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Media Alert

Contact:
Stacey Beckhardt
610-738-6198 office
610-247-0212 mobile
sbeckhardt@cephalon.com

Catherine Collier
212-886-2214 office
ccollier@cooneywaters.com

Cephalon Announces that FENTORA™ May Offer Therapeutic Option for Breakthrough Pain in Patients with Chronic Low Back Pain

WHAT: Roughly one-quarter of U.S. adults – nearly 50 million – experience chronic low back pain. An evolving understanding of pain is showing that like other serious chronic pain conditions, low back pain often has two components, which require recognition and individualized treatment:

- Persistent pain – pain that is continuous throughout the day that is typically managed with around-the-clock medication
- Breakthrough pain (BTP) – flares of pain characterized by rapid onset, intensity, and relatively short duration that occur in the context of well-managed persistent pain

Data in this month's issue of the journal *Current Medical Research and Opinion* report that a new opioid pain medication, *FENTORA*™ (fentanyl buccal tablet) [C-II], may provide an option for the management of breakthrough pain in patients with chronic low pain back who are already taking opioids for persistent pain. In this study, *FENTORA* provided signifcant pain relief, with some patients experiencing such relief within 10 minutes. Onset of pain relief was significantly greater with *FENTORA* than with placebo, with differences sustained over the two hours measured.

FENTORA is the first tablet formulation of the opioid fentanyl approved by the U.S. Food and Drug Administration (FDA) to manage breakthrough pain in opioid-tolerant patients with cancer. It is also the first new medication approved for this condition in seven years, and the first fentanyl tablet that is absorbed across the lining of the cheek.

WHO: **John F. Peppin, MD**
Iowa Pain Management Clinic, PC
(insert any additional credentials)

WHEN: **XXXXX, December x, 2006, xx a.m. EST**
To register, call x or e-mail x

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WHY: Chronic low back pain restricts functioning, interferes with work and routine daily activities, and can lead to major disability. An estimated 74 percent of patients treated for persistent pain associated with chronic pain conditions such as low back pain experience breakthrough pain.

Data reveal back pain is the:

- Leading cause of limited activity in young and middle-aged persons
- Second most common reason for doctor visits
- Fifth-ranking cause of hospital admission
- Third most common cause for surgical procedures

Low back pain accounts for an estimated 30 million office visits per year.

Together, acute and chronic low back pain are responsible for direct health care expenditures of more than $20 billion annually. Roughly two percent of the U.S. workforce is compensated for back injuries each year; less than half of those disabled for longer than six months are able to return to work.

While there are data on the economic impact of chronic low back pain on the workforce and health care system, it is more difficult to quantify the emotional toll on individuals' well being and overall quality of life.

FENTORA

Manufactured by Cephalon, Inc., *FENTORA* was approved by the U.S. Food and Drug Administration on September 25, 2006, for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. This novel medication employs the OraVescent® drug delivery system, which generates a reaction that is accompanied by transient changes in pH believed to optimize how well the tablet dissolves and how quickly the medicine passes across the lining of the cheek, or buccal mucosa. In clinical trials involving patients with cancer, *FENTORA* was generally well tolerated; most adverse events with *FENTORA* are typical opioid side effects and mild to moderate in severity. The most common (≥10%) adverse events observed in clinical trials of *FENTORA* were nausea, vomiting, application site abnormalities, fatigue, anemia, dizziness, constipation, edema, asthenia, dehydration, and headache. No attempt was made to correct for concomitant use of around-the-clock opioids or cancer-related symptoms. The most serious adverse events associated with all opioids are respiratory depression (potentially leading to apnea or respiratory arrest), circulatory depression, hypotension, and shock. All patients should be followed for symptoms of respiratory depression. Opioid side effects should be expected and managed accordingly.

FENTORA is currently not FDA-approved for the management of breakthrough pain in patients with chronic low back pain.

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Breakthrough Pain

Breakthrough pain – a component of chronic pain – is a transitory flare of moderate-to-severe pain in patients with otherwise stable persistent pain. Breakthrough pain can reach peak intensity in as little as three minutes and typically lasts for 30 to 60 minutes. An estimated 64 percent of all cancer patients treated for persistent pain – and an estimated 74 percent of patients treated for persistent pain from other chronic pain conditions – will experience breakthrough pain.

IMPORTANT WARNINGS AND SAFETY INFORMATION

FENTORA contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. FENTORA can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing FENTORA in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances which include morphine, oxycodone, hydromorphone, oxymorphone, and methadone have the highest potential for abuse and risk of fatal overdose due to respiratory depression.

FENTORA is indicated for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

Because life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients, FENTORA is **contraindicated** in the management of acute or postoperative pain. **This product is not indicated for use in opioid non-tolerant patients**.

Patients and their caregivers must be instructed that FENTORA contains a medicine in an amount which can be fatal to a child. Patients and their caregivers must be instructed to keep all tablets out of the reach of children (see Information for Patients and Their Caregivers contained within the prescribing information for disposal instructions).

Due to the higher bioavailability of fentanyl in FENTORA, when converting patients from other oral fentanyl products, including oral transmucosal fentanyl citrate (OTFC and Actiq®), to FENTORA, do not substitute FENTORA on a mcg per mcg basis and adjust doses as appropriate (see DOSAGE AND ADMINISTRATION contained within the prescribing information).

FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

**Full prescribing information about *FENTORA*, including boxed warning,
is available from www.*FENTORA*.com
or Cephalon Professional Services and Medical Information (1-800-896-5855)**

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