Zogenix Submits New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) for Zohydro(TM) for Treatment of Chronic Pain

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First NDA Submission for an Extended-Release Hydrocodone Therapy without Acetaminophen

SAN DIEGO, May 2, 2012 /PRNewswire via COMTEX/ --Zogenix, Inc. (NASDAQ: ZGNX), a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain, announced today that the Company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Zohydro(TM) (hydrocodone bitartrate extended-release capsules), Zogenix's lead investigational product candidate for the treatment of chronic pain.

Zohydro is a novel, oral, single-entity (without acetaminophen) extended-release formulation of various strengths of hydrocodone intended for administration every 12 hours for around the clock management of moderate to severe chronic pain. If approved, Zohydro could be the first hydrocodone product to offer the benefit of less frequent dosing and the ability to treat patients with chronic pain without the risk of acetaminophen-related liver injury. Currently, hydrocodone is only available in immediate-release, combination products, most commonly with the analgesic acetaminophen, and requires dosing every 4 to 6 hours. Zohydro, classified as a Drug Enforcement Agency (DEA) Schedule II drug product, would carry more strict prescription and dispensing rules as compared to the currently available hydrocodone combination products. In addition, Zogenix has included in the NDA a comprehensive Risk Evaluation and Mitigation Strategy (REMS) that is consistent with current FDA and industry-wide guidelines for extended-release opioid products. The REMS is intended to control inappropriate prescribing, misuse and abuse of extended-release opioids while maintaining patient access to essential pain medications.

"The NDA submission for Zohydro is a significant milestone, bringing us another step closer to making this important acetaminophen-free hydrocodone treatment option available to patients in need of around the clock therapy for chronic pain," said Stephen Farr, Ph.D., president and chief operating officer of Zogenix. "Hydrocodone is often a physician's first opioid recommendation for treating acute, moderate or moderately severe pain. However, many patients are being treated with hydrocodone combination products that include acetaminophen and, when used in high dosages or over long periods of time, put themselves at risk for developing liver injury. Zohydro could provide a significant new treatment alternative that does not contribute to this health risk."

The NDA submission is based on data from over 1,100 patients with chronic pain participating in the pivotal Phase 3 efficacy study (Study 801), and an open-label Phase 3 safety study (Study 802) of Zohydro. Study 801 successfully met its primary efficacy endpoint, demonstrating that Zohydro resulted in significantly ($p=0.008$) improved chronic pain relief compared to placebo. The two key secondary endpoints in this study - the proportion of patients with at least 30% improvement in pain intensity and the improvement of overall satisfaction of medication - were also met. Additional study endpoints were supportive of the efficacy of Zohydro compared to placebo. The study demonstrated that Zohydro was generally safe and well tolerated. Overall, the most commonly reported adverse events (greater than or equal to 2%) in the placebo-controlled pivotal Phase 3 efficacy Study 801 in opioid-experienced patients were consistent with those typically seen with chronic opioid therapy and were constipation, nausea, somnolence, fatigue, headache, dizziness, dry mouth, vomiting and pruritus. Study 802, in which patients received Zohydro for up to 12 months, further demonstrated that Zohydro was generally safe and well tolerated, and the incidence of adverse events was consistent with that seen in the pivotal Phase 3 efficacy study.

In conjunction with Zohydro's NDA submission, Zogenix is required to make a milestone payment of $1.0 million to Alkermes Pharma Ireland Limited (APIL), a subsidiary of Alkermes, plc, under the Company's exclusive license agreement with APIL in the U.S. for Zohydro.

About Zohydro

Zohydro is a novel, oral, single-entity extended-release formulation of hydrocodone without acetaminophen for the management of moderate to severe chronic pain in patients requiring around the clock opioid therapy. If approved, Zohydro could be the first single-entity hydrocodone therapy, avoiding the potential for liver injury associated with the use of acetaminophen in high doses or over long periods of time.

Zohydro uses APIL's patented Spheroidal Oral Drug Absorption System (SODAS®) drug delivery technology which serves to enhance the release profile of hydrocodone to provide extended-release pain relief relative to existing immediate-release combination products.

About Chronic Pain

Chronic pain is defined as ongoing or recurrent pain that adversely affects an individual's well-being. An estimated 116 million people in the United States are burdened with chronic pain, at an estimated national economic cost of $560 to $635 billion annually.

Chronic pain can be treated with both immediate-release and extended-release opioids. Currently marketed hydrocodone products are only immediate-release and contain an analgesic combination ingredient, primarily acetaminophen. Acetaminophen may cause liver injury when used in high dosages, over long periods of time or in accidental overdoses due to multiple acetaminophen products being taken at once.

About Zogenix

Zogenix, Inc. (NASDAQ: ZGNX), with offices in San Diego and Emeryville, California, is a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Zogenix's first commercial product, SUMAVEL® DosePro® (sumatriptan injection) Needle-free Delivery System, was launched in January 2010 for the acute treatment of migraine and cluster headache. Zogenix's lead investigational product candidate, Zohydro(TM) (hydrocodone bitartrate), is a novel, oral, single-entity (without acetaminophen) extended-release formulation of various strengths of hydrocodone intended for administration every 12 hours for around the clock management of moderate to severe chronic pain. Zogenix submitted an NDA to the FDA for Zohydro in May 2012. Zogenix's second DosePro investigational product candidate, Relday(TM), is a proprietary, long-acting injectable formulation of risperidone for the treatment of schizophrenia.

For additional information, please visit www.zogenix.com.

Forward Looking Statements

Zogenix cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed" and similar expressions are intended to identify forward-looking statements. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding: the potential for Zohydro to be the first approved oral, single-entity extended-release formulation of hydrocodone; and the size of the chronic pain market and the potential of Zohydro to provide a significant new treatment alternative and be well positioned in that market. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that

any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the top-line data Zogenix has reported for Zohydro is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial, and may also change in connection with the continued review of such data as part of Zogenix's submission and the FDA's review of the NDA for Zohydro; the potential for delays associated with any additional data required to be submitted by Zogenix in support of the NDA; the potential for Zohydro to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro to delay or prevent regulatory approval or commercialization; the impact of any inability to raise sufficient capital to fund ongoing operations; the ability of Zogenix and its licensors to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its products and product candidates and the ability to operate its business without infringing the intellectual property rights of others; and other risks described in Zogenix's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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