Probuphine® Approved as First Implant for Treating Opioid Dependence

Braeburn Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) approved Probuphine®, the first implant for the maintenance treatment of opioid dependence in patients who have sustained clinical stability on low-to-moderate doses of buprenorphine (specifically 8 mg or less per day). Probuphine delivers buprenorphine continuously for up to 6 months and should be used as part of a complete treatment program to include counseling and psychosocial support.

Buprenorphine is a commonly prescribed medication for the treatment of opioid dependence. Until now, it has only been available in sublingual (oral) formulations. Probuphine received a priority review based on the potential to reduce accidental pediatric exposure.

Probuphine was developed using ProNeura™, Titan Pharmaceuticals’ continuous drug delivery system that comprises a small, solid implant made from a mixture of ethylene-vinyl acetate and a drug substance. The resulting construct is a solid matrix that is placed subdermally, normally in the upper arm in an outpatient office procedure, and removed in a similar manner at the end of the treatment period.

Eli Lilly and Company and AstraZeneca Move Forward With Phase 3 Trial of Treatment for Early Alzheimer’s Disease

Eli Lilly and Company and AstraZeneca announced that AMARANTH, a Phase 2/3 study of AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for early Alzheimer’s disease, will continue to Phase 3 of the Phase 2/3 seamless trial.

AZD3293 has been shown in Phase 1 studies to reduce levels of amyloid beta in the cerebrospinal fluid of individuals with Alzheimer’s disease and healthy volunteers. The progression of Alzheimer’s disease is characterized by accumulation of amyloid plaque in the brain. BACE is an enzyme associated with the development of amyloid beta. Inhibiting BACE is expected to prevent the formation of amyloid plaque and eventually slow the progression of the disease.