

# ANANDA Scientific and NYU Grossman School of Medicine Announce First Patient Enrolled in the Clinical Trial for Opioid Sparing in Participants with Radiculopathic Pain

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GREENWOOD VILLAGE, Colo. & NEW YORK--(BUSINESS WIRE)--**ANANDA Scientific Inc.**, a biotech pharmaceutical company, and **NYU Grossman School of Medicine** today announced that the first patient has been enrolled in a clinical trial evaluating **Nantheia™ A1002N5S**, an investigational drug using cannabidiol in ANANDA's proprietary **Liquid Structure™** delivery technology. This trial is evaluating **Nantheia™ A1002N5S** for Opioid Sparing in the treatment of participants with Radiculopathic Pain Syndromes.

This trial is being conducted at NYU Grossman School of Medicine, led by **Stephen Ross, MD**, Associate Professor of Psychiatry. Funding for this trial is from the National Institute of Drug Abuse (NIDA), with additional support from ANANDA. The NYU Grossman School of Medicine is No. 2 in the nation for research in the 2022 *U.S. News & World Report* "Best Graduate Schools" rankings.

"We are excited to get this important trial underway and expanding research on therapeutic alternatives to opioid pharmacotherapies," said Dr. Ross. "This research protocol creates an opportunity for the possible development of evidence-based CBD medicinal products to reduce opioid intake and pain."

“We are very pleased to be continuing our collaboration with NYU Grossman School of Medicine. We are impressed by the scientific rigor and professionalism of the NYU team in putting a cutting-edge program in place to test the efficacy of this very promising drug,” said **Sohail R. Zaidi, ANANDA’s CEO**. “The initiation of patient enrollment in this study is an important step in efforts to provide patients with Radiculopathic Pain with an alternative to the use of Opioids for the management of pain.”

This is a randomized, double-blind, placebo-controlled trial with 40 participants receiving four months of treatment with **Nantheia™ A1002N5S**, or placebo with a follow-up after 2 months. The primary efficacy outcome is a change in opioid maintenance dose from baseline to the end of the treatment period. Safety and tolerability of CBD will also be assessed throughout the trial. (**ClinicalTrials.gov Identifier: NCT04760613**).

### **ABOUT NANTHEIA™ A1002N5S**

**Nantheia™ A1002N5S** is an investigational drug that uses CBD in ANANDA’s propriety Liquid Structure delivery technology. Pre-clinical and initial clinical studies show that ANANDA’s Liquid Structure™ delivery technology (licensed from **Lyotropic Delivery Systems (LDS) Ltd.** in Jerusalem, Israel) enhances the effectiveness and stability of CBD. **Nantheia™ A1002N5S** is an oral product with 50 mg of CBD per soft gel capsule.

### **ABOUT ANANDA SCIENTIFIC**

ANANDA is a leading research-focused biotech company pioneering high-caliber clinical studies evaluating therapeutic indications such as **PTSD, Radiculopathic Pain**, Anxiety and **Opioid Use Disorder** (Mt. Sinai, UCLA). The company employs patented delivery technology to make cannabinoids and other plant derived compounds highly bioavailable, water soluble, and shelf-life stable and focuses on producing effective, premium quality pharmaceutical products. Consistent with its strong research-based data, the company also has a growing pipeline of nutraceutical over-the-counter products. The company has successfully launched these products in the US, Australia, and the UK, with expansion planned into additional markets such as the EU, China, Africa, and other countries in Asia. The company is expanding its research base through multiple sponsored research agreements with universities to diversify its technology portfolio.

### **ABOUT OPIOID SPARING FOR PATIENTS WITH CHRONIC NON-CANCER RADICULOPATHY**

Chronic pain (pain lasting 3 or more months) (1) is a highly prevalent public health problem (2) (3), and constitutes the greatest economic burden of any medical condition (4). Of the Chronic Non-Cancer Pain (CNCP) conditions, radicular pain disorders (particularly low back pain) have particularly high rates of opioid prescribing (5), and higher opioid doses predict poorer functional outcomes in this cohort of chronic pain patients (6). Estimates of the prevalence of opioid use disorders (OUDs) in CNCP range from 5% in a meta-analysis (7) to 20-35% (8), (9), (10), (11). All of this notwithstanding, chronic opioid therapy (COT)

prescribing for CNCP increased markedly between 1990 and 2010, and is one of the root causes of the current opioid epidemic (12). Our goal is to develop an intervention to reduce opioid use in patients with radicular CNCP syndromes receiving moderate to high-dose COT to safer doses while at the same time maintaining or improving pain management.

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