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## Sumavel™ DosePro™ (sumatriptan injection) Approved by FDA for Acute Migraine and Cluster Headache

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### *First Product Featuring Novel DosePro Needle-Free Delivery System*

**SAN DIEGO, Calif., (July 16, 2009):** Zogenix, Inc. ("Zogenix"), a privately held pharmaceutical company, today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for Sumavel DosePro (sumatriptan injection) needle-free delivery system to treat acute migraine, with or without aura, and cluster headache. Sumavel DosePro is a first-of-its-kind needle-free delivery system for subcutaneous sumatriptan, a treatment that provides migraine relief within 10 minutes for some patients.

"In my 28 years treating migraine patients, a consistent challenge has been delivering fast relief in a patient acceptable form," said Roger K. Cady, M.D., director of the Headache Care Center in Springfield, Mo. "Sumavel DosePro will be a welcome treatment option because it combines key benefits – the rapid efficacy of subcutaneous sumatriptan and a simple to use needle-free delivery system."

Triptans, the most commonly prescribed class of drugs for the treatment of migraine, are a \$3.3 billion market in the U.S. (Source: Wolters Kluwer Health, Source® Pharmaceutical Audit Suite (PHAST). Based on AWP for U.S. retail prescriptions of drugs in the triptan market, May 2008 —April 2009.) According to the National Headache Foundation acute migraines affect nearly 30 million Americans. Tablets are a treatment option for some migraine sufferers, but many patients are not satisfied with tablet therapy. Fast-acting, non-oral options are needed particularly for those who experience migraine episodes associated with sudden onset, waking, nausea or vomiting.

The FDA approval of Sumavel DosePro is based on extensive efficacy and safety data from original filings for needle-based sumatriptan injection (IMITREX®), in addition to clinical studies conducted by Zogenix on bioequivalence, usage and safety specific to the Sumavel DosePro combination drug/needle-free delivery system.

"We are pleased to receive approval from the FDA for Sumavel DosePro, our first commercial product. We believe our DosePro technology represents a ground-breaking advancement in the self-administration of subcutaneous medication without a needle," said Stephen Farr, Ph.D., president, chief operating officer and director of Zogenix. "We fully expect this FDA approval to catalyze DosePro licensing discussions in several other therapeutic areas."

"During market research sessions with health care providers and migraine patients, 'cool' was one of the most common responses to Sumavel DosePro – that's a very unusual description in this industry," said Roger Hawley, chief executive officer and director of Zogenix. "We believe our novel DosePro delivery system could transform the future of subcutaneous drug delivery of pharmaceuticals. This first approval was made possible by years of dedication and shared entrepreneurial spirit of our Zogenix team, our business partners and our investors."

Zogenix plans to launch Sumavel DosePro with its own sales force and a co-promotion partner, and will make the product commercially available as soon as possible.

### **About Sumavel DosePro**

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