

ADOLOR CORPORATION ANNOUNCES POSITIVE RESULTS FROM PHASE 2 PROGRAM IN OIC

Statistically Significant Results Achieved

Management to Host Conference Call, Wednesday, August 10, 2011, at 8:30 a.m.

EXTON, Pa., Aug 10, 2011 (BUSINESS WIRE) -- Adolor Corporation (NasdaqGM:ADLR) today announced positive, statistically significant top line results from its two Phase 2 studies of ADL5945 in chronic non-cancer pain patients with opioid-induced constipation (OIC). ADL5945, a peripherally-acting mu opioid receptor antagonist, is an investigational drug being evaluated for the treatment of OIC as well as other associated gastrointestinal (GI) complications. Both randomized, double-blind, placebo-controlled studies were identical in design; Study 242 evaluated 0.25 mg and 0.10 mg of ADL5945 administered twice daily (BID) and Study 243 evaluated 0.25 mg of ADL5945 administered once daily (QD).

"Opioid analgesics have become a cornerstone of multimodal therapy for the management of patients who suffer with chronic non-cancer pain," said Neil Singla, M.D., Department of Anesthesiology, Director, Clinical Research, Huntington Memorial Hospital in Pasadena, California, and lead investigator for the Phase 2 program. "Unfortunately, OIC presents a very serious burden to most patients treated on long-term opioid therapy, and currently there are no adequate therapies to address this common and debilitating condition. The results of these studies of ADL5945 are very encouraging - demonstrating both clinically meaningful effects and a favorable tolerability profile."

"Our Phase 2 program achieved all of our objectives and validates our view that ADL5945 is a potentially important drug for patients suffering from OIC and related GI symptoms," said Michael R. Dougherty, Adolor's President and CEO. "Adolor has extensive experience in this therapeutic area that we will continue to leverage as we now focus on the Phase 3 program. There has been significant interest in ADL5945 and we look forward to sharing these data and initiating pivotal studies as expeditiously as possible."

Study Results

Twice-daily Dosing (Study 242)

Statistical significance ($p = 0.0003$) was achieved for the primary endpoint in the 0.25 mg BID dose group. The primary endpoint of both studies was the change from baseline in the weekly average number of spontaneous bowel movements (SBMs). Response to treatment was dose dependent in Study 242, with an average change from baseline in SBM frequency over the 4-week treatment period of 1.4 SBMs for the placebo group, and 2.0 and 3.4 SBMs for the 0.10 mg and 0.25 mg doses of ADL5945, respectively. Statistical significance was not achieved for the 0.10 mg dose.

Statistical significance ($p = 0.005$) also was achieved in the 0.25 mg BID dose group for a key secondary endpoint, a responders analysis, with a 56% response rate for the active arm and a 26% response rate for the placebo arm of the study. This translates into a clinically relevant number needed to treat (NNT) of 3.3. For this analysis, responders were defined as those patients who achieved an average weekly frequency of at least three SBMs and an increase of at least one SBM above baseline.

Other exploratory endpoints (patients' global impression of change, BM comfort and satisfaction scores) demonstrated greater improvement as compared to baseline in the ADL5945 0.25 mg treatment group as compared to placebo.

Once-daily Dosing (Study 243)

In Study 243, statistical significance ($p = 0.01$) also was achieved for the primary endpoint. The average change from baseline in SBM frequency over the 4-week treatment period was 1.4 SBMs for the placebo group and 2.6 SBMs for the 0.25 mg ADL5945 treatment group.

Although the proportion of responders was higher in the 0.25 mg treatment group (42.5% vs. 29.3% in placebo), statistical significance was not achieved.

Other exploratory endpoints evaluating changes in bowel function trended in favor of ADL5945 as compared to placebo.

Safety and Tolerability

ADL5945 was well tolerated in both studies. The overall number of patients reporting at least one treatment-emergent adverse event was comparable across both studies (ADL5945: 29%; placebo: 26%). There was no evidence of drug-related central opioid withdrawal or reversal of analgesia in any of the ADL5945 treatment groups across both studies.

Additional information concerning the efficacy and safety results from Study 242 and Study 243 is included in the slide presentation that will accompany the investor conference call.

Conference Call Information

Adolor's management will discuss the results of the Phase 2 studies in a conference call with investors beginning at 8:30 a.m. ET Wednesday, August 10, 2011.

To participate in the audio portion and have the opportunity to pose questions, dial 866-202-3109 for domestic callers or 617-213-8844 for international callers, and enter Conference ID # 62949696. Investors also can listen to the call live and view a slide presentation by logging on to the Company's website at www.adolor.com and clicking on "Investor Insights," then "Calendar of Events."

A replay of the call will be available beginning approximately two hours after the event. To listen to a replay of the conference call, dial 888-286-8010 (domestic) or 617-801-6888 (international) and enter Conference ID # 75827916 or listen via Adolor's website. The replay will be available for one week.

About ADL5945

ADL5945 is a potent, peripherally-acting mu opioid receptor antagonist intended to block the adverse effects of opioid analgesics on the GI tract without compromising centrally-mediated analgesia. Peripheral mu opioid receptors in the GI tract regulate functions such as motility, secretion and absorption. Stimulation of these GI mu opioid receptors by morphine, or other opioid analgesics, disrupts normal gut motility.

About OIC

Over 250 million opioid prescriptions are written annually in the United States. For those patients treated with prescription opioids for long-term pain management, many will develop constipation, as well as other associated gastrointestinal complications. Currently, there are no FDA-approved therapies to treat opioid-induced constipation in patients with chronic non-cancer pain.

About Adolor

Adolor Corporation is a biopharmaceutical company specializing in the discovery, development and commercialization of novel prescription pain and pain management products.

Adolor's first approved product in the United States is ENTEREG(R) (alvimopan), which is indicated to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis. ENTEREG is available only for short-term (15 doses) use in hospitalized patients. Only hospitals that have registered in and met all of the requirements for the ENTEREG Access Support and Education (E.A.S.E.) program may use ENTEREG. For more information

on ENTEREG, including its full prescribing information, the Boxed Warning regarding short-term hospital use and the E.A.S.E.(R) Program, visit www.ENTEREG.com.

The Company's research and development pipeline includes novel mu opioid receptor antagonists undergoing clinical development for chronic OIC; and several earlier-stage compounds under development for the management of pain and CNS disorders.

For more information, visit www.adolor.com.

Forward-Looking Statements

This press release, and oral statements made with respect to information contained in this release, may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements provide Adolor's current expectations or forecasts of future events. These may include statements regarding market prospects for ENTEREG; the development of potential pharmaceutical products such as ADL5945, including whether the results seen in the Phase 2 studies will be seen in future clinical studies, whether ADL5945 will be an important drug for patients suffering from OIC, whether the Company will be able to successfully leverage its experience in the OIC therapeutic area in the Phase 3 program, whether there will continue to be external interest in ADL5945 and the timetable for the initiation of pivotal testing; prospects for regulatory approvals; anticipated scientific progress on Adolor's research programs; and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning or that otherwise express contingencies, goals, targets or future development. These statements are based upon management's current expectations and are subject to risks and uncertainties, known and unknown, that could cause actual results and developments to differ materially from those expressed or implied in such statements due to general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries, as well as more specific risks and uncertainties facing Adolor such as those set forth in its reports on Forms 8-K, 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Adolor urges you to carefully review and consider the disclosures found in its filings which are available at www.sec.gov and from Adolor at www.adolor.com. Given the uncertainties affecting pharmaceutical companies such as Adolor, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Adolor undertakes no obligation to publicly update or revise the statements made herein or the risk factors that may relate thereto whether as a result of new information, future events, or otherwise, except as may be required by law.

Adolor Corporation

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