

Adolor's Complete Response to Approvable Letter for Entereg(R) (Alvimopan) in POI Accepted for Review by FDA; FDA Performance Goal Date is Targeted for November 2006

EXTON & PHILADELPHIA, Pa.--(BUSINESS WIRE)--May 31, 2006--Adolor Corporation (Nasdaq: ADLR) and GlaxoSmithKline (NYSE: GSK) announced today that the Food and Drug Administration (FDA) has accepted as complete, Adolor's response to the July 2005 New Drug Application (NDA) approvable letter for Entereg for the management of post-operative ileus (POI). The FDA informed Adolor that the response is considered a class 2 resubmission with a user fee goal date of November 9, 2006.

"We are pleased the Agency has accepted the complete response for review," stated James Barrett, Ph.D., senior vice president, chief scientific officer and president, research of Adolor Corporation. "The early achievement of this milestone takes us one step closer to achieving our goal of bringing this novel treatment to patients and surgeons. We look forward to working with the Agency throughout the review."

"We were delighted to announce positive results of Study 314 in February of this year, setting the stage for this complete response to the Agency," said Kevin Lokay, vice president of oncology and acute care at GlaxoSmithKline. "This is an important step toward our goal of bringing a new treatment option to physicians who treat POI and to patients who may benefit. We will be working closely with Adolor in the regulatory review process."

On July 21, 2005 the FDA issued an approvable letter for Entereg(R) (alvimopan), an investigational drug under review for the management of postoperative ileus (POI) by acceleration of the time to recovery of gastrointestinal (GI) function following bowel resection surgery. The FDA indicated in the letter that before the NDA may be approved, it was necessary to provide additional proof of efficacy to support the proposed use of Entereg following bowel resection surgery. The FDA indicated that this may be achieved by demonstrating statistically significant results in at least one additional clinical study, and that this could potentially be addressed with the positive results from Adolor's Study 14CL314. The FDA also indicated that Adolor must provide justification that the median reduction in time to gastrointestinal recovery seen in bowel resection patients treated with Entereg is clinically meaningful.

About Postoperative Ileus (POI)

Many patients undergoing abdominal surgery experience transient gastrointestinal impairment. This condition, known as postoperative ileus, may be exacerbated and prolonged by multiple factors including the use of opioid analgesics for pain relief. POI is characterized by abdominal distension and pain, nausea and vomiting, reduced desire to eat, and an inability to pass gas or stool. POI is a major contributor to prolonged hospital stays. Consequently, POI represents a substantial burden on healthcare resources.

Despite the negative impact, there have been few advances in the treatment of POI since the introduction of nasogastric decompression over 100 years ago, which has limited effectiveness and is uncomfortable for patients. Currently, there are no drugs approved for the management of POI.

Entereg Collaboration

Adolor Corporation and GlaxoSmithKline are collaborating on the worldwide development and commercialization of Entereg(R) for POI and the gastrointestinal side effects of opioids associated with extended use for persistent pain.

About Adolor Corporation

Adolor Corporation (Nasdaq: ADLR) is a biopharmaceutical company specializing in the discovery, development and commercialization of novel prescription pain management products. Entereg(R) (alvimopan) is Adolor's lead product candidate under development for the management of the gastrointestinal side effects associated with opioid use. Adolor is developing a sterile lidocaine patch which is in Phase 2 clinical development for post-surgical incisional 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.

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.

This release, and oral statements made with respect to information contained in this release, 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 obtain FDA approval for the NDA for Entereg(R) in POI, whether due to the risk that: Adolor is not able to provide additional data satisfactory to the FDA to obtain approval for the NDA; Adolor is not able to justify that the median reduction in time to gastrointestinal (GI) recovery seen in bowel resection patients treated with Entereg(R) is clinically meaningful; the adequacy of the results of the Studies 14CL302, 14CL306, 14CL308, 14CL313 and 14CL314 to support FDA approval of Entereg(R), the results from other clinical trials of Entereg(R), including the Glaxo Phase 3 Study 001, the adequacy of the development program, the conduct of the clinical trials, changing regulatory requirements, different methods of evaluating and interpreting data, reliance on third-party manufacturers, adverse safety findings or otherwise; the risk that the FDA may not agree with Adolor's analyses of Studies 14CL302, 14CL306, 14CL308, 14CL313 and 14CL314 and may evaluate the results of these studies by different methods or conclude that the results from the studies are not statistically significant, clinically meaningful or do not support safety or that there were human errors in the conduct of the studies or otherwise; the risk that further studies of Entereg(R) in OBD are not positive; the risk that the results of Study 001 do not support a submission of a marketing approval application for alvimopan in Europe for POI; the risk of unfavorable results of trials in other indications; the risk that filing targets or user fee goal dates for regulatory submissions are not met; the risk that FDA does not remove the clinical hold on the Delta IND; 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 Glaxo, in connection with the development and commercialization of Entereg(R); 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.

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 Operating and Financial Review and Prospects in the company's Annual Report on Form 20-F for 2005.

This press release is available on the website <http://www.adolor.com>.

CONTACT: Adolor Corporation
Corporate Communications:
Lizanne Wentz, 484-595-1500
or
GlaxoSmithKline
Product Communications:
Michele L. Meeker, 919-483-2839
or
Sam Brown Inc.
Media:
Mike Beyer, 773-463-4211
SOURCE: Adolor Corporation