July 14, 2026

Acurx Pharmaceuticals

Acurx Pharmaceuticals Announces Scientific Poster Presentation of Ibezapolstat's Microbiome Preservation Data in Multiply-recurrent C. difficile Infection

- Data demonstrated beneficial bacterial taxa persist in fecal samples from patients with rCDI despite multiple prior CDI treatments with the antibiotic standards of care, vancomycin (VAN) and/or fidaxomicin (FDX)
- Following acute treatment with ibezapolstat (IBZ), these beneficial microorganisms will have the opportunity to repopulate the microbiome in a beneficial way that may prevent recurrence
- IBZ and FDX were superior in biofilm experimental models with IBZ significantly more effective at killing *C. difficile* than VAN and FDX
- Trial start-up activities for a ground-breaking clinical trial in patients with multiply-recurrent CDI (rCDI) have been initiated with the first patient expected to enroll in the next quarter; a successful trial outcome has the potential to shift the paradigm of treatment and prevention of rCDI from two agents to one
- With mutually consistent feedback from both EMA and FDA, Acurx is well positioned to commence its international Phase 3 registration program in the broader CDI patient population ("acute CDI")
- Acurx has previously been granted FDA QIDP and Fast-Track Designation and has received SME (Small and Medium-sized Enterprise) designation by the EMA

STATEN ISLAND, N.Y., July 14, 2026 /PRNewswire/ -- Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) a clinical stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, announced today that a poster presentation entitled: *Microbiome Restoration Potential of Ibezapolstat vs. Comparator Antibiotics in Patients with Multiply-recurrent Clostridioides difficile Infection (CDI)* was presented by Kevin Garey, PharmD, MS, FIDSA, Professor and Chair, University of Houston College of Pharmacy, Principal Investigator for microbiology and microbiome aspects of the IBZ clinical trial program at the 18th Biennial Congress of the Anaerobe Society of the Americas held at Columbia University Irving Medical Center in New York City from July 8 to 10, 2026.

Studies were performed at the University of Houston to determine whether beneficial gut microbes are present in patients with multiple (≥2) recurrences of *Clostridioides difficile* infection (rCDI). The objectives of this study were to determine whether beneficial microbes identified in the IBZ Phase 2 studies in patients with initial and 1st recurrent CDI are still present in patients with multiple (≥2) recurrent CDI and to assess killing effects of IBZ vs. comparators in planktonic (non-biofilm) and biofilm mono- and duo-culture studies; specifically, measuring killing of VRE by VAN, FDX, and IBZ in planktonic and biofilm

cultures.

Commenting on the poster presentation, Dr. Garey stated: "Until now, it has not been known whether repeated courses of VAN and/or FDX destroyed the gut microbiome population of beneficial organisms, namely, those bacterial species that are responsible for metabolizing bile acids and protecting against recurrent episodes of CDI. Our new data indicate that sufficient numbers of such bacteria are preserved to allow regrowth when rCDI treatment consists of an antibiotic like ibezapolstat, which has been shown in our laboratory to be highly selective and preserves the beneficial gut flora." He further stated, "We also showed in our laboratory studies that ibezapolstat was highly effective at killing *C. difficile* when grown in co-culture with Enterococcus in liquid, planktonic cultures or as part of a biofilm. Ibezapolstat actually outperformed fidaxomicin in biofilm killing effects without causing VRE overgrowth observed with vancomycin."

Robert J. DeLuccia, Executive Chairman of Acurx, stated: "These new data provide scientific support for our upcoming trial of ibezapolstat to treat patients with multiply-recurrent CDI which begins with a 20-patient, open-label pilot trial in patients with at least 3 episodes of CDI in the past 12 months and will inform elements of a planned active-controlled, Phase 3 registration trial in rCDI. Upon subsequent successful completion of a Ph3 pivotal rCDI trial, and per the operative FDA procedure, Acurx plans to request FDA approval for treatment and prevention of rCDI under the FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (Guidance for Industry, 2020). He added: "Along with results from IBZ's international Phase 3 registration program in patients with acute CDI, we believe IBZ has the potential to be the first agent to demonstrate clinical success in both the treatment of acute CDI and reduction of recurrence in rCDI and such success would shift the paradigm of treatment and prevention of rCDI from two agents to one."

The poster is available on the Acurx Pharmaceuticals website www.acurxpharma.com

About the Anaerobe Society of the Americas
Founded in 1992, The Anaerobe Society of the Americas is an international organization, promoting the study and application of knowledge of anaerobic bacteriology. The primary activity of the society is organizing the biennial Anaerobe Congress for researchers, clinicians, and laboratory scientists from around the world to engage in presentations, exchanges, and dialogues related to anaerobes.

Acurx previously announced it has received mutually consistent positive feedback from both FDA and EMA which included details on Acurx's two planned international Phase 3 clinical trials in patients with acute CDI. Accordingly, if successful, these trials will support the submission of a U.S. New Drug Application (NDA) and a Marketing Authorization Application (MAA) for regulatory approval in Europe. The trial design not only allows determination of ibezapolstat's ability to achieve Clinical Cure of CDI as measured 2 days after 10 days of oral treatment but also includes assessment of ibezapolstat's potential effect on reduction of CDI recurrence in the target population. The primary efficacy analysis will be performed using a Modified Intent-To-Treat (mITT) population.

About the Ibezapolstat Phase 2 Clinical Trial
The completed multicenter, open-label single-arm segment (Phase 2a) study was followed by a double-blind, randomized, active-controlled, non-inferiority, segment (Phase 2b) at 28 US clinical trial sites which together comprise the Phase 2 clinical trial. (see

https://clinicaltrials.gov/ct2/show/NCT04247542). This Phase 2 clinical trial was designed to evaluate the clinical efficacy of ibezapolstat in the treatment of CDI including pharmacokinetics 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. (Data published in Lancet, August 2025 https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(25)00054-0/fulltext).

About Ibezapolstat
Ibezapolstat is the Company's lead antibiotic candidate planning to advance to international Phase 3 clinical trials to treat patients with *C. difficile* infection. Ibezapolstat is a novel, orally administered antibiotic, being developed as a Gram-Positive Selective Spectrum (GPSS®) antibacterial. It is the first of a new class of DNA polymerase IIIC inhibitors under development by Acurx to treat bacterial infections. Ibezapolstat's unique spectrum of activity, which includes *C. difficile* but spares other Firmicutes and the important Actinobacteria phyla, appears to contribute to the maintenance of a healthy gut microbiome.

In June 2018, ibezapolstat was designated by the U.S. Food and Drug Administration (FDA) as a Qualified Infectious Disease Product (QIDP) for the treatment of patients with CDI and will be eligible to benefit from the incentives for the development of new antibiotics established under the Generating New Antibiotic Incentives Now (GAIN) Act. In 2019, FDA granted "Fast Track" designation to ibezapolstat for the treatment of patients with CDI. The CDC has designated *C. difficile* as an urgent threat highlighting the need for new antibiotics to treat CDI.

About *Clostridioides difficile* Infection (CDI) and Recurrent CDI (rCDI)
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, 2015, NEJM). Recent estimates suggest C. difficile approaches 500,000 infections annually in the U.S. and is associated with approximately 30,000 deaths annually. (Guh, 2020, NEJM. Based on internal estimates, the recurrence rate for the 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%.

In recent studies, rCDI ranges from 4% to 19.5% following treatment with fidaxomicin and 17 to 27% following treatment with vancomycin. In patients with multiple prior episodes of CDI, rCDI following treatment with vancomycin is even more problematic, with an incidence of up to 40%. Consequently, the principal unmet medical need in this disease is the prevention of recurrence. The estimated annual public health cost burden in the U.S. annually is ~$5 billion annually with ~$2.8 billion due to recurrent CDI.

About the Microbiome in *C. 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. Beneficial effects of bile acids include a decrease in primary bile acids and an increase in secondary bile acids in patients with CDI, which was observed in the Company's Ph2a trial results and previously reported (CID, 2022). In the Ph2b trial, ibezapolstat-treated patients showed lower concentrations of fecal primary bile acids, and higher beneficial ratio of secondary to primary bile acids than vancomycin-treated patients.

About Acurx Pharmaceuticals, Inc.
Acurx Pharmaceuticals is a late-stage biopharmaceutical company focused on developing a new class of small molecule antibiotics for difficult-to-treat bacterial infections. The Company's approach is to develop antibiotic candidates with a Gram-positive selective spectrum (GPSS®) that blocks the active site of the Gram-positive specific bacterial enzyme DNA polymerase IIIC (pol IIIC), inhibiting DNA replication and leading to Gram-positive bacterial cell death. 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), drug- resistant*Streptococcus pneumoniae* (DRSP) and *B. anthracis* (anthrax; a Bioterrorism Category A Threat-Level pathogen). Acurx's lead product candidate, ibezapolstat, for the treatment of *C. difficile* Infection is preparing to advance into international Phase 3 trials.

Additionally, the Company has initiated start-up activities for a ground-breaking clinical trial in patients with rCDI with the first patient expected to enroll in the fourth quarter this year. This trial is a 20-patient, open-label pilot trial in patients with multiply-recurrent CDI with at least 3 episodes of CDI in the past year and will inform elements of a planned active-controlled, Phase 3 registration trial in the rCDI. Upon subsequent successful completion of a Ph3 pivotal rCDI trial, and per the operative FDA procedure, Acurx plans to request FDA approval for treatment and prevention of rCDI under the FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (Guidance for Industry, 2020). Successful trial outcome has the potential to shift the paradigm of treatment and prevention of rCDI from two agents to one.

The Company's preclinical pipeline includes development of an oral product candidate for treatment of ABSSSI (Acute Bacterial Skin and Skin Structure Infections), upon which a development program for post-exposure prophylaxis of inhalation anthrax is being planned in parallel.

Learn more about Acurx Pharmaceuticals and its product pipeline, please visit www.acurxpharma.com

Forward-Looking Statements
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 FDA or equivalent foreign regulatory agencies where approval is sought; whether, if ibezapolstat obtains approval, it will be successfully distributed and marketed; and other risks and uncertainties described in the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2026, as filed with the Securities and Exchange Commission on May 12, 2026, and in the Company's subsequent filings with the Securities and Exchange Commission. Such forward- looking statements speak only as of the date of this press release, and Acurx disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements, except as may be required by law.

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