U.S. Food and Drug Administration Approves Novel Once-Daily Capsule AZSTARYS™ (serdexmethylphenidate and dexmethylphenidate), First and Only Product Containing Dexmethylphenidate Prodrug for ADHD in Patients Age 6 Years and Older

Boston, MA, March 3, 2021 (PR NEWSWIRE) – 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) approval of once-daily oral capsule AZSTARYS™ (serdexmethylphenidate [SDX] and dexmethylphenidate [d-MPH]), the first and only product containing a d-MPH oral prodrug for the treatment of attention deficit hyperactivity disorder (ADHD) symptoms in patients aged 6 years and older.

AZSTARYS contains 30 percent immediate-release d-MPH and 70 percent extended-release novel SDX, a prodrug of d-MPH. After absorption via the gastrointestinal tract, SDX is converted to d-MPH with a design to gradually release d-MPH throughout the day. The result is a therapy designed to provide symptom control both rapidly with the d-MPH and for an extended duration with SDX. The dual action of AZSTARYS is designed to address the unmet needs in the market, including early onset of action and long duration of therapy, with steady ADHD symptom control in one capsule. The Prescribing Information for AZSTARYS includes a Boxed Warning stating CNS stimulants, including AZSTARYS, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence.

“The data documenting the efficacy and safety of this new dual-action medicine, the first ever to use the novel prodrug serdexmethylphenidate together with d-methylphenidate, is welcome news for clinicians and families to consider when choosing an appropriate ADHD therapy for children,” said Ann Childress, M.D., president of the Center for Psychiatry and Behavioral Medicine and lead investigator of the pivotal AZSTARYS clinical trial.

Corium, a wholly-owned portfolio company of Gurnet Point Capital (GPC), will be leading the U.S. commercialization activities for AZSTARYS. “The FDA approval of AZSTARYS means Corium is one step closer to bringing this innovative therapy to market and providing patients with ADHD and their clinicians a new option for rapid and extended symptom control via the dual action of d-MPH and the novel d-MPH prodrug SDX,” said Perry J. Sternberg, President and CEO of Corium. “The team at Corium is energized to leverage their deep ADHD and commercialization expertise to launch and market AZSTARYS, which is an important milestone for Corium and its focus on CNS therapies.”

AZSTARYS Clinical Study Efficacy and Safety Data

AZSTARYS was evaluated in a multicenter, double-blind, randomized, placebo-controlled, laboratory classroom phase 3 study in 150 children aged 6 to 12 years diagnosed with ADHD (NCT03292952). The results of this study were presented in January 2021 at the American Professional Society of ADHD and Related Disorders Annual Meeting. In this study, AZSTARYS

significantly improved ADHD symptoms with a single dose, as measured by the primary endpoint, the change from baseline in Swanson, Kotkin, Agler, M-Flynn, and Pelham Rating Scale – Combined (SKAMP-C) scores averaged over a 13-hour laboratory classroom day. As ADHD symptoms improve, SKAMP-C scores decline.

In the study, the improvements significantly differed for children treated with AZSTARYS compared to those receiving a placebo, with an average SKAMP-C score reduction of -5.4 points more in the AZSTARYS group [95% CI: (-7.1, -3.7)]. Adverse events (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). No serious AEs were reported in this study.

Commonly reported (5 percent or more of the MPH group and at least twice the rate of the placebo group) adverse reactions from placebo-controlled trials of methylphenidate products include: decreased appetite, decreased weight, nausea, abdominal pain, dyspepsia, vomiting, insomnia, anxiety, affect lability, irritability, dizziness, increased blood pressure, and tachycardia.

AZSTARYS Scheduling and Launch

Because AZSTARYS contains d-MPH, classified as a Schedule II stimulant, the FDA has recommended that AZSTARYS also receive a Schedule II controlled substance classification. The U.S. Drug Enforcement Administration (DEA) has accepted this proposal and is anticipated to render a final scheduling decision within 90 days. The AZSTARYS label will be available after the medication receives its final scheduling designation. Pending this DEA action, the launch of AZSTARYS is anticipated in Summer 2021. AZSTARYS will be available in three once-daily dosage strengths of SDX/d-MPH: 26.1/5.2 mg, 39.2/7.8 mg, and 52.3/10.4 mg, providing dosing flexibility to meet the needs of each patient.

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 central nervous system (CNS) therapies that provide clinicians with important 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.coriumintl.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

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