Cebranopadol Data Presented at World Institute of Pain Congress Highlight Clinically Significant Reductions in Pain, Low Abuse Potential and a Favorable Respiratory Profile

May 23, 2016

NEWARK, Calif. , May 23, 2016 (GLOBE NEWSWIRE) -- Depomed, Inc. (NASDAQ:DEPO) today announced that clinical data from Phase IIb trials of cebranopadol in chronic lower back pain (cLBP) and diabetic peripheral neuropathy (DPN) as well as from the human abuse potential and respiratory depression studies conducted by Grünenthal GmbH ("Grünenthal") were presented this weekend at the 8th World Congress of the World Institute of Pain (WIP) in New York, New York . Cebranopadol is a novel, first-in-class analgesic in development for the treatment of moderate to severe chronic nociceptive and neuropathic pain. In December 2015 , Depomed acquired the U.S. and Canadian rights to cebranopadol from Grünenthal.

Poster 160480 "Cebranopadol: A Novel First-In-Class Analgesic in Development for Chronic Pain Conditions – Results from a Human Abuse Potential Study in Non-Dependent Recreational Opioid Users" reported data from a Phase I study of 48 healthy, non-dependent recreational opioid users. The study assessed the abuse potential of three different orally administered doses of cebranopadol (200, 400 and 800 µg), placebo and two doses of hydromorphone (8 and 16 mg) as a comparator to rate "drug liking", a traditional endpoint for this type of study. Data show that, as expected, hydromorphone generated a dose-dependent increase in likeability, whereas placebo showed little likeability with cebranopadol at therapeutic doses exhibiting similar likeability scores to placebo.
Link: http://simul-europe.com/2016/wip/HtmlPage1.html?prodId=(marielle.eerdekens@grunenthal.com)Cebranopadol%20Poster%20human%20abuse%20WIP%20160480_X4.pdf.jpg

Poster 160319 "Cebranopadol: A Novel, First-In-Class Analgesic: Efficacy, Safety, Tolerability in Patients with Mixed Chronic Low Back Pain" reviewed data from the Phase IIb trial of 635 patients with moderate-to-severe cLBP. This randomized, double-blind, placebo- and active-controlled, five-arm, monotherapy trial assessed the analgesic efficacy, safety, and tolerability of once daily oral dose of cebranopadol at three fixed doses (i.e., 200, 400, and 600 µg) compared to placebo and tapentadol prolonged release, as the active comparator. Data show all three doses of cebranopadol resulted in robust, clinically and statistically significant, and dose-dependent improvements in pain, with p values of 0.0095, 0.0122, and 0.0021 for 200, 400, and 600 µg, respectively, compared to placebo.
Link: http://simul-europe.com/2016/wip/HtmlPage1.html?prodId=(marielle.eerdekens@grunenthal.com)Cebranopadol%20Poster%20LBP%20WIP160319.pdf.jpg

Poster 160303 "Cebranopadol: A Novel, First-In-Class Analgesic in Development for Chronic Pain Conditions – Effects on Respiration in Healthy Human Volunteers" reported data from a Phase I trial of 12 healthy male subjects. This study assessed the effects of a single oral dose of cebranopadol (600 µg) compared to an intravenous dose of fentanyl (3.5 µg/kg). Data show that cebranopadol demonstrated a less pronounced and significantly delayed effect upon respiratory parameters (respiratory rate, ventilation and oxygen saturation) as compared to fentanyl, and that these changes appear to demonstrate a "ceiling effect".
Link: http://simul-europe.com/2016/wip/HtmlPage1.html?prodId=(marielle.eerdekens@grunenthal.com)Cebranopadol%20Poster%20respiration%20WIP160303.pdf.jpg

Poster 160478 "Cebranopadol: A Novel, First-In-Class Analgesic: Efficacy, Safety, Tolerability in Patients with Pain Due to Diabetic Peripheral Neuropathy (DPN)" reviewed data from an exploratory Phase IIb trial of 314 patients with moderate to severe chronic pain due to DPN. This 5-arm, placebo- and active-controlled, parallel design trial compared the analgesic efficacy, safety and tolerability of once daily orally administered cebranopadol at 3 fixed doses (100, 300 and 600 µg) compared to placebo and pregabalin at 600 mg (300 mg twice-a-day) as the active comparator. Data show that at the highest dose of 600 µg, patients achieved clinically and statistically significant improvements in pain (p=0.0153). The other two cebranopadol arms demonstrated a trend towards statistical significance, but did not achieve it in this exploratory trial. Results also showed an absolute reduction in pain, which was -2.56, -2.28, and -2.24 on an 11-point scale for the 600, 300 and 100 µg doses, respectively as compared to -1.55 for placebo with evidence of a dose-response relationship.
Link http://simul-europe.com/2016/wip/HtmlPage1.html?prodId=(marielle.eerdekens@grunenthal.com)Cebranopadol%20Poster%20DPN%20WIP%20160478.pdf.jpg

Electronic copies of these posters are available upon request.

Top-line data from these trials were presented as part of Depomed's Investor and Analyst Day in March. The replay of the presentation as well as the corresponding slide deck can be found in the Investors section of Depomed's website at www.Depomed.com.

About Cebranopadol

Cebranopadol is a novel, first-in-class analgesic that acts as a nociceptin/orphanin FQ peptide (NOP) receptor and opioid receptor agonist. These mechanisms, which have been shown to synergize, result in both a comparable efficacy and broader analgesic spectrum versus standard mu-opioid receptor agonists as well as an improved safety profile, particularly as it pertains to respiratory depression. In total, cebranopadol has been studied in approximately 2,000 patients worldwide having completed several Phase II trials in painful diabetic peripheral neuropathy (PDPN), osteoarthritis (OA) and chronic lower back pain (cLBP) and is ready for Phase III development.

About Depomed

Depomed is a leading specialty pharmaceutical company focused on enhancing the lives of the patients, families, physicians, providers and payors we serve through commercializing innovative products for pain and neurology related disorders. Depomed markets six medicines with areas of focus that include mild to severe acute pain, moderate to severe chronic pain, neuropathic pain, migraine and breakthrough cancer pain. Depomed is headquartered in Newark, California . To learn more about Depomed , visit www.depomed.com.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995. The statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties including, but not limited to, risks related to the outcome of the Company's ANDA litigation with Actavis, Alkem , Roxane and Watson , and the resulting exclusivity periods for NUCYNTA, NUCYNTA ER and NUCYNTA oral solution, as well as other risks detailed in the company's Securities and Exchange Commission filings, including the company's most recent Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q. There can be no assurance of a positive outcome in such litigation, or other assurance that actual results will be as expected or anticipated. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

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