Jazz Pharmaceuticals and UCB Announce Second Phase III Study of Sodium Oxybate in Patients With Fibromyalgia Meets Primary Endpoints

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--Preliminary top-line results of second Phase III study show highly significant decreases in pain and fatigue and improved daily function in fibromyalgia patients and confirm results from the first Phase III study

PALO ALTO, Calif., and BRUSSELS, June 24, 2009 /PRNewswire-FirstCall via COMTEX/ -- press release, regulated information -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) and UCB (Euronext Brussels: UCB) announced today positive preliminary top-line results from the second of two Phase III clinical trials of sodium oxybate (JZP-6) for the treatment of fibromyalgia. Confirming the positive results from the first Phase III study, this international, placebo-controlled trial of sodium oxybate to treat fibromyalgia achieved its key endpoints. As in the first randomized, double-blind fibromyalgia study, sodium oxybate significantly decreased pain and fatigue and improved daily function and patient global impression of change. Sodium oxybate has not been evaluated by regulators for the treatment of fibromyalgia and is not approved for this use.

"Fibromyalgia is a chronic illness, characterized by widespread pain, unrefreshing sleep, chronic fatigue, and psychological distress," said I. Jon Russell, M.D., Ph.D., lead investigator in the first Phase III study and Associate Professor of Medicine, Division of Clinical Immunology and Rheumatology, and Director, University Clinical Research Center, University of Texas Health Science Center at San Antonio. "Sodium oxybate has shown a positive effect on a number of the symptoms of fibromyalgia, and thus could have a significant impact on patients' quality of life."

The second 14-week Phase III trial, conducted in the United States and seven European countries, included 573 adult patients with fibromyalgia randomized to one of three treatment arms: sodium oxybate 4.5 g/night, sodium oxybate 6 g/night, or placebo. The primary outcome measure, viewed by both U.S. and E.U. regulatory authorities as a clinically meaningful endpoint, was the proportion of patients who achieved at least 30 percent reduction in pain from baseline to endpoint based on the Pain Visual Analog Scale (VAS). Data from the Fibromyalgia Impact Questionnaire (FIQ) are considered equally relevant as Pain VAS data in the E.U. FIQ data are considered supportive data by U.S. regulators.

In the top-line results, significantly more patients treated with sodium oxybate achieved 30 percent or greater improvement in their pain compared to patients treated with placebo. Of those patients receiving sodium oxybate treatment, 35 percent of patients on 4.5 g/night and 35 percent of patients on 6 g/night reported this level of pain relief on the Pain VAS, compared with 20 percent of patients on placebo. These results were highly statistically significant.

Patients' physical functioning and ability to perform daily tasks, as measured by the FIQ, were highly statistically significantly different from placebo for the 4.5 g/night dose and for the 6 g/night dose. Sodium oxybate-treated patients also reported highly statistically significant improvement in fatigue, another common symptom of fibromyalgia.

The most common adverse events (greater than or equal to five percent and at least twice the rate of placebo) were nausea, dizziness, vomiting, insomnia, anxiety, somnolence, fatigue, muscle spasms, and peripheral oedema. Sodium oxybate was generally well tolerated, with the majority of adverse events reported being mild to moderate in nature.

"These results from our second Phase III trial, confirming the positive results of our first Phase III study, are an exciting milestone for Jazz Pharmaceuticals," said Bruce Cozadd, Chairman and Chief Executive Officer of Jazz Pharmaceuticals. "I'd like to thank the investigators, patients, and Jazz Pharmaceuticals employees who helped us complete this trial."

"UCB is committed to improving the lives of people living with severe CNS diseases," said Iris Loew-Friedrich, Chief Medical Officer of UCB. "The positive results of the two Phase III trials are encouraging and suggest that subject to regulatory approval, this may offer a new treatment option for people with fibromyalgia."

Only preliminary top-line efficacy and safety data are available at this time. Further analyses are planned, including analyses of additional secondary endpoints. Jazz Pharmaceuticals anticipates submitting a New Drug Application for sodium oxybate to the U.S. Food and Drug Administration (FDA) by the end of 2009. UCB will consult with the European Medicines Agency (EMEA) to define the path forward. UCB has the exclusive marketing and distribution rights to sodium oxybate for fibromyalgia in Europe and some other countries outside North America and will manage registrations accordingly.

For further information

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Notes to the editor

About Sodium Oxybate

Sodium oxybate is the sodium salt form of gamma-hydroxybutyrate, an endogenous neurotransmitter and metabolite of GABA. While the precise mechanism of action is unknown, the effects may be mediated in part through interaction with GABA(B) and GHB receptors. Sodium oxybate is the active ingredient in XYREM(R), approved by the FDA and marketed by Jazz Pharmaceuticals in the U.S. for the treatment of excessive daytime sleepiness and cataplexy (the sudden loss of muscle tone) in adult patients with narcolepsy. The American Academy of Sleep Medicine recommends sodium oxybate as a standard of care for the FDA-approved indications. UCB markets XYREM(R) (sodium oxybate oral solution) in Europe, where it is approved by the EMEA for the treatment of narcolepsy with cataplexy in adult patients under a license from Jazz Pharmaceuticals. Most commonly reported adverse drug reactions in narcolepsy patients are dizziness, nausea and headaches. Sodium oxybate has the potential to induce respiratory depression and neuropsychiatric events. Sodium oxybate has not been evaluated by regulators for the treatment of fibromyalgia and is not approved for this use.

About Fibromyalgia

Fibromyalgia, a chronic condition characterized by widespread pain, affects 0.5% - 5% of adults worldwide. Fibromyalgia is believed to be a central nervous system condition, resulting from neurological changes in how the brain perceives and responds to pain. In addition to pain, the main symptoms are fatigue, disturbed sleep and morning stiffness. The exact causes of fibromyalgia are unknown. It may be triggered by physical trauma, emotional stress, chronic pain or infection. Genetics, neurochemicals that affect pain modulation, neurohormones and sleep physiology abnormalities are thought to play a role. Research also has suggested a relationship between sleep and pain. Fibromyalgia patients experience a high prevalence of sleep problems, including a reduction in non-restorative or deep sleep.

About Jazz Pharmaceuticals, Inc.

Jazz Pharmaceuticals (Nasdaq: JAZZ) is a specialty pharmaceutical company that identifies, develops and commercializes innovative treatments for important, underserved markets in neurology and psychiatry. For further information see www.JazzPharmaceuticals.com.

About UCB

UCB (Brussels, Belgium, www.ucb.com) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on central nervous system and immunology disorders. Employing around 10,000 people in over 40 countries, UCB achieved revenue of EUR 3.6 billion in 2008. UCB is listed on Euronext Brussels (symbol: UCB).

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

This press release contains forward-looking statements related to the development and commercial potential of Jazz Pharmaceuticals' sodium oxybate (JZP-6) product candidate for the treatment of fibromyalgia, including further analysis of the study results and the anticipated timing for the submission of a New Drug Application to the FDA. These forward-looking statements are based on the company's current expectations and inherently involve significant risks and uncertainties. Jazz Pharmaceuticals' 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 related to the outcome of further analysis of the data from the study, risks related to the company's financial position and default on its senior debt, and risks that regulatory filings may not be made, or may be delayed, and that the sodium oxybate (JZP-6) product candidate may not be approved for marketing for the treatment of fibromyalgia by regulatory authorities. These and other risk factors are discussed under "Risk Factors" in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 filed by Jazz Pharmaceuticals with the Securities and Exchange Commission on May 7, 2009. Jazz Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

UCB Forward-looking Statement

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of employees.

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