November 4, 2019 Acurx Pharmaceuticals

Acurx Pharmaceuticals to Present at Two Prominent International Healthcare Conferences

- 7th Annual International C.diff. Conference & Health EXPO

- The World Antimicrobial Resistance Congress

WHITE PLAINS, N.Y., Nov. 4, 2019 /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 it will present the Phase 1 clinical trial results for its lead antibiotic candidate, ACX-362E, under development for the oral treatment of patients with *C. difficile* Infection (CDI). Successfully completed in August 2019, this was a first-in-human trial for a new class of antibiotics which has a novel mechanism of action by inhibiting DNA synthesis in certain bacterial cells (DNA pol IIIC inhibitors). These data will be presented at The 7th Annual International C. diff. Conference to be held in St. Louis, MO on November 5-6, 2019, https://cdifffoundation.org/2019cdiffconference/. Results from the trial "Randomized, Double-blind, Placebo-controlled, Single and Multiple Ascending Dose Phase 1 Study to Determine the Safety, Pharmacokinetics, Food, and Fecal Microbiome Effects of ACX-362E Administered Orally to Healthy Subjects," will be presented by the Company's Medical Director, Michael H. Silverman, M.D., FACP. Dr Silverman will highlight the impressive ACX-362E safety data along with fecal concentrations comparable to or better than those observed with precedent products that have advanced to demonstrate clinical success. The Phase 1 clinical trial had a secondary endpoint to determine the fecal microbiome effects of ACX-362E compared to those of the standard of care, oral vancomycin. This microbiome comparison is ground-breaking as it has not been done in prior CDI studies in Phase 1 clinical trials in the U.S. Microbiome analysis demonstrated that ACX-362E has a significantly more favorable effect than oral vancomycin on the microbiome due to less disruption of the favorable microbiota in the gastrointestinal tract.

Acurx will also present at The World Antimicrobial Resistance (AMR) Congress, https://www.terrapinn.com/conference/antimicrobial-resistance-congress-usa/speakers.stm , being held in Washington, D.C. on November 6-8, 2019. Robert J. DeLuccia, Acurx's Co-Founder and Managing Partner, will present the company's performance history and planned development milestones of its portfolio of novel antimicrobials, DNA pol IIIC inhibitors, during the Partnering Session of the Conference. The World AMR Congress is a commercially focused conference that gathers global leaders in infectious diseases to meet, brainstorm and discuss the challenges and opportunities for advancing the development of antibiotics and non-traditional therapies and improving commercialization strategies.

The Company also recognizes the month of November as*C. Difficile* Awareness Month as designated by the C diff Foundation and supports their work in educating and advocating for the Prevention, Treatments, Clinical Trials, and Environmental Safety of *Clostridioides*

difficile (*C.difficile*) Infections worldwide. https://cdifffoundation.org/

Robert DeLuccia, Co-Founder & Managing Partner of Acurx stated: "We are very pleased to have the opportunity to present at both these prominent conferences and to support the work of the C Diff Foundation and its efforts to control *C. difficile* Infection as well as participating in the World AMR Conference to be part of the solution to combat the global crisis of antimicrobial resistance."

About the Phase 1 Clinical Trial. ACX-362E, has successfully completed a 62-subject, double-blind, placebo- controlled, multiple-ascending dose Phase 1 clinical trial of ACX-362E as an oral treatment in healthy volunteers. The Phase 1 clinical trial was first-in-man for a new class of antibiotics which work by inhibiting DNA synthesis in certain bacterial cells (pol IIIC inhibitors). Pol IIIC is required for DNA replication of many Gram-positive pathogens, including *Clostridioides* as well as *Enterococcus*, *Staphylococcus*, and *Streptococcus*. Safety information was analyzed through assessment of adverse events and other standard safety measures, while concentrations of ACX-362E were determined in both the blood and the feces, the latter being the critical site of drug delivery for treating CDI. For the microbiome analysis, daily stool samples from subjects in the multiple-ascending arm (MAD) were collected for microbiome analysis. DNA was extracted from stool and sent for shotgun metagenomic sequencing to assess diversity changes in the microbiome. In addition, DNA samples were tested by quantitative polymerase chain reaction (qPCR) to test for quantitative changes in relevant host microbiota.

For the multiple-ascending dose studies, subjects received either ACX-362E 300 mg and 450 mg given twice daily. There were 6 subjects at each dose range compared to six patients that received vancomycin 125 mg given four times daily. All treatments were given for 10 days. Results of the metagenomic sequencing demonstrated a unique microbiome profile for subjects given either dose of ACX-362E compared to the microbiome of subjects that received vancomycin. In qPCR analysis, significantly decreased taxa of Bacteroides, Firmacutes, Prevotella, and two Clostridia species (*C. leptum* and *C. coccoides*) were observed.

About ACX-362E, FDA QIDP and Fast Track Designation. In June 2018, FDA granted Qualified Infectious Disease Product (QIDP) designation to ACX-362E as an oral treatment for patients with CDI. In addition, in January 2019, FDA granted Fast Track designation to ACX-362E 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. ACX- 362E 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 ACX-362E from GLSynthesis, Inc. in February 2018.

FDA's QIDP Designation provides that ACX-362E 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, ACX-362E is eligible for an additional five-year extension of Hatch-Waxman marketing exclusivity. ACX-362E is being developed as a

targeted, narrow spectrum oral antibiotic for the treatment of patients with CDI. Acurx is planning to advance ACX-362E 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

ACX-362E 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 ACX-362E 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 atwww.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 ACX- 362E will benefit from the QIDP designation; whether ACX-362E will advance through the clinical trial process on a timely basis; whether the results of the clinical trials of ACX-362E will warrant the submission of applications for marketing approval, and if so, whether ACX-362E will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies where approval is sought; whether, if ACX-362E 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 4, 2019. 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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