Company Aims to Advance Prodrug of Oxycodone to FDA

KemPharm, Inc., a clinical stage biopharmaceutical company, announced the advancement of a new pain therapy program, KP606, a first-in-class oral prodrug of oxycodone. KP606 adds to the company's franchise of abuse-deterrent prodrugs, which includes KP201 (hydrocodone) and KP511 (hydro-morphone).

KemPharm announced the discovery of KP606 at PAINWeek 2013, the nation's largest pain conference for frontline clinicians with an interest in pain management.

In preclinical studies, KP606 exhibited superior pharmacological characteristics that suggest an improved safety profile compared to currently marketed oxycodone products, possibly reducing or preventing symptoms of constipation and limiting abuse potential. KP606 also features tamper resistant properties that make it difficult to extract oxycodone from the prodrug, which is not active until cleaved in the body.

The company is working toward filing a New Drug Application with the U.S. Food and Drug Administration in the second quarter of 2014.


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Progesterone Formulation Being Studied in TBI Patients

The 1,180th and final patient has been randomized into BHR Pharma, LLC’s global Phase III SyNAPSe© Trial. The study is evaluating the safety and efficacy of BHR’s proprietary intravenous progesterone formulation, BHR-100, for treating severe traumatic brain injury (TBI). If the final data support BHR-100 efficacy, the drug could be the first-ever approved treatment for TBI.

The study’s last patient was enrolled in the United States at the University of Iowa Hospitals and Clinics. In total, the SyNAPSe trial has 154 participating sites in the United States, Israel, Argentina, and 18 other countries in Europe and Asia.

SyNAPSe patients are evaluated at 6 months post-injury using the Glasgow Outcome Scale (GOS), the study’s primary endpoint. Secondary endpoints include GOS evaluation at 3 months post-injury, GOS-Extended and quality of life (SF-36) evaluations at 3 and 6 months post-injury, and mortality assessment at 1 month and 6 months post-injury. Results are expected in May 2014.

In addition to its well-known effects on the female reproductive system, progesterone is a potent neurosteroid, and progesterone receptors are abundant and widely distributed in the central nervous system in both men and women. Previous research has shown progesterone exerts its neuroprotective effects by protecting or rebuilding the blood-brain barrier, decreasing development of cerebral edema, down-regulating the inflammatory cascade, and limiting cellular necrosis and apoptosis (programmed cell death)—all potentially fatal injuries set in motion by TBI.

The European Medicines Agency, responsible for evaluating medicines developed for use in the European Union, granted an orphan medicinal product designation for treating moderate and severe TBI to BHR-100 in February of this year. In 2009, the U.S. Food and Drug Administration (FDA) granted BHR-100 an Orphan Drug designation also for treating moderate and severe TBI. The FDA had previously placed the drug on Fast Track status designed to accelerate its potential approval.

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JPN would like to hear about it.

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