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ROXRO Pharma Announces Positive Clinical Proof of Concept Results for Novel Intranasal Migraine Treatment

MENLO PARK, CA (April 28, 2008) – ROXRO PHARMA, Inc. today announced positive top-line data from a clinical study of the company's novel investigational intranasal pain reliever in the treatment of migraine and related symptoms.

The placebo-controlled proof of concept study evaluated the efficacy and safety of ROX-828, an intranasal formulation of the non-steroidal anti-inflammatory (NSAID) pain reliever ketorolac. Conducted at 17 sites in Germany and Finland, the trial involved 68 patients who received ROX-828 and 72 patients who received placebo. The study was conducted on an out-patient basis, with participants instructed to self-administer one dose of study drug when they experienced a migraine attack.

„While in-depth analysis of the data is currently under way, we are very excited about the positive response to ROX-828 among patients suffering from migraine,“ said ROXRO's Chief Scientific Officer Roger Whiting. „This is a condition for which rapid onset of action is very important, and we believe this novel nasal formulation of ROX-828 may offer a meaningful advantage for patients.“

Migraine is a common recurring condition marked by severe, disabling headaches that are often accompanied by nausea and vomiting. Up to 17 percent of women and 6 percent of men suffer from migraines, which can last as long as 72 hours if untreated and have a significant impact on quality of life and productivity. Current treatment options include oral NSAIDs and triptan pain relievers, yet neither is either suitable or effective for all migraine sufferers.

„Treating migraine with a potent NSAID in a nasal spray is a sound scientific approach,“ said Dr. Volker Pfaffenrath, neurology specialist and principal study investigator in Germany. „With this novel mode of NSAID administration and ability to provide pain relief to migraine patients, ROX-828 clearly merits further clinical investigation.“

In the study, patients reported their pain levels at baseline and at regular intervals (0.5, 1, 1.5, 2, 3, 4, 24, and 48 hours) and those treated with ROX-828 showed a statistically significant improvement in pain relief at all time points except 0.5 and 24 hours compared with those who received placebo.

Statistically significantly more patients achieved pain-free status with ROX-828 than placebo at 1.5, 3, 4, 24 and 48 hours. At two hours following dosing, a self-reported measurement tool (the Patients' Global Impression of Study Efficacy) showed statistically significantly better results for patients receiving ROX-828 than placebo. Associated migraine symptoms, including nausea and vomiting, also showed statistically significant improvement when ROX-828 was compared to placebo at several time points throughout the observation period.

ROX-828 was generally well-tolerated, with no difference in overall adverse events between the ROX-828 and the placebo groups. The most common side effects with ROX-828 were related to nasal irritation.

The analgesic ketorolac has been widely used in the hospital setting either intravenously or as an intramuscular injection to treat moderate-to-severe acute pain. ROXRO's clinical data show ROX-828 achieves peak blood levels at least as fast as an intramuscular injection of ketorolac without the inconvenience and discomfort of a needle.

„These early results represent an important milestone for our young company and provide further validation of our strategy to focus on the unmet needs of patients who suffer from various forms of pain,“ Dr. Whiting said.

ROXRO also is developing ROX-888, a different investigational intranasal formulation of ketorolac, for the treatment of moderate-to-severe acute pain, such as post-operative pain. The Phase 3 clinical program for ROX-888 is completed, and ROXRO anticipates submitting a New Drug Application with the U.S. Food and Drug Administration later this year. If approved, ROX-888 would be the first non-opioid intranasal analgesic indicated for the treatment of moderate-to-severe acute pain.



ABOUT ROXRO PHARMA

ROXRO PHARMA, Inc., of Menlo Park, Calif., is a privately owned specialty pharmaceutical company focused on the treatment of pain. Founded in 1999, ROXRO in-licenses promising drug candidates for rapid development in acute pain conditions. The company's highly experienced staff engages a global network of external experts to conduct pre-clinical and clinical studies and to manufacture drug products. ROXRO plans to submit an NDA with the FDA for approval of its lead investigational compound, ROX-888 in 2008.

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Statements in this press release that are not historical facts are forward-looking statements that involve risks and uncertainties. The inclusion of forward-looking statements, including those related to expectations regarding clinical programs, potential business transactions, product development, and potential benefits of our products and product candidates, should not be regarded as a representation that any of our plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation, risks and uncertainties related to: our research and development efforts, including pre-clinical and clinical testing; the timing of regulatory submissions and approvals; and our need for and ability to raise additional capital. You are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date hereof. We undertake no obligation to revise or update this release to reflect events or circumstances that occur after the date of this release.