

Zavante®

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David Hirsch, MD, PhD

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Stephen Newman, MD

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Andrew N. Schiff, MD

Observer, Aisling Capital

About Zavante Therapeutics

Zavante is passionately committed to improving the care and outcomes of hospitalized patients by identifying, developing and commercializing novel therapeutics that address significant unmet medical needs.

Zavante's lead product candidate is an investigational, first-in-class injectable antibiotic under development to combat serious, life-threatening infections, including those due to multi-drug resistant (MDR) bacteria. In 2017, Zavante completed its pivotal Phase 2/3 ZEUS™ study, in which CONTEPO™ (fosfomycin for injection, previously referred to as ZTI-01 and ZOLYD) demonstrated efficacy and safety for the treatment of patients with complicated urinary tract infections (cUTI), the product's first indication. The company expects to file a New Drug Application utilizing the FDA's 505(b)(2) pathway in late 2018.

The company is backed by leading life science investors Frazier Healthcare Partners, Longitude Capital and Aisling Capital. Each firm has an excellent track record of identifying clinically de-risked assets and building successful anti-infective companies.

Zavante® Timeline & Financing History

- September 2014 ▼ CONTEPO™ granted QIDP designation for cUTI
- June 2015 ▼ Zavante Therapeutics secured first private investment
- December 2015 ▼ FDA agreed to single pivotal trial for CONTEPO
- December 2015 ▼ Three additional indications granted QIDP designation
- December 2015 ▼ Fast-track granted for all four indications
- December 2015 ▼ Zavante raised \$10+ million convertible notes
- March 2016 ▼ Zavante raised \$35 million new Series A financing
- July 2016 ▼ First patient enrolled in CONTEPO ZEUS™ study
- August 2016 ▼ Infectious disease experts joined Scientific Advisory Board
- April 2017 ▼ CONTEPO met primary endpoint in pivotal ZEUS study
- November 2017 ▼ Pre-NDA Meeting

Therapeutic Focus

Growing antimicrobial resistance creates a significant demand for novel therapies.

Bacterial resistance to currently available antimicrobials has reached alarmingly high levels in recent decades, resulting in a global health crisis. Antibiotic treatment options with differing mechanisms of action are urgently needed, particularly agents with activity against MDR Gram-negative bacteria.

Zavante believes it is uniquely poised to address the critical need for new antibiotics through the development of CONTEPO™ (previously referred to as ZOLYD), an antibiotic with a broad spectrum of Gram-negative and Gram-positive activity, including activity against MDR pathogens associated with life-threatening infections, such as carbapenem resistant enterobacteriaceae.

“The lack of available and effective antibiotics for these life-threatening multidrug-resistant pathogens has created an important unmet medical need. An antibiotic with a unique mechanism of action like CONTEPO (previously referred to as ZOLYD) would be an important addition to our antibacterial armamentarium when treating seriously ill patients in the hospital.”

George Drusano, MD,
Professor of Medicine and Director of the Institute for Therapeutic Innovation, Department of Medicine, College of Medicine, University of Florida

Upcoming Milestones

- ▼ New Drug Application for CONTEPO™ (previously referred to as ZOLYD) expected to be filed with FDA in late 2018.

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CONTEPO™: Addressing Hospital Infections

CONTEPO™ (fosfomycin for injection, previously referred to as ZTI-01 and ZOLYD) is an investigational, first-in-class epoxide antibiotic with a broad spectrum of bactericidal *in vitro* activity against both Gram-negative and Gram-positive bacteria, including activity against most contemporary multi-drug resistant (MDR) strains that threaten hospitalized patients. CONTEPO utilizes a new dosing approach to optimize the compound's pharmacokinetics and pharmacodynamics. Zavante believes that these attributes, along with extensive clinical experience outside of the U.S., support CONTEPO as a first-line treatment for complicated urinary tract infections (cUTI) suspected to be caused by MDR pathogens. Non-clinical data have also shown that CONTEPO acts synergistically with certain other antibiotics to improve bacterial killing and restore susceptibility to infective agents otherwise demonstrating resistance.

The pivotal ZEUS™ (ZTI-01 Efficacy and Safety) study was designed to obtain regulatory approval for CONTEPO for the treatment of cUTI, including acute pyelonephritis (AP). CONTEPO met the primary endpoint of statistical non-inferiority to piperacillin/tazobactam in the ZEUS trial in this patient population. Approximately 25% of cUTIs are caused by multi-drug resistant bacteria with limited treatment options available. Fosfomycin IV has an established safety profile based upon its use in markets outside the U.S., where it has been utilized for over 40 years in nine indications.

The FDA has granted CONTEPO Qualified Infectious Disease Product (QIDP) and Fast Track designations for:

- ▼ Complicated urinary tract infections (cUTI)
- ▼ Complicated intra-abdominal infections (cIAI)
- ▼ Hospital-acquired bacterial pneumonia (HABP)/ Ventilator-associated bacterial pneumonia (VABP)
- ▼ Acute bacterial skin and skin structure infections (ABSSSI)

These designations make CONTEPO eligible for certain incentives including priority FDA review and an additional five years of market exclusivity under the Generating Antibiotic Incentives Now (GAIN) Act.

CONTEPO™ (Fosfomycin for injection)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3
cUTI	[Progress bar spanning all phases]			
cIAI	[Progress bar spanning Pre-clinical, Phase 1, and Phase 2]			
ABSSSI	[Progress bar spanning Pre-clinical, Phase 1, and Phase 2]			
HABP/VABP	[Progress bar spanning Pre-clinical, Phase 1, and Phase 2]			
Other Unmet Need Indications	[Progress bar spanning Pre-clinical]			

CONTEPO is an investigational medication that has not been found by the U.S. Food and Drug Administration to be safe or effective for any indication. This fact sheet contains forward-looking statements within the meaning of U.S. federal securities laws, including statements about the anticipated effectiveness of CONTEPO in treating serious infections in hospitalized patients, and the company's plans and timing for submitting a new drug application for CONTEPO. The company's actual results may differ materially from those indicated in the forward-looking statements. May 2018 © Copyright 2018 Zavante Therapeutics, Inc. All rights reserved. ZAVANTE, CONTEPO, ZOLYD and ZEUS are trademarks or registered trademarks of Zavante Therapeutics, Inc.