Jazz Pharmaceuticals Completes U.S. Divestiture of Sunosi® (solriamfetol) to Axsome Therapeutics

May 9, 2022

DUBLIN, May 9, 2022 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that it has completed the divestiture of Sunosi® (solriamfetol) in the U.S. to Axsome Therapeutics, Inc. (Nasdaq: AXSM).

Under the terms of the agreement, Jazz received an upfront payment of $53 million, and will receive a high single-digit royalty on Axsome's U.S. net sales of *Sunosi* in current indications and a mid-single-digit royalty on Axsome's U.S. net sales of *Sunosi* in future indications. Subject to the satisfaction of conditions to closing, the ex-U.S. transaction is expected to close within 60 days.

"The divestiture of *Sunosi* enables us to sharpen our focus on the strategic areas where we see the most opportunity for sustainable growth and enhanced shareholder value," said Bruce Cozadd, chairman and CEO of Jazz Pharmaceuticals. "Looking forward, Jazz will continue to invest in our highest strategic priorities, driving the transformation of Jazz to an innovative, global biopharmaceutical leader, and delivering improved top- and bottom-line growth through operational excellence."

About Sunosi® (solriamfetol)

Sunosi is a dual-acting dopamine and norepinephrine reuptake inhibitor shown to improve wakefulness in adults living with excessive daytime sleepiness (EDS) due to narcolepsy or obstructive sleep apnea (OSA). *Sunosi* received U.S. Food and Drug Administration approval on March 20, 2019, to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA and was designated a Schedule IV medicine by the U.S. Drug Enforcement Agency on June 17, 2019. In 2014, Jazz Pharmaceuticals acquired a license to develop and commercialize solriamfetol from Aerial Biopharma LLC. Jazz Pharmaceuticals has worldwide development, manufacturing, and commercialization rights to solriamfetol, excluding certain jurisdictions in Asia. SK Biopharmaceuticals Co., Ltd., the discoverer of the compound, maintains rights in 12 Asian markets, including Korea, China and Japan. *Sunosi* has orphan drug designation for narcolepsy in the United States.

Important Safety Information for Sunosi

SUNOSI (solriamfetol) is available in 75 mg and 150 mg tablets and is a federally controlled substance (C-IV) because it contains solriamfetol that can be a target for people who abuse prescription medicines or street drugs. Keep SUNOSI in a safe place to protect it from theft. Never give or sell your SUNOSI to anyone else, because it may cause death or harm them and it is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Before taking SUNOSI, tell your doctor about all of your medical conditions, including if you:

- have heart problems, high blood pressure, kidney problems, diabetes, or high cholesterol
- have had a heart attack or a stroke
- have a history of mental health problems (including psychosis and bipolar disorders), or of drug or alcohol abuse or addiction
- are pregnant or planning to become pregnant. It is not known if SUNOSI will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if SUNOSI passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take SUNOSI.

What are the possible side effects of SUNOSI?

SUNOSI may cause serious side effects, including:

- **Increased blood pressure and heart rate.** SUNOSI can cause blood pressure and heart rate increases that can increase the risk of heart attack, stroke, heart failure, and death. Your doctor should check your blood pressure before and during treatment with SUNOSI. Your doctor may decrease your dose or tell you to stop taking SUNOSI if you develop high blood pressure that does not go away during treatment with SUNOSI.
- **Mental (psychiatric) symptoms including anxiety, problems sleeping (insomnia), irritability, and agitation.** Tell your doctor if you develop any of these symptoms. Your doctor may change your dose or tell you to stop taking SUNOSI if you develop side effects during treatment with SUNOSI.

The most common side effects of SUNOSI include:

- headache
- decreased appetite
- problems sleeping
- nausea
- anxiety

These are not all the possible side effects of SUNOSI. Call your doctor for advice about side effects.

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.

Please find full prescribing information here: https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (NASDAQ: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases – often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. For more information, please visit www.jazzpharma.com and follow @JazzPharma on Twitter.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to: the proposed ex-U.S. divestiture of *Sunosi* to Axsome, royalties to be received by Jazz in connection with the U.S. divestiture and the other anticipated benefits thereof; Jazz's expectation of delivering sustainable growth and enhanced shareholder value; Jazz's expectations with respect to delivering improved top- and bottom-line growth through operational excellence; and other statements that are not historical facts. These forward-looking statements are based on Jazz's current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties.

Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: Jazz's and Axsome's ability to complete the proposed ex-U.S. divestiture of *Sunosi* on the proposed terms or on the anticipated timeline, or at all; Jazz's ability to meet its projected long-term goals and objectives; and other risks and uncertainties affecting Jazz, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz's Securities and Exchange Commission filings and reports, including Jazz's Annual Report on Form 10-K for the year ended December 31, 2021, and future filings and reports by Jazz. Other risks and uncertainties of which Jazz is not currently aware may also affect Jazz's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by Jazz on its website or otherwise. Jazz undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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