November 8, 2021 Acurx Pharmaceuticals

# Acurx Announces New Microbiome Data from Its Phase 2a Clinical Trial of Ibezapolstat for CDI at the 9th International C. diff. Conference

**- Patient fecal samples were evaluated for C. difficile culture and microbiome changes**

**- Ph2a trial demonstrated 100% clinical cure and 100% sustained clinical cure**

**- Favorable microbiome changes included overgrowth of Actinobacteria and Firmicutes phylum species while on therapy**

**- New findings demonstrate potentially beneficial effects on bile acid metabolism**

**- Clinical results support the expectation that microbiome effects may be predictive of beneficial patient outcomes including low rates of recurrence**

**-Phase 2b trial comparing ibezapolstat to vancomycin in CDI patients to begin this month**

STATEN ISLAND, N.Y., Nov. 8, 2021 /PRNewswire/ -- Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("Acurx" or the "Company"), a clinical stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, announced today that new microbiome data from its Phase 2a clinical trial for *C. difficile* Infection (CDI) were presented at the 9th International *C. diff* Conference & Health Expo entitled: "*Can Emerging Microbiome Findings Contribute to CDI Anti-Recurrence Effect*?" The presentation was made on November 5, 2021, by Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy and the Principal Investigator for microbiome aspects of the ibezapolstat clinical trial program.

Phase 2a data demonstrated complete eradication of colonic *C. difficile* by day three of treatment with ibezapolstat as well as the observed overgrowth of healthy gut microbiota, Actinobacteria and Firmicute phyla species, during and after therapy. Very importantly, emerging data show an increased concentration of secondary bile acids during and following ibezapolstat therapy which is known to correlate with colonization resistance against *C. difficile*. Additionally, a decrease in primary bile acids and the favorable increase in the ratio of secondary-to-primary bile acids suggest that ibezapolstat may reduce the likelihood of

CDI recurrence when compared to vancomycin.

Dr. Garey's Presentation can be viewed on the company's website at www.acurxpharma.com, Tab: News Media, Presentations.

According to Dr. Garey, "The totality of pre-clinical and clinical data-to-date demonstrate that ibezapolstat fulfills the three key criteria for an ideal anti-CDI antibiotic: Ibezapolstat achieves high colonic concentrations with minimal systemic absorption; it has potent activity against *C. difficile* while, in contrast to oral vancomycin, causes minimal disruption of the gut microbiome; and it shows a potentially beneficial effect on gut bile acid metabolism. Taken together, these features contribute to the observed clinical success rate and make ibezapolstat, which also shows good tolerability, an attractive potential therapeutic option for CDI."

The Company's upcoming Phase 2b segment of this clinical trial also will evaluate pharmacokinetics (PK) and microbiome changes from baseline and continue to test for anti-recurrence microbiome properties seen in the Phase 2a trial, including the treatment-related changes in alpha diversity and bacterial abundance and effects on bile acid metabolism.

Robert J. DeLuccia, Executive Chairman of Acurx, stated, "We are particularly excited by these results in our Phase 2a CDI patients which are consistent with the favorable microbiome profile when compared with vancomycin in our earlier Phase 1 healthy volunteer trial; particularly this newest information on the beneficial effect on bile acids." He further stated that "We look forward to beginning enrollment in our Phase 2b trial this month, which will compare ibezapolstat to vancomycin, the standard of care in CDI."

**About the C. diff Conference:** Sponsored by the C Diff Foundation, clinical professionals gathered for eleven (11) hours and presented up-to-date data to expand on the existing knowledge and raise awareness of the urgency focused on, but not limited to, *C. difficile* infection (CDI) Prevention, Treatments, Research, Diagnostics, Clinical Trials, AMR, and Environmental Safety.

Additionally, the Company recognizes the month of November as*C. difficile* Awareness Month as designated by the US Centers for Disease Control and Prevention (CDC) and supports the work of the C Diff Foundation in educating and advocating for the Prevention, Treatments, Clinical Trials, and Environmental Safety of *Clostridioides difficile* (*C. difficile*) Infections worldwide. https://cdifffoundation.org/.

**About *Clostridioides difficile* Infection (CDI)**. According to the 2017 Update (published February 2018) of the *Clinical Practice Guidelines for C. difficile Infection by the Infectious Diseases Society of America (IDSA) and Society or Healthcare Epidemiology of America (SHEA),* CDI remains a significant medical problem in hospitals, in long-term care facilities and in the community. *C. difficile* is one of the most common causes of health care-associated infections in U.S. hospitals (Lessa, et al, 2015, New England Journal of Medicine). Recent estimates suggest *C. difficile* approaches 500,000 infections annually in the U.S. and is associated with approximately 20,000 deaths annually. (Guh, 2020, New England Journal of Medicine). Based on internal estimates, the recurrence rate of two of the three antibiotics currently used to treat CDI is between 20% and 40% among approximately 150,000 patients treated. We believe the annual incidence of CDI in the U.S. approaches 600,000 infections and a mortality rate of approximately 9.3%.

**About the Microbiome in *Clostridioides difficile* Infection (CDI) and Bile Acid Metabolism**

*C. difficile* can be a normal component of the healthy gut microbiome, but when the microbiome is thrown out of balance, the *C. difficile* can thrive and cause an infection. After colonization with *C. difficile*, the organism produces and releases the main virulence factors, the two large clostridial toxins A (TcdA) and B (TcdB). (Kachrimanidou, Microorganisms 2020, 8, 200; doi:10.3390/microorganisms8020200.) TcdA and TcdB are exotoxins that bind to human intestinal epithelial cells and are responsible for inflammation, fluid and mucous secretion, as well as damage to the intestinal mucosa.

Bile acids perform many functional roles in the GI tract, with one of the most important being maintenance of a healthy microbiome by inhibiting *C. difficile* growth. Primary bile acids, which are secreted by the liver into the intestines, promote germination of *C. difficile* spores and thereby increase the risk of recurrent CDI after successful treatment of an initial episode. On the other hand, secondary bile acids, which are produced by normal gut microbiota through metabolism of primary bile acids, do not induce *C. difficile* sporulation and therefore protect against recurrent disease. Since ibezapolstat treatment leads to minimal disruption of the gut microbiome, bacterial production of secondary bile acids continues which may contribute to an anti-recurrence effect.

**About the Ibezapolstat Phase 2 Clinical Trial**

The multicenter, open-label single-arm segment of this study (Phase 2a) is to be followed by a double- blind, randomized, active-controlled segment (Phase 2b) which, together, comprise the Phase 2 clinical trial. The Phase 2 clinical trial is designed to evaluate ibezapolstat in the treatment of CDI. Phase 2a of this trial is completed and was an open-label cohort of up to 20 subjects from study centers in the United States. In this cohort, 10 patients with diarrhea caused by *C. difficile* were treated with ibezapolstat 450 mg orally, twice daily for 10 days. All patients were followed for recurrence for 28± 2 days. Per protocol, after 10 patients of the projected 20 Phase 2a patients completed treatment, the Trial Oversight Committee assessed the safety and tolerability and made its recommendation regarding early termination of the Phase 2a study. Based on the recommendation of Acurx's Scientific Advisory Board (SAB) and Trial Oversight Committee, we terminated enrollment in Phase 2a early and are now advancing to Phase 2b. The SAB unanimously supported the early termination of the Phase 2a trial after 10 patients were enrolled in the trial instead of 20 patients as originally planned. The early termination was based on the evidence of meeting the primary and secondary endpoints of eliminating the infection (100%), with no recurrences of infection (100%), and with an acceptable adverse event profile. In the upcoming Phase 2b, approximately 64 additional patients with CDI will be enrolled and randomized in a 1:1 ratio to either ibezapolstat 450 mg every 12 hours or vancomycin 125 mg orally every 6 hours, in each case, for 10 days and followed for 28 ± 2 days following the end of treatment for recurrence of CDI. The two treatments will be identical in appearance, dosing times, and number of capsules administered to maintain the blind. This Phase 2 clinical trial also will evaluate pharmacokinetics (PK) and microbiome changes and continue to test for anti-recurrence microbiome properties, including the change from baseline in alpha diversity and bacterial abundance, especially overgrowth of healthy gut microbiota Actinobacteria and Firmicute phylum species during and after therapy.

**About Acurx Pharmaceuticals, Inc.**

Acurx Pharmaceuticals is a clinical stage biopharmaceutical company focused on developing

new antibiotics for difficult to treat infections. The Company's approach is to develop antibiotic candidates that target the DNA polymerase IIIC enzyme and its R&D pipeline includes antibiotic product candidates that target Gram-positive bacteria, including *Clostridioides difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin resistant Enterococcus (VRE) and drug-resistant *Streptococcus pneumoniae* (DRSP). To learn more about Acurx Pharmaceuticals and its product pipeline please visit www.acurxpharma.com.

Any statements in this press release about our future expectations, plans and prospects, including statements regarding our strategy, future operations, prospects, plans and objectives, and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether ibezapolstat will benefit from the QIDP designation; whether ibezapolstat will advance through the clinical trial process on a timely basis; whether the results of the clinical trials of ibezapolstat will warrant the submission of applications for marketing approval, and if so, whether ibezapolstat will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies where approval is sought; whether, if ibezapolstat obtains approval, it will be successfully distributed and marketed; and other factors. In addition, the forward-looking statements included in this press release represent our views as of November 8, 2021. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward- looking statements at some point in the future, we specifically disclaim any obligation to do so.

**Investor Contact:**
Acurx Pharmaceuticals, Inc. David P. Luci, President & CEO Tel: 917-533-1469
Email: davidluci@acurxpharma.com

View original content:https://www.prnewswire.com/news-releases/acurx-announces-new-microbiome-data-from-its-phase-2a-clinical-trial-of-ibezapolstat-for-cdi-at-the-9th-international-c-diff-conference-301417335.html

SOURCE Acurx Pharmaceuticals, Inc.