U.S. Food and Drug Administration Supporting Development of Opioid Drugs With Abuse-Deterrent Formulations

The U.S. Food and Drug Administration (FDA) issued a draft guidance intended to support industry in their development of generic versions of approved opioid drugs with abuse-deterrent formulations (ADF) while ensuring generic ADF opioid drugs are no less abuse-deterrent than brand name drugs.

To better understand the real-world impact of ADF therapies and continue to support innovation in this space, the FDA has required all sponsors of brand name products with approved abuse-deterrent labeling to conduct long-term epidemiological studies to assess their effectiveness in reducing abuse in practice. The draft includes recommendations about studies that should be conducted to demonstrate a generic opioid drug is no less abuse-deterrent than the brand name product, with respect to all potential routes of abuse.

Oryzon Investigating Use of ORY-2001 for Patients With Alzheimer’s Disease

Oryzon Genomics announced that the first patient has been dosed in a Phase I, randomized, double-blind, placebo-controlled single and multiple ascending dose program study to investigate the safety, pharmacokinetics, and pharmacodynamics of its oral LSD1-MAOB dual selective inhibitor ORY-2001 in healthy patients. With a successful study outcome, ORY-2001 is expected to proceed to a Phase II study in patients with Alzheimer’s disease in 2017.

ORY-2001 is a highly selective dual LSD1-MAOB inhibitor. The molecule, which focuses on cognitive decline and memory loss, has a good safety profile and therapeutic index in preclinical trials. Oryzon is further exploring the potential of ORY-2001 in other neurodegenerative diseases, such as Huntington’s disease, Parkinson’s disease, and other dementias.