July 7, 2021 Acurx Pharmaceuticals

Acurx Announces Filing of Provisional Patent Application for Ibezapolstat to Treat CDI While Reducing Recurrence of Infection and Improving the Health of the Gut Microbiome

STATEN ISLAND, N.Y., July 7, 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 it has filed a provisional patent application in the United States Patent and Trademark Office (USPTO). The filing of this patent application relates to ibezapolstat and its use to treat C. *difficile* Infection while reducing the recurrence of the infection, as well as improving the health of the gut microbiome. This is the latest in the series of patent applications that Acrux has filed to protect its proprietary technologies in the field of antimicrobials. Acurx is commencing a Phase 2b clinical trial in patients with CDI (*Clostridioides difficile* Infection) during the second half of this year after having recently completed a Ph2a clinical trial which demonstrated that 10 of 10 patients with CDI (100%) met the study's primary and secondary efficacy endpoints of Clinical Cure at end of treatment and Sustained Clinical Cure with no recurrence of CDI at the 28-day follow-up visit.

Acurx continues to pursue protection for its technologies in the United States and internationally. Acurx aims to protect the technology, inventions, know-how, and improvements that are important to the development of its business using the most effective intellectual property instruments.

Robert J. DeLuccia, Executive Chairman of Acurx, stated "We believe that ibezapolstat's Gram-Positive Selective Spectrum (GPSS™), kills *C. difficile,* but not other Firmicutes necessary for maintaining a healthy microbiome, and it spares the important Actinobacteria phylum needed for maintaining a healthy microbiome." He further stated: "This concept of a dual-effect treatment which includes bactericidal activity against *C. difficile* bacteria while at the same time providing a restorative effect on the microbiome has the potential to position ibezapolstat as an important first-line therapy for CDI."

David P. Luci, President & CEO of Acurx, stated: "We believe ibezapolstat's dual effect to effectively treat patients with CDI while simultaneously and dramatically reducing the likelihood of recurrence by restoring the microbiome would be a significant therapeutic advance. This dual effect would substantially reduce CDI recurrences and if this trend continues in later-stage clinical trials, and ibezapolstat is ultimately approved, it could have a dramatically positive impact on patient outcomes and on reducing downstream healthcare costs."

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)
C. difficile can sometimes 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.

About the Ibezapolstat Phase 2 Clinical Trial.
The multicenter, open-label single-arm segment of this study is to be followed by a double-blind, randomized, active-controlled segment comprise the Phase 2 clinical trial designed to evaluate ibezapolstat in the treatment of CDI. Segment 2a of this trial was an open-label cohort of up to 20 subjects from study centers in the United States. In this cohort, all 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 recommendation regarding study continuation. Based on the recommendation of Acurx's Scientific Advisory Board (SAB), 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 further based on the evidence of meeting the treatment goals of eliminating the infection (100%), with no recurrences of infection, and with an acceptable adverse event profile. In Segment 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 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.

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 early stage antibiotic candidates that target other Gram-positive bacteria, including Methicillin-Resistant Staphylococcus aureus (MRSA), Vancomycin-Resistant Enterococcus (VRE) and Penicillin-Resistant Streptococcus pneumoniae (PRSP). For more information,

please visit: **www.acurxpharma.com.**

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the potential of Ibezapolstat, Acurx's future expectations, plans and prospects, including without limitation, Acurx's expectations regarding its growth, strategy, progress and timing of its clinical trials, the potential of its antibiotics, and its intellectual property protection. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify such forward-looking statements. All such forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include the possibility that data from clinical trials will be inconsistent with the data observed in subsequent clinical trials, 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, competition from third parties that are developing products for similar uses, Acurx's ability to obtain, maintain and protect its intellectual property, Acurx's dependence on third parties for development and manufacture of product candidates including to supply any clinical trials, Acurx's ability to manage expenses and to obtain additional funding when needed to support its business activities and establish and maintain strategic business alliances and new business initiatives, and the impacts of public health pandemics such as COVID-19 on business operations including its clinical trials. Additional detailed information concerning a number of the important factors that could cause actual results to differ materially from the forward-looking information contained in this release is readily available in Acurx's publicly filed Registration Statement on Form S-1 and will also be included in quarterly, annual and other reports. Acurx disclaims any obligation to update developments of these risk factors or to announce publicly any revision to any of the forward-looking statements contained in this release, or to make corrections to reflect future events or developments.

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