FDA ACCEPTS LABOPHARM'S RESPONSE TO APPROVABLE LETTER FOR ONCE-DAILY TRAMADOL AS COMPLETE

Labopharm Inc. has announced that its response to matters raised by the US Food and Drug Administration (FDA) in the approvable letter for Labopharm's once-daily formulation of tramadol has been accepted for review by the FDA as complete. The action date assigned by the FDA under the Prescription Drug User Fee Act is June 19, 2007. Labopharm received the approvable letter for its once-daily formulation of tramadol on September 28, 2006, following submission of its New Drug Application, sent November 28, 2005. Following discussions with the FDA, Labopharm submitted its response to the matters raised in the approvable letter for once-daily tramadol on December 19, 2006.

Labopharm Inc. is an international specialty pharmaceutical company focused on the development of drugs that incorporate the company's proprietary controlled-release technologies. The once-daily tramadol formulation has already been approved in Europe. Last week, the company said tramadol is available, under differing brand names, in Italy, Germany, Spain, and the United Kingdom, and it will soon be available in France and Belgium. For more information, please visit *www.labopharm.com.*

This press release contains forward-looking statements that involve a number of risks and uncertainties relating to the company's once-daily tramadol product in the United States that could cause actual results to differ materially from those indicated here. These statements reflect the company's current expectations regarding future events. Specifically, the risks and uncertainties the company faces include but are not limited to the company's ability to resolve the issues identified by the FDA to the FDA's satisfaction in a timely manner; the uncertainties related to the regulatory process, including regulatory approval; and the commercialization of the drug thereafter. There can be no assurance that Labopharm will be able to resolve the issues identified by the FDA using existing data, or at all. If the company is unable to resolve the issues identified by the FDA using existing data, it will need to generate additional data in order to obtain FDA approval. (Source: LAVAL, QC, January 16, 2006.)

STUDY FINDS 90 PERCENT OF ACTIQ "LOLLIPOP" PRESCRIPTIONS ARE OFF-LABEL

A recent Prime Therapeutics (Prime) study found significant patterns of "off-label" prescribing for Actiq among patients using the powerful painkilling "lollipop." Prescribing Actiq according to FDA guidelines is important for patient safety reasons because of the drug's serious side effects, including the risk of addiction. The results of the Prime study confirm concerns about the drug which have been highlighted recently by the national news media. Prime, a thought leader in pharmacy benefit management, provides programs that manage the use of Actiq and other dangerous drugs in an effort to promote health and safety while ensuring that patients get the treatment they need.

"The FDA has only approved Actiq for use by cancer patients who are already taking a long-acting, chronic painkiller but suffer from severe spikes in pain," stated Pat Gleason, PharmD, Director of Medical and Pharmacy Integration Services for Prime. "The Prime study, however, found that only slightly more than 10 percent of the patients receiving the drug over a three-month period in 2005 met those guidelines. Nearly 90 percent of Actiq prescriptions in our study were off-label, or not prescribed according to the guidelines set forth by the FDA."

Actiq contains fentanyl, a potent synthetic opioid with a high potential for abuse and overdose. In addition, fentanyl has been linked to fatal respiratory complications. As a result, while physicians are allowed to prescribe medications for unapproved or "off-label" use, the FDA recommends strict adherence to Actiq's prescribing guidelines.

Last year, in response to the safety concerns highlighted in the study, Prime began offering programs to promote Actiq's safe use. These programs include a monthly limit of 120 doses of Actiq or a newer, related drug, Fentora. Patients are also required to have prior authorization from their doctor, and prescriptions are limited to a 12-month period. Prime's program also encourages members to take a long-acting opioid for chronic pain. The program guidelines follow FDA recommendations.

"There are serious safety issues regarding Actiq, so doctors need to be careful how it is prescribed," said Gleason. "Prime integrates pharmacy and medical data to identify misuse of drugs such as Actiq and then develops programs to ensure patient safety. Our drug-utilization programs not only keep members safe but save health plans thousands of dollars a month."

The study analyzed Actiq patient claims from a Midwestern commercial health plan between April and June 2005. Of the 95 patients who received prescriptions for the lollipop during that time, only 21 had a diagnosis of cancer or AIDS. In addition, only 10 of those 21

patients were taking a long-acting opioid painkiller. Overall, 84 of the 95 Actiq prescriptions—nearly 90 percent—were for off-label purposes. The study also found that more than 15 percent of Actiq prescriptions were for more than the FDA's recommended 120 lollipops per month, suggesting that some patients may be overusing the drug. (Source: Prime Therapeutics, LLC/PRNewswire, January 16, 2007.)

A QUICK-RELIEF OPIOID: CEPHALON REPORTS POSITIVE RESULTS FROM PHASE III TRIALS WITH FENTORA

Fentora, approved by the FDA in September 2006, is the first pain reliever in seven years to be approved for the management of breakthrough pain in cancer patients who are already taking opioids for underlying, persistent cancer pain. In the earlier clinical trials submitted as part of the Fentora New Drug Application, the company reported pain relief at 15 minutes. It usually takes 30 to 45 minutes for other pain medications to take effect.

The trial, which assessed the efficacy of Fentora in a variety of chronic conditions associated with neuropathic pain, was a double-blind, placebo-controlled study involving 75 opioid-tolerant patients. In patients treated with Fentora, the onset of pain relief began in 10 minutes; the results seen in patients receiving placebo were consistent with a previously announced study of opioid-tolerant patients with chronic low back pain. In a different placebo-controlled study that evaluated Fentora in 78 opioid-tolerant patients with cancer, the result was much the same, with the patients beginning to experience pain relief in 10 minutes. (Source: The Connors Group, Inc., January 13, 2007.)

DOCTOR FREES INMATE IN ORDER TO ADMINISTER DRUG

A Madison County Jail policy that forbids anyone from bringing prescription medicine to inmates, even doctors, prompted a doctor to post $1,000 to bail out a patient who suffers from cerebral palsy and was apparently denied painkillers by jail staff. Madison County's sheriff said the man was not treated differently from other inmates.

Jim Stewart, who lives outside Granite City, takes multiple medications every day, including one to six tablets of hydrocodone to control severe muscle pain and help him sleep. He was arrested December 27, 2006, after fighting with his brother and was charged with a felony count of aggravated battery.

Stewart's mother was worried that he wasn't getting his hydrocodone while in custody. Hours after the arrest, she called his doctor, Alexander Kalk, who has a general medicine practice in Creve Coeur. Kalk said he drove to Edwardsville that night and dropped off a new bottle of hydrocodone for Stewart, along with a written prescription. Stewart has been taking the drug for about 15 years, and Kalk said he was concerned about withdrawal effects that would result if he were suddenly taken off it.

The next day, a nurse called Kalk and said she had concerns about giving such a strong pain medication to a person in jail. Kalk said the nurse told him that Stewart had been given just one dose of hydrocodone since he had been in jail. Stewart also said he only received one tablet, despite complaining of severe muscle pain and asking a dozen times to be taken to the hospital.

Kalk said he faxed details of Stewart's medical history to the jail, but he wasn't satisfied it would do any good. "I could tell he wasn't going to get his medicine," Kalk said. So on December 28 he made a second trip to Edwardsville and posted Stewart's $1,000 bond.

Kalk, 36, said Stewart looked haggard and in pain when he was released and didn't feel better until he took his hydrocodone. Kalk said it's unbelievable that a jail would not allow a physician to bring medicine to a sick inmate. "That's a medical mistake to have that policy," Kalk said.

Madison County Sheriff Bob Hertz would not comment on Stewart's case because of confidentiality concerns, but he said the jail simply followed its policy. "We don't allow medication to come into the jail from the outside," Hertz said. The sheriff said it would be too risky to accept someone's word that the medicine in a bottle was indeed the prescribed medicine and that it's up to the jail's medical staff to determine what prescriptions inmates receive.

Each Illinois jail can choose its own policy about how inmates get prescription drugs, said Derek Schnapp, a spokesman for the state's Department of Corrections, which oversees county jails. No information was available about how many jails ban bringing in such medications. The St. Clair County Jail allows family members and doctors to drop off medicine with a written prescription, said Capt. Thomas Knapp, the acting jail superintendent. Jail staff then call the doctor who wrote out the prescription to make sure it's valid, and they also check the medicine itself to confirm it's the prescribed medication. (Source: Leah Thorsen, St. Louis *Post-Dispatch*, January 17, 2007.)