September 14, 2026

Acurx Pharmaceuticals

Acurx Announces Presentation of a Scientific Poster at the Premier International C. difficile Symposium (ICDS) Demonstrating Superior In Vitro Kill Kinetics of Ibezapolstat vs. Vancomycin and Fidaxomicin (Standards of Care) in Clostridioides difficile and Vancomycin-Resistant Enterococcus Co-Cultures

- The microbiome of patients experiencing recurrent CDI is frequently dominated by overgrowths of *Enterococcus* species
- This study evaluated the *in vitro* bactericidal and molecular efficacy of ibezapolstat (IBZ), vancomycin (VAN), and fidaxomicin (FDX) against *C. difficile* and *Enterococcus* in standalone and complex co-culture environments
- These findings demonstrate that *Enterococcus* creates a protective microenvironment that actively impairs *C. difficile* killing using standard of care antibiotic regimens
- IBZ maintained superior bactericidal activity under co-culture conditions, including further decreasing *Clostridioides difficile* toxin B (TcdB) expression while simultaneously eradicating vancomycin-resistant bacterial overgrowth
- 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., Sept. 14, 2026 /PRNewswire/ -- **Acurx Pharmaceuticals, Inc.** (NASDAQ: ACXP) a late clinical stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, announced today that a scientific poster entitled: *Comparative In Vitro Killing Kinetics of Ibezapolstat and Comparator Antibiotics in Clostridioides difficile and Vancomycin-resistant Enterococcus Co-Cultures* was presented at the 9th International *C. difficile* Symposium held in Bled, Slovenia from September 8-10, 2026. The poster was presented by Dr. Eugenie Bassères, Research Scientist, University of Houston College of Pharmacy.

All vancomycin-resistant Enterococcus (VRE) strains demonstrated high-level resistance to VAN (MIC >128 µg/mL), whereas IBZ and FDX exhibited equivalent lower susceptibility thresholds (MIC range: 2–16 µg/mL). In monoculture, IBZ displayed potent bactericidal activity against *C. difficile* non-inferior to FDX ($p \geq 0.2381$). *Enterococcus* co-culture with *C. difficile* created severe microbial interference that impaired *C. difficile* killing across all antibiotic arms, decreasing killing by up to 2.90 logs; however, IBZ maintained the highest residual anti-*C. difficile* performance (5.51-log reduction), significantly outperforming VAN ($p = 0.0112$). Conversely, *C. difficile* presence exerted negligible interference on VRE killing,

where IBZ and FDX maintained robust anti-VRE killing while VAN remained inactive. At the transcriptional level, all treatments significantly suppressed *TcdB* gene abundance compared to the experimental laboratory control while IBZ showed statistically significant superiority over the other two antibiotics in decreasing the VanA cluster (ibezapolstat, vancomycin and fidaxomicin)

The study was performed at the University of Houston laboratory of Kevin Garey, PharmD, MS, FIDSA, Professor and Chair, University of Houston College of Pharmacy, and Principal Investigator for microbiology and microbiome aspects of the ibezapolstat clinical trial program. Commenting on the significance of the results of the study, Dr. Garey stated: "These new data add to the growing body of evidence supporting ibezapolstat's unique antibacterial pharmacology to kill *C. difficile* while preserving the microbiome. Prior studies have shown that Enterococcus increases the severity of *C. difficile* infection. This study adds in vitro evidence that ibezapolstat doesn't cause overgrowth of vancomycin-resistant Enterococcus and also maintains killing efficacy against *C. difficile* strains."

Robert J. DeLuccia, Executive Chairman of Acurx, stated: "If these results are validated in our Phase 3 registration program, and ultimately in clinical practice, for the treatment of patients with CDI, ibezapolstat's activity has the potential to reduce the nosocomial emergence of the critical pathogen VRE while treating CDI." He further stated: "Adding to the totality of data on ibezapolstat from studies such as this increase our confidence in a successful outcome of our clinical trial program and continue to elevate our favorable product profile and attractive value proposition, including in-market competitive advantage compared to vancomycin and fidaxomicin, the current standards of care for acute CDI, particularly for the reduction of recurrence".

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

Acurx previously reported the successful outcome of a Type C Meeting conducted with FDA on July 13, 2026 to discuss ibezapolstat's Phase 3 clinical program and scope of its planned NDA. The Agency stated that it is open to further discussion at a Pre-NDA Meeting regarding the possibility of submitting an NDA with only a single Phase 3 trial, depending on the totality of the clinical data plus any other supportive data that Acurx may generate by that milestone. The Agency noted that determination of acceptability of one Phase 3 clinical trial for an NDA is made on a case-by-case basis, taking into consideration such factors as the magnitude, consistency, and overall robustness of the efficacy results; generalizability of the results to the US population; relevance of the results to US patient care and clinical practice guidelines; Phase 2 data; and an adequate safety database. The Agency acknowledged Acurx's planned clinical trial in recurrent CDI (rCDI) and noted the data from this rCDI trial, if successful, will support an NDA submission. If the IBZ-ASPIRE trial does not meet these criteria, then a second trial consistent with the agreement reached at the end of Phase 2 (EOP2) meeting on April 27, 2024 is recommended.

The currently planned IBZ-ASPIRE trial is of non-inferiority design with the primary efficacy analysis in the Modified Intent-To-Treat (mITT) population. This will result in approximately 550 subjects in the mITT population, randomized in a 1:1 ratio to either ibezapolstat or standard-of-care vancomycin. The Agency also agreed with the overall trial design and evaluation criteria and further agreed that the trial testing criteria, if successful, could support indications for both the acute treatment and the reduction of recurrence of CDI. In the event non-inferiority of ibezapolstat to vancomycin for Clinical Cure of CDI is demonstrated, further

analyses will be conducted to test for superiority for reduction of recurrence and for clinical cure of CDI.

Acurx also previously announced that it is conducting a new clinical trial (IBZ-PATHFINDER) in patients with multiply recurrent *C. difficile* Infection (rCDI) while its program in the broader CDI patient population is ready to advance to Phase 3 international clinical trials (IBZ-ASPIRE), subject to receiving appropriate funding. This new IBZ-PATHFINDER clinical trial in rCDI involves an open-label pilot trial to gain experience with IBZ in patients with multiply-recurrent CDI with at least 3 episodes of CDI within the past 12 months.

About the International C. difficile Symposium (ICDS)
The International *C. difficile* Symposium (ICDS) is established as the premier venue for the review of Clostridium difficile research. The first meeting was held in Kranjska Gora in 2004, the 2nd in Maribor in 2007, while all earlier meetings were in Bled in 2010, 2012, 2015 and in 2018. ICDS in 2020 was held virtually. The 2026 meeting will provide a forum for the C. difficile community to exchange knowledge across disciplines, from epidemiology and diagnostics to clinical trials and basic research, fostering innovative approaches to understanding pathogenesis and improving disease control.

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 the Society of 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%. 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 described in the Company's annual report on Form 10-K for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on March 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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