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Purdue Pharma L.P. Comments on FDA Announcement On REMS For Extended-Release And Long-Acting Opioid Analgesics

Stamford, CT – July 9, 2012 – The U.S. Food and Drug Administration (FDA) is requiring opioid analgesic companies to implement a new, shared Risk Evaluation & Mitigation Strategy (REMS) for all extended-release and long-acting opioid pain medications to ensure that the benefits continue to outweigh the risks of adverse outcomes (addiction, unintentional overdose, and death) resulting from inappropriate prescribing, abuse, and misuse. The principal components of this REMS are:

- prescriber training on all ER/LA opioid analgesics,
- a *Patient Counseling Document on Extended-Release and Long-Acting Opioid Analgesics (PCD)*, and
- a Medication Guide for each ER/LA opioid analgesic drug product.

These components are intended to help healthcare professionals better understand the risks and benefits of selecting and prescribing these important medicines, and to educate patients about how to use as directed, their risks, and proper storage and disposal.

Purdue supports the goals of enhanced prescriber and patient education as part of a comprehensive approach necessary to address the misuse, abuse, and diversion of prescription medicines, while ensuring these medications remain accessible for people with chronic, moderate to severe pain, when appropriate.

Purdue first developed and implemented risk management programs for its opioid products in 1998, to provide prescribers with information on proper patient selection and assessment, when considering the use of opioid analgesics. The company has continually provided resources and tools to healthcare professionals to help them recognize and minimize diversion, abuse and addiction. The company launched FDA-approved product-specific REMS for OxyContin® (oxycodone HCl controlled release) Tablets CII and Butrans® (buprenorphine) Transdermal System CIII in 2010. The new shared REMS that is being required by the FDA was developed with support and input from the medical community, patient advocacy groups, and the pharmaceutical industry, and will supersede the individual product REMS for these and other extended-release and long-acting opioid medications. More information on the new shared REMS will soon become available at www.ER-LA-opioidREMS.com or on the FDA web site at www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.

The misuse, abuse and diversion of prescription pain medicines – as well as untreated and undertreated chronic pain – are serious, complex, and interrelated public health issues. Purdue is committed to reduce and prevent the abuse of prescription medicines by supporting healthcare professional and public education; promoting proper storage and disposal of medications in the home; encouraging better monitoring and tracking of medicines; and assisting law enforcement efforts to combat illegal diversion of prescription medication.

For more information about the company's efforts to address prescription medicine abuse and diversion, visit www.rxsafetymatters.org.

The professional prescribing information for OxyContin Tablets contains the following boxed warning:

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

OxyContin® contains oxycodone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit [see Warnings and Precautions (5.1)].* Assess each patient's risk for opioid abuse or addiction prior to prescribing OxyContin. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving OxyContin for signs of misuse, abuse, and addiction during treatment [see Drug Abuse and Dependence (9)].*

Life-Threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of OxyContin, even when the drug has been used as recommended and not misused or abused [see Warnings and Precautions (5.2)].* Proper dosing and titration are essential and OxyContin should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of OxyContin or following a dose increase. Instruct patients to swallow OxyContin tablets intact. Crushing, dissolving, or chewing the tablet can cause rapid release and absorption of a potentially fatal dose of oxycodone.

Accidental Exposure

Accidental ingestion of OxyContin, especially in children, can result in a fatal overdose of oxycodone [see Warnings and Precautions (5.3)].*

INDICATIONS AND USAGE

OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Limitations of Use

OxyContin is not for use:

- As an as-needed (prn) analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- In the immediate postoperative period (the first 24 hours following surgery) for patients not previously taking the drug, because its safety in this setting has not been established.
- For postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.

OxyContin 60 mg and 80 mg tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for patients in whom tolerance to an opioid of comparable potency is established. Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

CONTRAINDICATIONS

OxyContin is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected paralytic ileus and gastrointestinal obstruction
- Hypersensitivity (e.g., anaphylaxis) to oxycodone [see Adverse Reactions (6.2)]*

The Full Prescribing Information for OxyContin, including the Boxed Warning and the Medication Guide, is available at ~~http://www.purduepharma.com/pi/prescription/OxycontinPI.pdf~~.

The professional prescribing information for Butrans Transdermal System contains the following boxed warning:

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

BUTRANS contains buprenorphine, an opioid agonist and Schedule III controlled substance with an abuse liability similar to other Schedule III opioids, legal or illicit [see Warnings and Precautions (5.1)].* Assess each patient's risk for opioid abuse or addiction prior to prescribing BUTRANS. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving BUTRANS for signs of misuse, abuse, and addiction during treatment [see Drug Abuse and Dependence (9)].*

Life-Threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of BUTRANS, even when the drug has been used as recommended and not misused or abused [see Warnings and Precautions (5.2)].* Proper dosing and titration are essential and BUTRANS should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of BUTRANS or following a dose increase.

Accidental Exposure

Accidental exposure to BUTRANS, especially in children, can result in a fatal overdose of buprenorphine [see Warnings and Precautions (5.3)].*

INDICATIONS AND USAGE

BUTRANS is indicated for the management of moderate to severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Limitations of Use

BUTRANS is not for use:

- As an as-needed (prn) analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time

CONTRAINDICATIONS

BUTRANS is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected paralytic ileus
- Hypersensitivity (e.g., anaphylaxis) to buprenorphine [see Warnings and Precautions (5.12), and Adverse Reactions (6)]*

*[Referenced sections and numbers in parentheses refer to sections of the Full Prescribing Information]

The Full Prescribing Information for Butrans, including the Boxed Warning and the Medication Guide, is available at http://app.purduepharma.com/xmlpublishing/pi.aspx?id=b.

About Purdue Pharma L.P.

Purdue Pharma L.P. and its associated U.S. companies are privately-held pharmaceutical companies known for pioneering research on persistent pain. Headquartered in Stamford, CT, Purdue Pharma is engaged in the research, development, production, and distribution of both prescription and over-the-counter medicines and hospital products. Additional information about Purdue can be found at www.purduepharma.com.

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James Heins
203-588-8069 (Office)
203-856-2121 (Mobile)
james.heins@pharma.com

Libby Holman
203-588-7670 (Office)
203-609-1291 (Mobile)
libby.holman@pharma.com

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