November 19, 2020 Acurx Pharmaceuticals

Acurx Announces Positive Phase 2A Clinical Trial Results for Ibezapolstat in C. difficile Infection at Prominent International Conference

- Ibezapolstat, is the first of a new class of antibiotics with a novel mechanism of action, a DNA polymerase IIIC inhibitor, to enter clinical efficacy trials

- 10 of 10 patients (100%) enrolled in a Ph2A trial met the study's primary and secondary efficacy endpoints of Clinical Cure at end of treatment and Sustained Clinical Cure of no recurrence of CDI at the 28-day follow-up visit

- Compelling evidence of efficacy and safety allowed early termination of Segment 2A and advancement to Segment 2B

- Favorable microbiome signature relative to vancomycin as evidenced by enhanced proportion of actinobacteria without proteobacteria overgrowth

WHITE PLAINS, N.Y., Nov. 19, 2020 /PRNewswire/ -- Acurx Pharmaceuticals, LLC ("Acurx" or the "Company"), a privately held, clinical stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, announced today that a Phase 2 clinical trial update of its novel lead antibiotic candidate, ibezapolstat, for the treatment of CDI (*C. difficile* Infection) was featured in a poster and a late-breaker video presentation at the 8th Annual International *C. diff*. Virtual Conference and Virtual Health Expo on November 14, 2020. The poster is entitled "DNA polymerase IIIC inhibitor ibezapolstat, first of a new chemical class of antibiotics with a novel mechanism of action, Clinical Trial Update," and the late-breaker presentation is entitled "Ibezapolstat Clinical Update." Both were presented by Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy and the Principal Investigator for the microbiome aspects of the trial. Taken together, the two presentations extend the positive findings from Phase 1 into the Phase 2 program and continue to build the scientific, clinical, and microbiological foundations for ongoing ibezapolstat development.

Dr. Garey's presentation highlighted the key properties of an ideal oral antibiotic for CDI: highly potent against *C. difficile*; safe and non-absorbable (high colonic concentrations); and microbiome properties that lessen the likelihood of recurrence. According to Dr. Garey, "The overall goal in treating CDI is to kill the *C. difficile* bacteria and allow restoration of the healthy microbiome." He further stated: "Ibezapolstat spares actinobacteria and suppresses

regrowth of proteobacteria, thereby potentially lessening the likelihood of recurrence. This is consistent with the Ph2A data showing no recurrence at 30-days post initial cure".

Both the poster and the video presentation remain accessible for viewing on the post-conference website at cdiff2020.com (Posters tab) and the Acurx website acurxpharma.com

Robert J. DeLuccia, Co-Founder & Managing Partner of Acurx, stated, "We are very excited by these excellent clinical results allowing early termination of our Phase 2A Segment and advancement to Segment 2B, which we expect to begin early next year. Particularly notable are the data showing that ibezapolstat enhances the population of actinobacteria without promoting proteobacteria overgrowth, suggesting the potential for ibezapolstat to have a "restorative" effect on the microbiome." He further stated "To build on the continuum of data analyses from the Phase 1, Phase 2A and Phase 2B studies, we look forward to results of ongoing non-clinical pharmacology experiments which will further guide the development program to increase our probability of clinical success".

In this Phase 2 clinical trial, Segment 2A was designed to enroll up to 20 patients with a data review planned by a Trial Oversight Committee after 10 patients completed the trial. All 10 patients enrolled in the trial met the study's primary and secondary efficacy endpoints of Clinical Cure at end of treatment and Sustained Clinical Cure of no recurrence of CDI at the 28-day follow-up visit. Ibezapolstat was well-tolerated, with no serious adverse events (SAEs) reported in the trial. Based on these successful treatment results, and in consultation with the Company's medical advisors, the Company has terminated enrollment in Segment 2A early and will advance to Segment 2B. These results also represent the first-ever clinical validation of DNA polymerase IIIC as a therapeutically relevant antibacterial target.

About the Phase 2 Clinical Trial. In Segment 2A of this trial, 10 subjects with diarrhea caused by *C. difficile* were treated with ibezapolstat 450 mg orally for 10 days and evaluated for clinical cure. All cured subjects were followed for sustained clinical cure at 28 ± 2 days. In Segment 2B, approximately 64 additional subjects 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 will be followed for 28 ± 2 days for recurrence. The two treatments will be identical in appearance, dosing times, and number of capsules administered to maintain the blind. Subjects in both segments will be evaluated for clinical and sustained clinical cure, safety, and tolerability. All subjects in both segments will have stool samples tested for microbiome profiles. Additional information about the trial, including eligibility criteria can be found at: www.clinicaltrials.gov (Study identifier: NCT04247542).

About Clostridioides Difficile Infection (CDI). Clostridioides (formerly Clostridium) difficile, also known as C. difficile or C. diff, 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 United States and is associated with approximately 20,000 deaths. (Guh, 2020, New England Journal of Medicine). Based on internal estimates including a recurrence rate of approximately 20%, we believe the annual incidence in the U.S. approaches 600,000.

About the C Diff Foundation: The Company recognizes the month of November as C. Difficile Awareness Month as designated by the US Centers for Disease Control and Prevention (CDC) and supports the work of the C Diff Foundation in educating and

advocating for the Prevention, Treatments, Clinical Trials, and Environmental Safety of *Clostridioides difficile* (*C.difficile*) Infections worldwide. **cdifffoundation.org/.** The C Diff Foundation recently announced the release of C diff and You app, available from the Apple Store (apple.com) and Google Store (play.google.com). Developed with patients, family members, and caregivers in mind, the app provides information about C. difficile infection prevention, treatments, clinical trials, support, guidelines, environmental safety and nutrition.

The U.S. Center for Diseases Control 2019 Update on Antimicrobial Resistance. **https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf** . CDC reported that more than 2.8 million antibiotic-resistant infections occur in the U.S. each year and more than 35,000 people die as a result, nearly twice as many annual deaths than previously reported by CDC in 2013. These deaths are attributed to antimicrobial-resistant pathogens including Enterococcus (including vancomycin-resistant strains or VRE), Staphylococcus (including methicillin-resistant strains or MRSA), and Streptococcus (including antibiotic-resistant strains), which are the targets of Company's antibiotic pipeline currently in preclinical development and also eligible for QIDP and FDA-Fast-Track-Designation for priority review.

About ibezapolstat, FDA QIDP and Fast Track Designation. In June 2018, FDA granted Qualified Infectious Disease Product (QIDP) designation to ibezapolstat as an oral treatment for patients with CDI. In addition, in January 2019, FDA granted Fast Track designation to ibezapolstat for the oral treatment for patients with CDI.

FDA's QIDP Designation provides that ibezapolstat will be eligible to benefit from certain incentives for the development of new antibiotics provided under the Generating Antibiotic Incentives Now Act (the GAIN Act). These incentives include Priority Review and eligibility for Fast Track status, the latter of which Acurx has already applied for and been granted by FDA. Further, if ultimately approved by the FDA, ibezapolstat is eligible for an additional five-year extension of Hatch-Waxman marketing exclusivity.

FDA Fast Track Designation is a process designed to facilitate the development and expedite the regulatory pathway of new drugs to treat serious or life-threatening conditions and that fill a high unmet medical need. Ibezapolstat is a novel, first-in-class, orally administered antibacterial. It is the first of a new class of DNA polymerase IIIC inhibitors in clinical development by Acurx to treat bacterial infections.

About DNA polymerase IIIC (pol IIIC). Working in scientific collaboration with WuXi AppTec, Acurx has identified additional potential therapeutic candidates to add to its pipeline of DNA pol IIIC inhibitors. Nonclinical research has established the mechanism of action of ibezapolstat as the selective inhibition of the enzyme DNA pol IIIC, which is required for bacterial replication and pathogenesis. This enzyme is found only in certain Gram-positive bacteria, including C. difficile as well as the pathogens Enterococcus (including vancomycin-resistant strains or VRE), Staphylococcus (including methicillin-resistant strains or MRSA), and Streptococcus (including antibiotic-resistant strains). Accordingly, chemically related molecules with the same mechanism of action as ibezapolstat have the potential to treat a variety of serious systemic Gram-positive infectious diseases.

About Acurx Pharmaceuticals, LLC. Acurx Pharmaceuticals is a privately held clinical stage biopharmaceutical company focused on developing new antibiotics for difficult to treat infections. Acurx'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 our website at **www.acurxpharma.com.**

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 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; and other factors. In addition, the forward-looking statements included in this press release represent our views as of November 19, 2020. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward- looking statements at some point in the future, we specifically disclaim any obligation to do so.

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