majority of treatment effected Adverse Events (TEAEs) were graded as mild or moderate in severity. The TEAEs were similar to those reported for approved methylphenidate drugs.

About AZSTARYS

AZSTARYS was approved by the FDA for once-daily treatment of ADHD symptoms in patients aged 6 years and older on March 3, 2021. AZSTARYS is the first and only medicine containing extended-release SDX, a prodrug of d-MPH. Corium launched AZSTARYS in three once-daily SDX/ immediate-release d-MPH doses in July 2021, providing dosing flexibility to meet the needs of each patient: 26.1/5.2 mg, 39.2/7.8 mg, and 52.3/10.4 mg.

As a prodrug, SDX is specifically designed to be chemically inactive until after absorption via the lower gastrointestinal tract, where SDX is converted to d-MPH that by design is gradually released throughout the day. The result is a treatment that provides symptom control both rapidly with the d-MPH and for an extended duration with SDX.

Additional Clinical AZSTARYS Data Reports

AZSTARYS investigators plan peer-reviewed presentations of additional clinical data about AZSTARYS at upcoming 2021 medical meetings:

- an evaluation of the drug's PK on body weight October 18-30 at the virtual American Academy of Child and Adolescent Psychiatry annual meeting;
- a PK evaluation of AZSTARYS regarding the relative bioavailability of SDX and d-MPH October 29 to November 1 at the U.S. Psych Congress 2021;
- and additional data on the 13-hour efficacy of AZSTARYS on November 4 - 6 at CHADD's 2021 Virtual International Conference on ADHD.

AZSTARYS data also have been accepted for publication in an upcoming peer-review journal.

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.

About Corium

Corium, Inc. is a commercial-stage biopharmaceutical company that is leading the development and commercialization of novel central nervous system (CNS) therapies that provide clinicians with important new treatment options for patients, their families, and their caregivers. Corium is commercializing AZSTARYS in the U.S. Corium's lead developmental compound is pending FDA review for patients with mild, moderate, or severe Alzheimer's disease, with a PDUFA date of March 11, 2022. Corium also has a Contract Development and Manufacturing Operation based in Grand Rapids, MI, which develops and manufactures transdermal drug and consumer products. 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.

###

Contact:

Heather Gartman

Gartmanpr@gmail.com

202-413-4226