

Trigemina, Inc. Reports Positive Results with its Lead Compound TI-001 in a Phase IIa Clinical Trial for Chronic Daily Headache

MOUNTAIN VIEW, Calif.--([BUSINESS WIRE](#))--Trigemina, Inc. (TI), a Mountain View, CA based pharmaceutical company, reports positive results from its Phase IIa proof-of-concept clinical trial for TI-001 in Chronic Daily Headache (CDH). The trial is a collaborative effort between Trigemina and Dr. Egilius Spierings of MedVadis Research Corporation located outside of Boston, and compares intranasal TI-001 with placebo in patients suffering from CDH.

CDH represents up to 3% of the US population, for which there currently is no effective treatment. Trigemina utilizes the recently elucidated nasal-cerebral pathway to directly target pain transmission in cranial nerves and the central nervous system, enabling important and effective new strategies for the treatment of acute and chronic pain.

In the trial, 40 CDH patients refractory to available medication underwent treatment with intranasal TI-001 versus placebo in a double blind, parallel trial. The treatment group demonstrated benefit in a wide range of metrics used to measure pain and secondary symptoms. Based on numeric pain scales, 50% of TI-001 treated patients reported at least a 50% reduction in pain at 4 hours compared to 11% of placebo treated patients - a statistically significant difference. In addition, 27% of TI-001 treated patients reported zero pain at 4 hours, compared to none of the placebo treated patients. Secondary symptoms including nausea, photophobia, and phonophobia also improved in the TI-001 group compared to the placebo group.

Trigemina CEO Daniel Jacobs, MD stated, "There is a significant effect size with the TI-001 treatment. With dose and formulation optimization still in progress, we were just looking for the first signs of a human response in this trial to validate our strong preclinical data. We were pleased to see that not only is there a clinical signal, but that it is robust. As we define the ideal dosing and formulation parameters, we look forward to even greater patient benefit. We continue to demonstrate that intranasal TI-001, an oxytocin formulation, has the potential to significantly reduce pain in CDH patients and improve the lives of millions of people suffering from this debilitating condition."

About Trigemina, Inc.

Trigemina, Inc. utilizes a newly discovered pathway that allows for direct targeting of the cranial nerves and central nervous system in order to access pain mediating sites while minimizing off-target side effects. Trigemina's drug

development pipeline includes intranasal TI-001 as well as TI-002, a molecule that may offer an alternative to the massive and problematic opiate market.

For more information on the Company, visit www.trigemina.com.

About MedVadis Research Corporation

MedVadis Research Corporation is a dynamic organization, which has conducted clinical trials for more than a decade in general and internal medicine, gastroenterology, and neurology, with a focus on headache, pain, and irritable bowel syndrome. MedVadis is lead by Egilius L.H. Spierings, M.D., Ph.D. (pharmacol.), C.P.I.; Associate Clinical Professor, Department of Neurology, Brigham & Women's Hospital, Harvard Medical School; Associate Clinical Professor, Craniofacial Pain Center, Department of General Dentistry, Tufts School of Dental Medicine.

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