

## **ADOLOR AND GLAXOSMITHKLINE REPORT FAVORABLE FDA ADVISORY COMMITTEE MEETING FOR ENTEREG(R) (ALVIMOPAN) FOR THE MANAGEMENT OF POSTOPERATIVE ILEUS IN BOWEL RESECTION**

EXTON, Pa. & PHILADELPHIA, Jan 23, 2008 (BUSINESS WIRE) -- Adolor Corporation (Nasdaq:ADLR) and GlaxoSmithKline (NYSE:GSK) today announced that a majority (9-6) of the Gastrointestinal Drugs Advisory Committee (GIDAC) of the U.S. Food and Drug Administration (FDA) voted that the overall benefits of treatment with Entereg(R) (alvimopan), an investigational mu-opioid receptor antagonist, outweighed potential risks for short-term, in-hospital use in patients following partial large or small bowel resection surgery with primary anastomosis. The FDA is reviewing Adolor's New Drug Application (NDA) for ENTEREG for the proposed indication of acceleration of upper and lower gastrointestinal (GI) recovery following partial large or small bowel resection surgery with primary anastomosis. There are no drugs approved for this indication.

With regard to the specific questions posed by the FDA to the committee, members voted 13-0, with two abstentions, that the efficacy results from the submitted studies in postoperative ileus (POI) were clinically meaningful. Although the panel voted (8 to 6 with one abstention) that a potential cardiovascular risk signal seen in one long-term OBD study (Study 014) remained a concern for short-term use in managing POI, a majority (9-6) agreed that the overall benefits of treatment with alvimopan outweighed the potential risks for short-term in-hospital use in the proposed bowel resection patient population. The panel voted 14 to 0 with one abstention that the preliminary risk management plan proposed by Adolor was not adequate to address potential risks.

"This is an important milestone for ENTEREG and we are pleased with the favorable outcome of the Committee meeting," said Michael R. Dougherty, president and chief executive officer of Adolor Corporation. "This is further validation of our confidence in ENTEREG and our belief in the clinical benefit offered by ENTEREG in this indication. I would like to commend the significant effort of the combined Adolor and GSK development team. We look forward to working with the FDA, including the further development of a risk management plan, as they complete the review of the NDA for ENTEREG."

The Committee's recommendation, although not binding, will be considered by the FDA as it completes its review of the NDA for ENTEREG. The Prescription Drugs User Fee Act (PDUFA) action date for the NDA is February 10, 2008.

"A majority of the Committee agreed that ENTEREG produced clinically meaningful acceleration in GI recovery in bowel resection patients," said Yvonne Greenstreet, senior vice president of the medicine development centre at GlaxoSmithKline. "Postoperative ileus can be uncomfortable for the patient, hinder post surgical recovery and delay hospital discharge in bowel resection patients. If approved, ENTEREG would be the first medication to address this common and burdensome complication."

### **About Adolor Corporation**

Adolor Corporation (Nasdaq:ADLR) is a biopharmaceutical company specializing in the discovery, development and commercialization of novel prescription pain management products. Adolor has two lead product candidates in development: ENTEREG(R) (alvimopan) for the management of the gastrointestinal side effects associated with opioid use; and novel Delta opioid receptor agonists for a variety of pain indications. Adolor and GlaxoSmithKline are collaborating in the worldwide development and commercialization of ENTEREG in multiple indications. Adolor and Pfizer are collaborating in the worldwide development and commercialization of two Delta agonists for pain. Adolor also has a number of discovery research programs focused on the identification of novel compounds for the treatment of pain. By applying its knowledge and expertise in pain management, along with ingenuity, Adolor is seeking to make a positive difference for patients, caregivers and the medical community. For more information, visit [www.adolor.com](http://www.adolor.com).

### **About GlaxoSmithKline**

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies and is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For more information, visit GlaxoSmithKline on the World Wide Web at [www.gsk.com](http://www.gsk.com).

### **Adolor Forward-Looking Statements**

This release, and oral statements made with respect to information contained in this release, may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those which express plan, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These statements are based upon management's current expectations and are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such known risks and uncertainties relate to, among other factors: the risk that Adolor may not receive regulatory approval of ENTEREG (R) (alvimopan) for POI, OBD, or any other indication; the risk that the February 10, 2008 PDUFA date is extended or not met; the risk that Adolor may not be able to adequately address the deficiencies in the November 2006 FDA approvable letter; the risk that a risk management plan could materially adversely affect the commercial prospects for ENTEREG, if regulatory approval is achieved; the risk that Adolor may not obtain FDA approval for ENTEREG in POI, whether due to Adolor's inability to provide additional data satisfactory to the FDA to obtain approval for the NDA, the adequacy of the safety and efficacy data from all of the ENTEREG studies, changing regulatory requirements, the risk that the FDA may not agree with Adolor's and GSK's analyses of the ENTEREG studies (including Study 014) and may evaluate the results of these studies by different methods or conclude that the results from the studies, whether or not statistically significant, do not support safety, efficacy, a favorable risk/benefit profile, or there were human errors in the conduct of the studies, or otherwise; adverse safety findings in any ENTEREG studies; the risk that the alvimopan Investigational New Drug Applications (INDs) remain on clinical hold indefinitely; the risk that filing targets for regulatory submissions or user fee goal dates are not met; the risk that the results of other clinical trials of Adolor's drug product candidates, including ENTEREG, are not positive; the risk of product liability claims; reliance on third party manufacturers; the costs, delays and uncertainties inherent in scientific research, drug development, clinical trials and the regulatory approval process; Adolor's history of operating losses since inception and its need for additional funds to operate its business; Adolor's reliance on its collaborators, including GSK, in connection with the development and commercialization of ENTEREG; market acceptance of Adolor's products, if regulatory approval is achieved; competition; and securities litigation.

Further information about these and other relevant risks and uncertainties may be found in Adolor's Reports on Form 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 in the SEC EDGAR database at <http://www.sec.gov> and from Adolor at <http://www.adolor.com>. Given the uncertainties affecting pharmaceutical companies in the development stage, you are cautioned not to place undue reliance on any such forward-looking statements, any of which may turn out to be wrong due to inaccurate assumptions, unknown risks, uncertainties or other factors. Adolor undertakes no obligation to (and expressly disclaims any such 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.

### **GSK Cautionary statement regarding forward-looking statements**

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this Announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect the Group's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2006.

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