Belbuca™ Approved for Chronic Pain Management

Endo Pharmaceuticals, Inc., announced that the U.S. Food and Drug Administration (FDA) has approved Belbuca™ (buprenorphine) buccal film for use in patients with chronic pain severe enough to require daily, around-the-clock, long-term opioid drug treatment and for which alternative treatment options are inadequate. Belbuca, which is the first and only buprenorphine drug developed with a dissolving film that is absorbed through the inner lining of the cheek for chronic pain management, is expected to be commercially available in the United States during the first quarter of 2016 in seven dosage strengths, allowing for flexible dosing ranging from 75 to 900 μg every 12 hours. This flexibility enables physicians to individualize titration and treatment based on the optimally effective and tolerable dose for each patient.

FDA approval of Belbuca was based on two double-blind, randomized, placebo-controlled, enriched-enrollment Phase 3 studies in patients with moderate to severe chronic low back pain. A total of 1,559 opioid-experienced and opioid-naïve patients received the study drug. Trials included an open-label period in which patients were titrated to a tolerated, effective dose of Belbuca and then randomized to either continue on Belbuca or receive a placebo buccal film.

In both studies, Belbuca demonstrated a consistent, statistically significant improvement in patient-reported pain relief at every week from baseline to Week 12 compared to placebo.


New Healthy Minds Videos Address Challenges of Caregiving for Alzheimer’s Disease

A new series of videos about caregiving in Alzheimer’s disease is being released by Janssen Research and Development as part of its Healthy Minds video library, which offers discussions about progress in brain research, treatment options, and resources for individuals with brain diseases, their families, and communities.

The videos capture discussions about the challenges faced by caregivers of individuals with Alzheimer’s disease and offer strategies and resources to help them. The videos also address the future of Alzheimer’s disease research and treatment.