July 23, 2020 Acurx Pharmaceuticals

Acurx Actively Enrolling Patients in Ph2 Clinical Trial of its Lead Antibiotic for Treatment of Clostridioides difficile Infection (CDI)

- 6 of 6 patients entered in the trial met the study's primary endpoint of Clinical Cure at end of treatment

- 2 of 2 patients achieved Sustained Clinical Cure, the study's secondary endpoint of no recurrence of CDI at the 30-day follow-up

- Ibezapolstat, a novel treatment for CDI, is the first of an entirely new class of antibiotics, DNA pol IIIC inhibitors, to enter clinical efficacy trials

- C. difficile bacteria remain on CDC Urgent Threat list, highlighting need for new antibiotics

- Ibezapolstat is QIDP and FDA-Fast-Track-Designated for priority review

WHITE PLAINS, N.Y., July 23, 2020 /PRNewswire/ -- Acurx Pharmaceuticals, LLC ("Acurx" or the "Company"), a privately held, clinical stage biopharmaceutical company developing new antibiotics for difficult-to-treat bacterial infections, announced today that a Phase 2 clinical trial of the Company's lead antibiotic product candidate is in progress. In this trial, orally-administered ibezapolstat given 450 mg twice daily for 10 days will be evaluated for the treatment of patients with CDI. FDA has granted Qualified Infectious Disease Product (QIDP) designation and Fast-Track status to ibezapolstat for patients with CDI.

Up to 6 study centers in the U.S. will participate in the first segment (Segment 2A) of the trial. Additional information about the trial, including eligibility criteria, can be found at www.clinicaltrials.gov (Study identifier: NCT04247542). This Phase 2, multicenter, open-label single-arm segment (Segment 2A) will be followed by a double-blind, randomized, active-controlled segment (Segment 2B), and is designed to evaluate both clinical cure and sustained clinical cure, safety, and pharmacokinetics. All patients in both segments will have stool samples tested for ibezapolstat concentrations and microbiome effects. Pharmacokinetic testing for systemic exposure will be performed on blood samples in Segment 2A. All of the first 6 patients enrolled in the trial have met the study's primary endpoint, Clinical Cure at end of treatment. All patients who have reached the 30-day follow-up milestone, no recurrence of CDI, have achieved Sustained Clinical Cure, the study's secondary endpoint. Ibezapolstat has been well-tolerated in all patients to date. After the first 10 patients have completed treatment, the study's Trial Oversight Committee will assess the

ibezapolstat safety profile in relationship to treatment outcomes and will advise the company on any recommended trial modifications which could include early termination of Phase 2A and acceleration of the double-blind Segment 2B.

Robert J. DeLuccia, Co-Founder & Managing Partner of Acurx, stated "With today's heightened awareness of antimicrobial resistance, even more so in the current Covid-19 environment, and the need for new classes of antibiotics to fight this global crisis, we are very excited to advance ibezapolstat to this stage of clinical development." He further stated, "This is a significant value-creating development milestone for our Company. We believe this now clinically validated target of inhibition of bacterial DNA pol IIIC will pave the way forward for our pipeline of new oral/I.V. antibiotics in pre-clinical development to treat other Gram-positive life-threatening infections in skin/skin structure, community acquired pneumonia, bone & joint and bacteremia. This will include pathogens resistant to currently available antibiotics, and classified as priority pathogens by the WHO, CDC and FDA, all of whom emphasize the need for new classes of antibiotics to prepare for the next global infectious disease threat."

Additionally, the U.S. Center for Diseases Control recently issued its 2019 update on antimicrobial resistance https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf and reaffirmed that CDI remains an URGENT threat causing at least 12,800 deaths in 2017, highlighting the need for new antibiotics, particularly those with a novel mechanism of action. It further 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 second antibiotic candidate currently in preclinical development.

About the Phase 2 Clinical Trial. In Segment 2A of this trial, up to 20 subjects with diarrhea caused by *C. difficile* will be treated with ibezapolstat 450 mg orally for 10 days and evaluated for clinical cure. All cured subjects will be 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 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 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 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 novel class of DNA polymerase IIIC inhibitors under development by Acurx to treat bacterial infections. Acurx acquired ibezapolstat from GLSynthesis, Inc. in February 2018.

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. Ibezapolstat is being developed as a targeted, narrow spectrum oral antibiotic for the treatment of patients with CDI. Acurx is planning to advance ibezapolstat into a Phase 2 clinical trial in first quarter 2020. The CDC (Centers for Disease Control & Prevention) has designated *Clostridium difficile* bacteria as an urgent threat highlighting the need for new antibiotics to treat CDI.

About *Clostridioides Difficile* Infection (CDI). The CDC has reported that there are nearly 500,000 patients per year treated for CDI in the U.S. alone, with a recurrence rate approximated at 20% to 30%, with limited antibiotics available to treat patients with CDI. CDI is also prevalent in Europe, Japan and Canada, which are countries where the Company has patent protection and anticipates further clinical development and commercialization.

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 polymerase IIIC inhibitors. Nonclinical research has established the mechanism of action of ibezapolstat as the selective inhibition of the enzyme DNA polymerase IIIC (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 could potentially block an entirely new molecular target, DNA polymerase IIIC (pol IIIC) and its R&D pipeline includes early stage antibiotic candidates that target other Gram-positive bacteria that are active parenterally, and potentially orally, 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.](http://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 July 23, 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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