

# Acorda Presents Phase 1 Data on CVT-427 for Acute Treatment of Migraine at 58th Annual Scientific Meeting of the American Headache Society

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Increased bioavailability, faster absorption, and less variability in plasma concentrations of inhaled zolmitriptan CVT-427, compared to oral and nasal delivery in healthy adults

ARDSLEY, N.Y.--(BUSINESS WIRE)-- Acorda Therapeutics, Inc. (Nasdaq:ACOR) today announced pharmacokinetic (PK) data from a Phase 1 study of CVT-427, an inhaled formulation of zolmitriptan, resulting in increased bioavailability and faster absorption compared to oral and nasal administration of the same active ingredient in healthy adults. The data on CVT-427, an investigational agent under development for the acute treatment of migraines, will be presented on June 10th, 2016, at the 58th Annual Scientific Meeting of the American Headache Society, in San Diego, CA.

“When surveyed, the majority of migraine sufferers said rapid pain relief is one of the most important factors influencing their medication preference,” said Rick Batycky, Ph.D., Acorda Therapeutics' Chief Technology Officer. “We’re encouraged by the findings of this PK study, which support advancing development of CVT-427 for the acute treatment of migraine.”

This Phase 1, open-label, intra-patient, single ascending dose trial enrolled 21 healthy adults; 17 completed all treatments. Each subject first received successively, single doses of the zolmitriptan reference formulations, a 5 mg oral tablet and a 5 mg nasal spray. Subjects then received four individual pre-metered doses of CVT-427 (0.825 mg (0.6 mg delivered to the lung), 1.65 mg (1.2 mg), 3.0 mg (2.4 mg), and 6.0 mg (4.8 mg) zolmitriptan). There was a one or two day washout period between each administration.

The oral and nasal spray formulations had a median Tmax of 1.5 hours and 3.0 hours, respectively; all four dose levels of CVT-427 had a median Tmax of 0.17 hours.

The mean C<sub>max</sub> for the oral formulation was 8.7 ng/mL, and the nasal spray formulation was 8.1 ng/mL. The mean C<sub>max</sub> values for CVT-427 were 6.0 ng/mL (0.825 mg dose), 11.8 ng/mL (1.65 mg), 17.8 ng/mL (3.0 mg), and 35.0 ng/mL (6.0 mg).

The mean AUC<sub>0-24</sub> (ng-hr/mL) values for the reference formulations were 49.0 for the oral, and 50.8 for the nasal spray, whereas the mean AUC<sub>0-24</sub> values for CVT-427 were 14.7 (0.825 mg dose), 27.3 (1.65 mg), 47.1 (3.0 mg), and 91.0 (6.0 mg). Coefficient of variation for AUC<sub>0-24</sub> with reference products ranged from 37.6%-38.4% compared with 26.7%-29.9% for CVT-427, showing less variability.

PK parameters (including bioavailability) of the reference formulations observed in the trial matched published reports. The study found that CVT-427 had better bioavailability than the reference formulations with less variability in plasma concentration.

There were no serious adverse events, dose limiting toxicities, or study discontinuations due to adverse events (AEs) reported for CVT-427. The most commonly reported treatment-emergent AEs for CVT-427 (=10%) were cough (0.825 mg – 11%, 1.65 mg – 11%, 3.0 mg – 22%, 6.0 mg – 18%), chest discomfort (0.825 mg – 11%), headache (1.65 mg – 11%) and feeling hot (3.0 mg – 11%, 6.0 mg – 24%). Other than cough, single dose CVT-427 tolerability was generally consistent with the known safety profile of zolmitriptan.

“Tolerability and Pharmacokinetics of Zolmitriptan Administered via CVT-427, a Novel Pulmonary Delivery System,” (Poster #PF72LB) will be presented on Friday, June 10th from 1:15pm – 2:30pm Pacific Time. Herbert R. Henney III, PharmD, Vice President, Clinical Pharmacology for Acorda, will present the poster. This study was supported by Acorda Therapeutics, Inc.

More detailed information on the meeting can be found on the conference website:

[http://www.americanheadachesociety.org/58th\\_annual\\_scientific\\_meeting/](http://www.americanheadachesociety.org/58th_annual_scientific_meeting/)

## About CVT-427

CVT-427 is an 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. An estimated 36 million people in the United States, 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 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 symptoms of OFF periods 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 has an industry leading pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, post-stroke walking difficulties, migraine, and multiple sclerosis. Acorda markets three FDA-approved therapies, including **AMPYRA®** (dalfampridine) Extended Release Tablets, 10 mg.

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

## Forward-Looking Statement

This press release includes forward-looking statements. 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 complete the Biotie transaction on a timely basis; the ability to realize the benefits anticipated from the Biotie and Civitas transactions, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; the ability to successfully integrate Biotie's operations and Civitas' operations, respectively, into our operations; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; our ability to successfully market and sell Ampyra (dalfampridine) Extended Release Tablets, 10 mg 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 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, any other products under development, or the products that we will acquire when we complete the Biotie transaction; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain and maintain regulatory approval of or to successfully

market Fampyra outside of the U.S. and our dependence on our collaborator Biogen 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 our filings with the Securities and Exchange Commission. We may not actually achieve the goals or plans described in our forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this presentation are made only as of the date hereof, and we disclaim any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this presentation.

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Source: Acorda Therapeutics, Inc.

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