



Cebranopadol Top-Line Data From Phase IIb Trial in Chronic Lower Back Pain Demonstrate Clinically and Statistically Significant Improvements in Pain Across All Arms

February 29, 2016

Results From a 635-Patient, Five-Arm, Placebo and Active-Controlled Trial

NEWARK, Calif., Feb. 29, 2016 (GLOBE NEWSWIRE) -- Depomed (NASDAQ:DEPO) today announced that top-line clinical results from a Phase IIb trial of GRT6005 ("cebranopadol") conducted by Grünenthal GmbH ("Grünenthal") in patients with moderate to severe chronic lower back pain (cLBP) have been posted to the European Clinical Trials Database (EudraCT). Results from the cLBP trial showed clinically and statistically significant improvements in pain at all three doses tested. In December, Depomed acquired the U.S. and Canadian rights to cebranopadol and its related follow-on compound from Grünenthal.

The trial "Efficacy, safety, and tolerability of GRT6005 (cebranopadol) in subjects with moderate to severe chronic low back pain" ([EudraCT Number: 2012-001920-36](#)) studied 635 patients with cLBP from 11 European countries. The objective of this 12 week, randomized, double-blind, placebo- and active-controlled, five-arm, monotherapy trial was to assess the analgesic efficacy, safety, and tolerability of once daily orally administered cebranopadol at three fixed doses (i.e., 200, 400, and 600 µg) compared to placebo and tapentadol prolonged release, as the active comparator, in patients with moderate-to-severe cLBP. Patients were initiated at 200 µg of cebranopadol once-a-day, and their doses were increased in increments of 200 µg, as applicable, every 3 days. Tapentadol titration was consistent with the United States Prescribing Information (USPI) and consisted of initiation at 50 mg twice-a-day, followed by escalation to 100, 150, and 200 mg twice-a-day at 3-day intervals, with 200 mg twice-a-day being the target dose.

Two separate primary endpoints were pre-specified, one applicable to ex-US territories including the EU and the other applicable to the US. The latter consisted of the change from baseline of the average 24-hour pain (as assessed by the "Numeric Rating Scale") during the 12th week of therapy. In summary, all 3 doses of cebranopadol resulted in robust, clinically 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. Moreover, the validity of the trial was confirmed by the results associated with the active comparator.

Across all five study arms, there were low levels of severe adverse events (SAEs), without any disproportionate attribution to any cebranopadol arms. Adverse event (AE) rates were generally higher with cebranopadol at any dose versus either placebo or tapentadol. This may be a result of the forced dose titration schedule employed in this trial, particularly compared to the optimized titration employed in the escalation of tapentadol. The four most common AEs were dizziness, nausea, vomiting, and constipation across the three cebranopadol and single tapentadol arms.

Results from additional Phase II trials as well as human abuse potential and respiratory depression studies are anticipated to be presented at upcoming scientific conferences later this year.

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.

"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, those related to further clinical development of cebranopadol and other risks detailed in the company's Securities and Exchange Commission filings, including the company's Annual Report on Form 10-K for the year ended December 31, 2015. The inclusion of forward-looking statements should not be regarded as a representation that any of the company's plans or objectives will be achieved. You 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.

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.

INVESTOR AND MEDIA CONTACT:

Christopher Keenan

VP, Investor Relations and Corporate Communications

510-744-8000

ckeenan@depomed.com

 Primary Logo

Depomed, Inc