

Acurx Pharmaceuticals Receives FDA Conditional Acceptance and USPTO Trademark Allowance for the Company's Brand Name for Ibezapolstat

- The proposed proprietary name, or brand name, CIFBEZY has received conditional acceptance from the FDA and also federal trademark allowance from the USPTO
- These initial milestones will form the basis for the commercial identity of Acurx's lead product candidate, ibezapolstat, as the Company prepares to advance it toward its international Phase 3 registration program for both the acute treatment and reduction of recurrence in *C. difficile* Infection (CDI)
- As required, a request for final FDA review and approval of the brand name will be submitted at time of marketing application for the NDA

STATEN ISLAND, N.Y., Aug. 17, 2026 /PRNewswire/ -- Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("Acurx" or the "Company"), a late-stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, today announced that the U.S. Food and Drug Administration (FDA) has conditionally accepted the proposed proprietary, or brand name, CIFBEZY for ibezapolstat, the Company's lead antibiotic product candidate being developed for both the acute treatment and the reduction of recurrence of CDI. The Company also announced that the U.S. Patent and Trademark Office (USPTO) has allowed the trademark application for CIFBEZY.

These independently-determined initial milestones to establish the proprietary name for ibezapolstat consider both regulatory and intellectual-property aspects. For the regulatory aspect, commercial use is contingent upon approval of a US NDA (New Drug Approval) and is focused on patient safety and the prevention of medication errors. For the intellectual property aspect, the notice of allowance shows that the trademark has passed through both the examination process and the opposition period. Securing both a registration and proprietary name will provide Acurx with a protected brand name as it advances ibezapolstat into international Phase 3 clinical trials toward an NDA approval and ultimate commercialization.

The proprietary name CIFBEZY (pronounced "sif-BEZ-ee") was developed through an extensive screening process involving external branding experts, prescribers, pharmacists and linguists, as required and evaluated by FDA's Division of Medication Error Prevention and Analysis (DMEPA) consistent with the FDA's Guidance for Industry: Contents of a Complete Submission for the Evaluation of Proprietary Names.

"Receiving both FDA conditional acceptance and USPTO trademark allowance for CIFBEZY are meaningful milestones as a placeholder that move ibezapolstat one step closer to preparation for commercialization" said Robert J. DeLuccia, Acurx's Executive Chairman: "With ibezapolstat preparing to advance into its international Phase 3 registration program

for treatment of both CDI and reduction of recurrence and the initiation of a ground-breaking clinical trial in patients with multiply-recurrent CDI (rCDI), we believe ibezapolstat has the potential to be the first anti-CDI antibiotic to demonstrate clinical success for both acute treatment and reduction of recurrence of *C. difficile* infection. Such success has the potential to shift the paradigm of treatment and prevention of rCDI from two treatments to one and if approved would be a game changer offering substantial in-market competitiveness."

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+ specific bacterial enzyme DNA polymerase III C (pol III C), 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 (CDI) is Phase 3 ready to advance to international clinical trials subject to obtaining appropriate financing. Acurx has received FDA guidance in meeting minutes from a July 13, 2026 Type C Meeting to discuss ibezapolstat's (IBZ) Phase 3 clinical program, including the potential to submit an NDA (New Drug Application) based on a single Phase 3 trial and a clinical trial design intended to support indications for both treatment and reduction of recurrence of *Clostridioides difficile* infection (CDI). FDA stated that it is open to further discussion on the totality of evidence from the clinical development program at a pre-NDA meeting after completion of a single Phase 3 trial and any other clinical trials conducted prior to the pre-NDA meeting, particularly if the clinical efficacy results are robust. Additionally, the Agency agreed that a successful clinical outcome from a single IBZ-ASPIRE Phase 3 trial, supported by the open-label IBZ-PATHFINDER Phase 2 trial in multiply-recurrent CDI (rCDI) will allow NDA filing for both the acute treatment and the reduction of recurrence of CDI. Trial start-up activities for the IBZ-PATHFINDER ground-breaking clinical trial in patients with rCDI have been initiated with patient enrollment expected to begin in the next few months.

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 treatment of inhaled anthrax is being planned in parallel.

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 III C 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 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](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(25)00054-0/fulltext)).

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 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% 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.

To 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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