October 3, 2019 Acurx Pharmaceuticals

Acurx's Novel Lead Antibiotic Candidate Presented at Two Prominent International Scientific Conferences

Phase 1 clinical trial results and more favorable effect on the host microbiome vs vancomycin support advancement to Phase 2 in patients with C. difficile Infection (CDI)

WHITE PLAINS, N.Y., Oct. 3, 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 its novel lead antibiotic candidate, ACX-362E, for the treatment of CDI was featured in three presentations at two recent, prominent scientific conferences. Data presented include the clinical results from its Phase 1 clinical trial that was successfully completed in August 2019. This was a first-in-human trial for a new class of antibiotics whose mechanism of action is inhibiting DNA synthesis in certain bacterial cells (pol IIIC inhibitors). These data were presented at **ID**Week™ in Washington, D.C. today. Clinical results were presented from the 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 which had a secondary objective to determine the fecal microbiome effects of ACX-362E compared to those of oral vancomycin.

Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy and the Principal Investigator for the microbiome aspects of the trial presented the results of the study and concluded: "The safety data from the Phase 1 trial are impressive with fecal concentrations comparable to those observed with precedent products that have advanced to demonstrate clinical success. Most notable is the ground-breaking comparison of the effects of ACX-362E versus the standard of care on the normal human gut microbiome. Microbiome analysis demonstrated that ACX-362E has a significantly more favorable effect than oral vancomycin due to less disruption of the microbiota in the gastrointestinal tract. This differential was especially pronounced among the phyla, Bacteroidetes and Firmicutes which generally comprise up to 90% of the healthy human gut microbiome." The abstract will be published as an online supplement to Open Forum Infectious Diseases (OFID), the Open Access Journal from IDSA. Complete study results are in preparation for submission to a scientific journal.

Robert DeLuccia, Co-Founder & Managing Partner of Acurx stated: "We are especially pleased that our Phase 1 clinical results highlighting the favorable effects on the gut microbiome were considered sufficiently novel and important to be accepted for the highly competitive 'latebreaker' oral presentation category at **ID**Week."

Additionally, results from *in vitro* studies of ACX-362E against contemporary isolates of *C. difficile* were presented by scientists in two posters at the joint ASM/ESCMID Conference on Drug Development in Boston, MA, Sept. 4-6, 2019. In a poster entitled "Time-kill Kinetics of

the Novel Antibacterial Agent ACX-362E against *Clostridioides difficile*" results were presented demonstrating rapid bacterial killing and potent bactericidal activity. In a poster entitled "In Vitro Activity of the Novel Antibacterial ACX-362E against *Clostridioides difficile*" the *in vitro* activity of ACX-362E was tested against 104 contemporary clinical isolates of*C. difficile* including 30 identified epidemic strains (e.g., ribotype 027) as well as 36 toxin-producing strains. ACX-362E had a range of MICs of 1-8 µg/mL against all strains with MIC_{50} and MIC_{90} values of 4 µg/mL for both measures, consistent with previous surveillance studies in the United States and in Europe. Copies of both poster presentations are available on the company's website: www.acurxpharma.com

About the Phase 1 Clinical Trial. ACX-362E, has successfully completed the 62-subject, double-blind, placebo-controlled, multiple-ascending dose Phase 1 clinical trial of ACX-362E 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 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, Prevotella, and two Clostridia species (*C. leptum* and *C. coccoides*) were observed.

About ACX-362E, FDA QIDP and Fast Track Designation.in January 2019, FDA granted Fast Track Designation to ACX-362E and prior to that in June, 2018, FDA granted designation of ACX-362E as a Qualified Infectious Disease Product (QIDP) for the oral treatment of patients with *Clostridium Difficile* Infection (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 is now 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 October 3, 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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