

# Acorda Initiates Phase 1 Clinical Trial of CVT-427, Inhaled Therapy for Acute Treatment of Migraines

12/3/2015

ARDSLEY, N.Y.--(BUSINESS WIRE)-- Acorda Therapeutics, Inc. (Nasdaq: **ACOR**) today announced initiation of enrollment in the first clinical study of CVT-427, an investigational agent under development for the acute treatment of migraines.

“CVT-427 represents an innovative approach to acute treatment of migraines. Applying Acorda’s proprietary ARCUS technology, we have developed an inhaled version of a well-established migraine therapy,” said Sean Plunkett, Executive Director, Device and Program Management at Acorda. “We are excited about evaluating the potential of CVT-427 to offer a unique way to treat people with migraine who are not completely satisfied with their current options.”

CVT-427 is a novel, inhaled formulation of zolmitriptan that uses the Company’s proprietary ARCUS® technology. Zolmitriptan belongs to a class of drugs known as triptans, which are a leading therapy for acute treatment of migraines. Triptans are most commonly administered orally, usually as a pill.

Oral migraine therapies can be associated with slow onset of action, as the medicine is absorbed through the gastrointestinal (digestive) tract before reaching the brain. Another consideration in acute treatment of migraine is nausea. It is estimated that almost 90% of people living with migraines have experienced nausea at least once during a migraine attack. Nausea and vomiting can be so debilitating that people either delay, or completely forgo, taking an oral medication; more than 50% of migraine sufferers experience this degree of nausea with the majority of their migraine attacks. Inhaled treatments, such as those that utilize the ARCUS technology, enter the body rapidly through the lungs, bypassing the digestive system.

This Phase 1 clinical trial is a single ascending dose study that is designed to enroll 32 participants. It will assess the pharmacokinetic profile, safety and tolerability of CVT-427 at four different dosages in healthy volunteers. More

information about the trial can be found at: <https://www.clinicaltrials.gov/ct2/show/NCT02609945?term=cvt-427&rank=1>.

## About Migraines

Migraines are painful headaches that may be accompanied by nausea, vomiting or sensitivity to light. An estimated 36 million people in the U.S., and over 40 million people in Europe, suffer from migraines.

## About ARCUS® Technology

Acorda's proprietary ARCUS technology platform is a dry-powder pulmonary delivery system that has potential applications in multiple disease areas. This platform allows consistent and precise delivery of significantly larger doses of medication than are possible with conventional pulmonary systems. The ARCUS inhaler is breath-actuated, operated by the user putting their lips to the device and simply breathing in.

The ARCUS technology has been used to successfully deliver more than one million doses to patients in clinical trials of various products. There are currently two clinical stage programs using the ARCUS technology: CVT-301 (Phase 3) is in development as a treatment for off episodes in Parkinson's disease; CVT-427 (Phase 1) is in development for the acute treatment of migraines. Acorda has an extensive patent portfolio relating to CVT-301, CVT-427 and the ARCUS technology, which covers aspects of the formulated drug product, the inhaler, the method of drug delivery and manufacturing processes.

## About Acorda Therapeutics

Founded in 1995, **Acorda Therapeutics** is a biotechnology company focused on developing therapies that restore function and improve the lives of people with neurological disorders.

Acorda markets three FDA-approved therapies, including **AMPYRA®** (dalfampridine) Extended Release Tablets, 10 mg. The Company has one of the leading pipelines in the industry of novel neurological therapies. Acorda is currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders including post-stroke walking deficits, Parkinson's disease, epilepsy, heart failure, MS and spinal cord injury.

For more information, please visit the Company's website at: [www.acorda.com](http://www.acorda.com).

## Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or prospects should be considered forward-looking. These statements are subject to risks and

uncertainties that could cause actual results to differ materially, including the ability to realize the benefits anticipated from the Civitas transaction and to successfully integrate Civitas' operations into our operations; our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including CVT-301, Plumiaz (diazepam) Nasal Spray, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen International GmbH in connection therewith; competition; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and, failure to comply with regulatory requirements could result in adverse action by regulatory agencies.

These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this release are made only as of the date hereof, and Acorda disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this release.

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Acorda Therapeutics

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