Jazz Pharmaceuticals Reaches Settlement with Hikma Pharmaceuticals Related to Xyrem Patent Litigation

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Hikma Granted Right to Sell Authorized Generic of Xyrem in 2023

DUBLIN, April 5, 2017 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that certain of its subsidiaries have entered into agreements with Hikma Pharmaceuticals PLC and related entities ("Hikma") resolving patent litigation related to Xyrem® (sodium oxybate) oral solution. The litigation, which has been pending in the U.S. District Court for the District of New Jersey since 2010, resulted from the submission by Roxane Laboratories, Inc. (which was subsequently acquired by Hikma) of an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking approval to market a generic version of Xyrem.

In connection with the settlement, Jazz has granted Hikma and its wholly owned subsidiary, West-Ward Pharmaceuticals Corp. (West-Ward), the right to sell an authorized generic (AG) version of Xyrem in the U.S. under the Xyrem New Drug Application (NDA), commencing on January 1, 2023, or earlier under certain circumstances customary for settlement agreements of this nature. The AG product will be marketed through the Xyrem Risk Evaluation and Mitigation Strategy (REMS) program. The initial term of the AG arrangement is six months, and Hikma has the option to continue the sale of the AG product for up to a total of five years. Jazz will receive a meaningful royalty on net sales of the AG product, with the royalty rate increasing during the initial AG term based on increased AG sales. There will be a substantial increase in the royalty rate should the AG term be extended beyond one year. Jazz will also be paid for supply of the AG product and will be reimbursed for a portion of the service costs associated with the operation of the Xyrem REMS and distribution of the AG. Specific financial and other terms related to the AG product are confidential. Hikma has been granted a license to sell its generic sodium oxybate product under its ANDA at the end of the AG term.

"This settlement arrangement provides additional clarity related to our Xyrem intellectual property as we continue our strategy to expand and diversify our product portfolio and R&D pipeline, in line with our goal of delivering new clinically meaningful therapeutic options for patients," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "We are pleased that this settlement positions us to facilitate the safe distribution of West-Ward's AG of Xyrem through the Xyrem REMS."

As required by law, Jazz Pharmaceuticals and Hikma will submit the settlement agreement to the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ) for review.

Similar patent litigation brought by Jazz Pharmaceuticals against four other companies that have filed ANDAs with the FDA seeking approval to market a generic version of Xyrem remains pending in the U.S. District Court for the District of New Jersey.

For additional information related to the settlement between Jazz Pharmaceuticals and Hikma, please refer to the Current Report on Form 8-K to be filed by Jazz Pharmaceuticals with the Securities and Exchange Commission.

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Defitelio® (defibrotide sodium) in the U.S. and markets Erwinase® and Defitelio® (defibrotide) in countries outside the U.S. For more information, please visit www.jazzpharmaceuticals.com.

About Xyrem

Xyrem® (sodium oxybate) oral solution, CIII, is indicated for the treatment of cataplexy in narcolepsy and for the treatment of excessive daytime sleepiness (EDS) in narcolepsy. Xyrem may only be dispensed to patients enrolled in the Xyrem REMS Program. Xyrem was first approved in the U.S. in 2002.

IMPORTANT SAFETY INFORMATION

Xyrem (sodium oxybate) is a Central Nervous System (CNS) depressant. In clinical trials at recommended doses, obtundation and clinically significant respiratory depression occurred in Xyrem-treated patients. Almost all of the patients who received Xyrem during clinical trials in narcolepsy were receiving central nervous system stimulants.

Xyrem (sodium oxybate) is the sodium salt of gamma hydroxybutyrate (GHB). Abuse of GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.

Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the Xyrem REMS Program using the central pharmacy that is specially certified. Prescribers and patients must enroll in the program. Further information is available at www.XYREMREMS.com or 1-866-XYREM88® (1-866-997-3688).

Xyrem is contraindicated in combination with sedative hypnotics or alcohol and in patients with succinic semialdehyde dehydrogenase deficiency. Use caution when considering the concurrent use of Xyrem with other CNS depressants. Healthcare providers should caution patients against hazardous activities requiring complete mental alertness or motor coordination within the first 6 hours of dosing or after first initiating treatment until certain that Xyrem does not affect them adversely. Xyrem is a Schedule III controlled substance. The rapid onset of sedation, coupled with the amnestic features of Xyrem, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (e.g. assault victim). Monitor patients for emergent or increased depression and suicidality and for impaired motor/cognitive function. Episodes of sleepwalking should be fully evaluated and appropriate interventions considered. Consider the amount of daily sodium intake in each dose of Xyrem in patients sensitive to salt

intake.

In three controlled clinical trials, the most common adverse reactions (incidence ≥ 5% and twice the rate of placebo) in Xyrem-treated patients were nausea (20%), dizziness (15%), vomiting (11%), somnolence (8%), enuresis (7%), and tremor (5%).

Please click here to see the full Prescribing Information for Xyrem, including BOXED Warning.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to anticipated results and actions to be taken under the settlement agreement and the transactions contemplated thereby, review of the settlement agreement by the FTC and DOJ, the anticipated dismissal of related pending litigation, the company's strategy to expand and diversify its product portfolio and R&D pipeline and its goal of delivering new clinically meaningful therapeutic options for patients, and other statements that are not historical facts. These forward-looking statements are based on the company'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: approval of the settlement agreement and dismissal of related pending litigation by the U.S. District Court for the District of New Jersey; review of the settlement arrangement by the FTC and DOJ; regulatory restrictions and requirements applicable to Xyrem; ongoing patent litigation and related proceedings; the regulatory approval process; protecting and enhancing the company's intellectual property rights; whether additional third parties may seek to market generic versions of Xyrem, including the risk that any company or companies may decide, before applicable ongoing patent litigation is concluded, to launch a generic sodium oxybate product at risk of potentially being held liable for damages; delays or problems in the supply or manufacture of the company's products and product candidates; complying with applicable U.S. and non-U.S. regulatory requirements; government investigations and other actions; and other risks and uncertainties affecting the company, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Annual Report on Form 10-K for the period ended December 31, 2016 and future filings and reports by the company. Other risks and uncertainties of which the company is not currently aware may also affect the company'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 the company on its website or otherwise. The company 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/jazz-pharmaceuticals-reaches-settlement-with-hikma-pharmaceuticals-related-to-xyrem-patent-litigation-300435524.html

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