First Patient Dosed in Pilot Study of Vitalis' VTS-K for Acute Musculoskeletal Pain

- *Vitalis' proprietary oral formulation of ketamine and aspirin in development for treatment of acute pain*
- *Top-line Data Expected First Quarter 2021*

NEW YORK, Jan. 12, 2021 (GLOBE NEWSWIRE) -- Vitalis LLC, a specialty pharmaceutical company leveraging its innovative VTS platform to overcome the limitations of existing drugs and enhance patient experience across a variety of therapeutic areas including pain and multiple sclerosis, today announced the dosing of the first patient in a pilot study evaluating safety and preliminary analgesic efficacy of VTS-K in patients with acute musculoskeletal pain. VTS-K is an oral combination of Vitalis' patented VTS-Aspirin and ketamine, a non-competitive N-methyl-D-aspartate (NMDA)/glutamate receptor complex antagonist that decreases pain by diminishing central sensitization, hyperalgesia, and "wind-up" phenomenon at the level of the spinal cord and central nervous system.

Ketamine in sub-dissociative doses (SDK) has demonstrated an ability to provide effective pain relief in patients with acute traumatic and non-traumatic pain, chronic pain including cancer pain, and in patients with opioid-tolerant pain. Ketamine works by providing anti-hyperalgesia, anti-allodynia, and anti-tolerance. SDK is commonly administered in the emergency department either intravenously, intramuscularly or intranasally.

"Physicians are increasingly using ketamine as an effective non-opioid pain medication," said Joseph Habboushe, MD, MBA., inventor of the VTS platform and founder of Vitalis "However, the only currently viable routes of administration – intravenous, intramuscular, and recently intranasal – make it difficult to administer and clearly unsuitable for outpatient use."

The prospective, observational pilot study aims to evaluate analgesic efficacy of orally administered VTS-K (injectable ketamine taken orally simultaneously with VTS-Aspirin) for pain management of adult ED patients presenting to the ED with acute musculoskeletal pain. The study will enroll 25 patients with an initial pain score of 5 on a standard 11-point numeric rating scale, who will receive 0.5 mg/kg of oral ketamine administered simultaneously with 325mg of aspirin. Pain scores and adverse events will be recorded at 15, 30, 60, 90 and 120 minutes post administration. The primary outcome will include a reduction of pain scores on numeric rating pain scale at 60 minutes post-administration. Secondary outcomes will include a need for rescue analgesia and rates of adverse events up to 90 minutes post-administration.

The study will be led by Sergey Motov, M.D., emergency medicine physician at Maimonides Medical Center. Dr. Motov is a Research Director who is passionate about safe and effective pain management in the ED. He has numerous publications on the subject of opioid alternatives in pain management and is actively involved in growing this body of work both nationally and globally.

"The need for safe and efficacious analgesics in the emergency department and on an outpatient basis is stronger than ever," said Dr. Motov. "Taking a novel approach to orally-administered ketamine has the potential to move physicians one step closer to successfully combatting the nation's ongoing opioid crisis. We look forward to leading this important study to further understand the benefits of reducing the use of opioids in an emergency department setting."

“We hope that VTS-K will strike the right balance of effective pain reduction and robust safety, which, if successful, would represent a potential breakthrough in the treatment of acute pain. We are grateful to Dr. Motov and the team at Maimonides for leading this trial and look forward to the results,” said Dr. Habboushe.

Additional information, including a detailed description of the study design, eligibility criteria, and investigator sites, is available at ClinicalTrials.gov using identifier NCT04702555.

About Vitalis

Vitalis is a privately-held specialty pharmaceutical company focused on overcoming the limitations of existing drugs using its proprietary VTS-Aspirin platform. Its most advanced product, VTS-72, uniquely combines aspirin with fumaric acid, the leading multiple sclerosis medication, to reduce its most common side effect while improving pharmacokinetics. Similarly, its second candidate, VTS-K, may be the first oral ketamine to enter the market, aiming to reduce opioid need while supplanting injectable blood thinners after joint replacements. For additional information, please visit www.vitalispharma.com.

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