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A novel intracutaneous microneedle delivery system for the treatment of acute migraine

A Novel Intracutaneous Microneedle Delivery System for zolmitriptan has been developed by Zosano. This delivery system provides:

- Rapid non oral delivery and pulsatile PK profile
- Room temperature stable formulations
- Patient friendly alternative to injection
- Versatile delivery platform capable of delivering large and small molecules, and vaccines

In a recent clinical trial zolmitriptan intracutaneous microneedle delivery system was highly effective for the treatment of migraine, with statistical significance compared to placebo achieved for the two co-primary endpoints of pain freedom at 2 hours and most bothersome symptom absence at 2 hours. The results in our clinical study show the usefulness of intracutaneous microneedle delivery system for delivering zolmitriptan rapidly and yielding pharmacologic effects quickly which may be a significant advantage compared to nasal and oral formulations of zolmitriptan. In combination

with our ongoing long-term safety study we believe this trial will form the basis for approval. In addition, patients have demonstrated that they are able to reliably apply the intracutaneous patches and find the product convenient and easy to use.

Speaker Biography

Hayley Lewis attained her Bachelors in Pharmaceutical Sciences from the University of Greenwich in England, and has attained several management diplomas from Kellogg School of Management, as well as Stanford's Graduate School of Business. She currently holds the position of Senior Vice President, Operations at Zosano Pharma where she oversees the functional areas of Nonclinical, R&D, Analytical Development and QC, Engineering, Manufacturing, and Regulatory Affairs. Prior to Zosano, she has spent her 26-year career in the field of Drug Delivery at Depomed, Inc, now Assertio Therapeutics, Nektar Therapeutics, Aradigm, GlaxoSmithKline, and Merck-Lipha Pharmaceuticals, involved the areas of Product Development, and Regulatory Affairs and Quality. She has published articles for Drug Development and Delivery, Pharmaceutical Technology, as well as co-authored papers published in Journal of Pharmaceutics and Journal of Pharmaceutical Sciences.

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