Jazz Pharmaceuticals Announces Agreement to Divest Sunosi® (solriamfetol) to Axsome Therapeutics

March 28, 2022

Jazz to receive $53 million upfront cash payment, and royalty rights

Transaction designed to ensure uninterrupted patient access to Sunosi

Jazz remains committed to neuroscience with growing franchises in sleep disorders and epilepsy

DUBLIN, March 28, 2022 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that it has entered into a definitive agreement to divest Sunosi® (solriamfetol), 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), to Axsome Therapeutics (Nasdaq: AXSM). Under the terms of the agreement, Axsome will receive the rights to *Sunosi* in all of the existing territories available to Jazz. Jazz will receive attractive financial terms including an upfront payment of $53 million, 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.

The divestiture of *Sunosi* to Axsome will enable Jazz to sharpen its focus on its highest strategic priorities designed to deliver sustainable growth and enhanced shareholder value. In assessing the positioning of *Sunosi* in the overall treatment landscape, Jazz determined Axsome would be well positioned to deliver access to this important medication and to maximize the value of *Sunosi* to Jazz through future growth. *Sunosi's* consistent positive feedback from patients, HCPs and providers is underscored by its well-established and clinically meaningful efficacy. Importantly, Jazz and Axsome are committed to ensuring that patients receive uninterrupted access to *Sunosi* throughout the transition.

Wake-promoting agents are most often prescribed by psychiatrists, neurologists and general practitioners. Therefore, Jazz believes Axsome is well placed to leverage its commercial business, which will have highly complementary call points, to drive *Sunosi* as one of the lead products in their portfolio and ensure *Sunosi* can continue to reach those patients who may benefit from this important medicine.

"This transaction advances our efforts to deliver sustainable growth, enhanced shareholder value and drive the transformation of Jazz to an innovative, global biopharmaceutical leader," said Bruce Cozadd, chairman and CEO of Jazz Pharmaceuticals. "Jazz will continue to be laser-focused on investing in our highest strategic priorities including our ongoing launches, advancing our pipeline, pursuing opportunistic corporate development and achieving margin expansion. Through our development and launch of *Sunosi*, the Jazz team has laid the foundation for Axsome to continue supporting people who may benefit from this much-needed treatment. As a leader in sleep medicine and rare epilepsies, with a growing oncology franchise, Jazz remains committed to developing new, innovative therapies in neuroscience and oncology for patients and delivering on our recently announced Vision 2025."

"We are impressed by the clinically meaningful efficacy, unique mechanism of action, positive patient and physician feedback and growth potential of *Sunosi*, and are excited by the excellent strategic fit with the Axsome portfolio. The addition of *Sunosi* will augment and accelerate our commercial preparedness ahead of the potential near-term launches of our two existing lead assets and allows us to fully leverage our first-in-class Digital Centric Commercialization™ platform with three complimentary assets," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics.

Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated for the treatment of excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA) in adult patients. *Sunosi* is the first DNRI approved to treat EDS in adults living with narcolepsy or OSA. More information about *Sunosi*, including Full Prescribing Information and Medication Guide, is available https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf.

Closing Conditions

The respective obligations of Jazz and Axsome to consummate the transactions contemplated by the definitive agreement are subject to the satisfaction or waiver of a number of customary conditions, including the expiration or early termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (HSR Act).

The transaction is structured to be completed in sequential closings for the U.S. and ex-U.S. territories. Subject to the satisfaction or waiver of the closing conditions, the companies expect the U.S. transaction to close in the second quarter of 2022 and the ex-U.S. transaction close to occur within 60 days following the close of the U.S. transaction.

Guggenheim Securities acted as financial advisor and Cooley LLP acted as legal counsel to Jazz.

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 divestiture of *Sunosi* to Axsome, the anticipated upfront payment and expected use thereof and royalties to be received by Jazz in connection therewith and the other anticipated benefits thereof; Jazz's expectation of delivering sustainable growth and enhanced shareholder value; Jazz's expectations with respect to Axsome's ability to maximize the value of *Sunosi* through future growth, including with respect to Axsome's ability to drive *Sunosi* as a one of the lead products in their portfolio and the expectation of uninterrupted access to *Sunosi* throughout the transition of *Sunosi* to Axsome; Jazz continuing to invest in its ongoing launches, advance its pipeline, pursue opportunistic corporate development, and focus on achieving anticipated margin expansion; Jazz's commitment to develop new, innovative therapies in neuroscience and oncology for patients and delivering on its recently announced Vision 2025; 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 divestiture of *Sunosi* on the proposed terms or on the anticipated timeline, or at all, including risks and uncertainties related to the expiration or securing early termination of the applicable waiting period under the HSR Act; maintaining or increasing sales of and revenue from Jazz's oxybate products, Zepzelca and other key marketed products; effectively launching and commercializing Jazz's other products and product candidates; obtaining and maintaining adequate coverage and reimbursement for Jazz's products; the time-consuming and uncertain regulatory approval process, including the risk that Jazz's current and/or planned regulatory submissions may not be submitted, accepted or approved by applicable regulatory authorities in a timely manner or at all; the costly and time-consuming pharmaceutical product development and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating or completing clinical trials and assessing patients such as those being experienced,

and expected to continue to be experienced, by Jazz as a result of the effects of the COVID-19 pandemic; the ultimate duration and severity of the COVID-19 pandemic and resulting global economic, financial, and healthcare system disruptions and the current and potential future negative impacts to Jazz's business operations and financial results; regulatory initiatives and changes in tax laws; market volatility; protecting and enhancing Jazz's intellectual property rights and Jazz's commercial success being dependent upon Jazz obtaining, maintaining and defending intellectual property protection for its products and product candidates; delays or problems in the supply or manufacture of Jazz's products and product candidates; complying with applicable U.S. and non-U.S. regulatory requirements, including those governing the research, development, manufacturing and distribution of controlled substances; government investigations, legal proceedings and other actions; identifying and acquiring, in-licensing or developing additional products or product candidates, financing these transactions and successfully integrating acquired product candidates, products and businesses; Jazz's ability to realize the anticipated benefits of its collaborations and license agreements with third parties; the sufficiency of Jazz's cash flows and capital resources to fund its debt service obligations; Jazz's ability to achieve expected future financial performance and results and the uncertainty of future tax, accounting and other provisions and estimates; Jazz's ability to achieve expected future financial performance and results and the uncertainty of future tax and other provisions and estimates; Jazz's ability to meet its projected long-term goals and objectives, including as part of Vision 2025, in the time periods that Jazz anticipates, or at all, and the inherent uncertainty and significant judgments and assumptions underlying Jazz's 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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