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Acurx Pharmaceuticals

Acurx Announces Scientific Poster Presentation of its DNA pol IIIC Inhibitors' Microbiome Evaluation at ESCMID Global 2026

DNA pol IIIC inhibitors demonstrate the unexpected benefit of gut microbiome preservation while demonstrating systemic antibacterial activity

- *Neutropenic CD-1 mice were infected intramuscularly with methicillin-resistant* Staphylococcus aureus *(MRSA) and subsequently treated with one of three Acurx DNA pol IIIC inhibitors, linezolid, or placebo administered orally*
- *Acurx compounds achieved potentially therapeutic plasma levels and reduced MRSA tissue burden*
- *Acurx antibiotics maintained a substantially higher gut microbial diversity and a community structure similar to baseline and distinct from linezolid*
- *Unlike linezolid, ACX compounds maintain Bacteroidota-dominant community structure and prevent Proteobacteria expansion in the gastrointestinal tract*
- *DNA pol IIIC inhibitors demonstrate a class effect of potentially clinically-relevant gut microbiome preservation while demonstrating systemic antibacterial activity*
- *Acurx's DNA pol IIIC inhibitor preclinical product candidates are FDA QIDP and Fast-Track eligible and target Gram-positive infections classified as Serious Threat priorities by CDC*

STATEN ISLAND, N.Y., May 4, 2026 /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, today announced presentation of a scientific poster at the 35th Congress of ESCMID Global (European Society of Clinical Microbiology and Infectious Diseases) held in Munich, Germany from April 17-21, 2026. Dr. Khurshida Begum, Research Scientist, University of Houston College of Pharmacy presented the poster entitled: *Preclinical Microbiome Evaluation of Novel PolC-Inhibitor Compounds*. Using microbiome profiling shotgun metagenomics (MetaPhlAn) the authors concluded that DNA pol IIIC compounds represent a targeted strategy to treat resistant Gram-positive infections while preserving microbiome structure, minimizing downstream complications associated with antibiotic-induced dysbiosis.

Kevin Garey, PharmD, MS, FIDSA and Principal Investigator for microbiology and microbiome aspects of Acurx's DNA pol IIIC program, and Robert L. Boblitt, Endowed Professor in Drug Discovery at the University of Houston College of Pharmacy, commented on the significance of the data presented: "Discovering highly selective antibacterial agents that specifically target systemic bacterial pathogens while avoiding the eradication of trillions of health-promoting bacteria in our gut microbiome is a "Holy Grail" of antibiotic development. Initial work in our laboratory with Acurx's novel DNA pol IIIC inhibitors has

demonstrated favorable gut microbiome-sparing effects. The novel findings presented at ESCMID demonstrate these positive microbiome results to be a class effect of DNA pol IIIC inhibitors, potentially positioning them as unique additions to the anti-Gram-positive therapeutic armamentarium."

Robert J. DeLuccia, Executive Chairman of Acurx, stated: "These data provide initial evidence that microbiome selectivity is a DNA pol IIIC inhibitor class effect. This novel and unexpected finding, to our knowledge not previously reported with any new antibiotic class, could have medical practice-changing implications for the treatment of serious and potentially life-threatening Gram-positive infections. To treat systemic infections without promoting antibiotic-induced gut dysbiosis is seemingly a paradox and has the potential for a transformational shift in the treatment paradigm for antibacterial therapy." He further stated: "This work, coupled with the recently announced new research grant by the Dutch government to Leiden University Medical Center and Acurx to pave the way for further rational design of novel DNA pol IIIC inhibitors based on new structure-activity relationship data, would expand our opportunities for lead optimization as well as expand our portfolio of groundbreaking anti-infective therapeutics".

Acurx's portfolio of preclinical compounds include clinical applications for infections caused by MRSA such as: ABSSI, Hospital Acquired and Ventilator Acquired Bacterial Pneumonia, bacteremia with or without sepsis and/or endocarditis, bone and joint and diabetic foot infections.

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

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 Phase 3 ready with plans in progress to begin international clinical trials. 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 inhaled anthrax is being planned in parallel.

About MRSA

While ibezapolstat for the treatment of *C. difficile* Infection (CDI) is ready to advance to Phase 3 international pivotal trials, Acurx's R&D platform has sustainability for additional new product candidates from its pipeline of systemic (oral and IV) antibiotics to treat infections caused by other susceptible and antimicrobial resistant bacteria, including infections caused by MRSA. The CDC estimates ~323,700 hospital cases of MRSA infections annually with

~10,600 deaths. In a recent CDC surveillance study in hospitalized patients in the US, MRSA accounted for 52% of all infections, almost twice as many as MDR Gram-negative infections.

Clinical applications for these infections include: ABSSI, Hospital Acquired and Ventilator Acquired Bacterial Pneumonia, bacteremia with or without sepsis and/or endocarditis, bone and joint, diabetic foot infections. Acurx's DNA pol IIIC inhibitor preclinical product candidates are FDA QIDP and Fast-Track eligible and target Gram-positive infections classified as Serious Threat priorities by CDC.

About ESCMID Global (formerly ECCMID)

ESCMID (European Society of Clinical Microbiology and Infectious Diseases) Global conference is recognized as the largest international forum for presentations and discussions of research in the fields of clinical microbiology and infection for experts from academia, the clinical setting and the industry. ESCMID's yearly congress attracts over 14,000 participants. ECCMID offers a wide range of sessions including: keynotes, symposia, poster sessions, educational workshops, meet-the-expert sessions and more. The society's executive power is vested in ESCMID in Executive Committee elected by the ESCMID members. The administrative ESCMID office is in Basel, Switzerland.

Acurx previously announced that it will conduct a new clinical trial in patients with recurrent *C. difficile* Infection (rCDI) while its program in the broader CDI patient population is ready to advance to Phase 3 international clinical trials, subject to receiving appropriate funding. This new clinical trial in rCDI begins with 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. This will inform elements of a planned active-controlled, Phase 3 registration trial in the rCDI indication to be implemented following favorable results from the open-label 20 patient trial. Upon subsequent successful completion of the 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).

About *C. difficile* Infection (CDI) and Recurrent *C. difficile* Infection (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.

Acurx had also previously announced that it had received positive regulatory guidance from the EMA during its Scientific Advice Procedure which confirmed that the clinical, non-clinical and CMC (Chemistry Manufacturing and Controls) information package submitted to EMA supports advancement of the ibezapolstat Phase 3 program and if the Phase 3 program is successful, supports the submission of a Marketing Authorization Application (MAA) for regulatory approval in Europe. The information package submitted to EMA by the Company to which agreement has been reached with EMA included details on Acurx's two planned international Phase 3 clinical trials, 1:1 randomized (designed as non-inferiority vs vancomycin), primary and secondary endpoints, sample size, statistical analysis plan and the overall registration safety database. With mutually consistent feedback from both EMA and FDA, Acurx is well positioned to commence our international Phase 3 registration program.

The primary efficacy analysis will be performed using a Modified Intent-To-Treat (mITT) population. This will result in an estimated 450 subjects in the mITT population, randomized in a 1:1 ratio to either ibezapolstat or standard- of-care vancomycin, enrolled into the initial Phase 3 trial. 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. In the event non-inferiority of ibezapolstat to vancomycin is demonstrated, further analysis will be conducted to test for superiority.

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 an 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 Microbiome in C. difficile Infection 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.) 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 (Garey, 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 uncertainties described in the Company's annual report filed with the Securities and Exchange Commission on Form 10-K for the year ended December 31, 2025, 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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