# MC1r Agonist for the Treatment of Inflammatory, Dermatologic and Ocular Indications



## **The Opportunity**

PL-8177, a highly selective melanocortin receptor-1 (MC1r) agonist, is the lead preclinical candidate under development by Palatin Technologies (Palatin) for treatment of inflammatory and autoimmune indications.

Palatin has completed the preclinical toxicology and CMC activities required to file an IND for PL-8177. A clinical trial start date is targeted in 1H 2016, and Palatin is actively exploring collaboration or licensing transactions for specific market areas.

### **MC1r Peptide Program**

Inflammation and corresponding proinflammatory mediators are initially a beneficial host response. However, unresolved inflammatory processes play a pathogenic role in numerous inflammatory diseases. Agonism of MC1r promotes the resolution of inflammation, opposes the effects of TNF- $\alpha$  by inhibition of NF- $\kappa$ B and inhibits recruitment of white blood cells. There is substantial academic research supporting the role MC1r plays in resolving inflammation. Research conducted by Palatin has demonstrated that MC1r agonists have significant anti-inflammatory effects and are involved in the resolution of inflammation. MC1r is upregulated in a number of diseases, including inflammatory bowel disease, nephritis, and rheumatoid arthritis. MC1r agonists also have potential application in a number of dermatologic and ophthalmic inflammatory indications.

Palatin's has designed and developed highly selective (>1000X) and potent (< 1 nM) MC1r peptide agonists with excellent chemical and metabolic stability. In vitro safety studies have shown that the MC1r peptide drug candidates have no activity at high concentrations (> 10 micromolar) in all receptors, ion channels and kinases tested to date.

### PL-8177

The MC1r program lead clinical candidate, PL-8177, has demonstrated significant efficacy in preclinical models for autoimmune uveitis, inflammatory bowel disease and nephritis. Preclinical animal studies show PL-8177 suppresses the physiologic activity of inflammatory challenges, resulting in the reduction of a number of inflammatory cytokines. Palatin continues to conduct studies on a number of different indications.

# **Intellectual Property**

Palatin has issued patents in the U.S., New Zealand and South Africa for highly selective MC1r agonist peptides, with pending patent applications on two broader classes of highly selective MC1r agonist peptides in the U.S., the European and Eurasian patent offices and selected other countries around the world. U.S. patent 8,492,517, issued July 23, 2013, claims PL-8177 and PL-8176. A second U.S. patent, 8,877,890, issued November 4, 2014, claims a broader family of MC1r peptides.

The presumptive terms of the issued patents and pending patent applications expire in 2030.