August 28, 2019 Acurx Pharmaceuticals

Acurx Successfully Completes Ph1 Clinical Trial for ACX-362E in CDI

- QIDP and FDA-Fast-Track-Designated first of a new class of antibiotics

- First evidence of human safety in multiple ascending doses and favorable PK profile

- Fecal concentrations exceeded those known to inhibit C. difficile several hundred-fold

- Significantly less disruption of the gut microbiome compared to vancomycin

- Blood levels show low systemic exposure indicating poor oral absorption as desired to treat CDI

WHITE PLAINS, N.Y., Aug. 28, 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 lead product candidate, ACX-362E, has successfully completed the 68-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*. Multiple dose levels up to 450 mg BID for 10 days were shown to be well tolerated. Any adverse events attributed to ACX-362E were mild, transitory, and did not interrupt treatment in any subject. Blood levels of ACX-362E show low systemic exposure, indicating poor oral absorption and desirable in treating CDI. Additionally, fecal concentrations of ACX-362E at higher dose levels rapidly exceeded the concentrations known to inhibit *C. difficile* by several hundred-fold and were sustained for the duration of the 10-day treatment period. Detailed data will be presented at the 7th Annual International *C. difficile* Conference in St. Louis on November 6 to 7, 2019

ACX-362E is a novel, oral antibacterial agent for the treatment of*Clostridioides difficile* infection (CDI), an acute, serious, potentially life-threatening, intestinal infection. This Phase 1 study included a 6-subject vancomycin treatment arm (the current standard of care for CDI) for comparative microbiome analysis by Dr. Kevin Garey, Professor, University of Houston College of Pharmacy and Principal Investigator for this aspect of the trial. ACX-362E effects on the fecal microbiome were compared to those produced by vancomycin over the 10-day treatment course. The results demonstrate that while vancomycin significantly disrupts Bacteroidetes and Firmicutes, deemed to constitute more than 80% of the favorable microbiota in the gastrointestinal tract, ACX-362E had minimal impact on the

Bacteroidetes and Firmicutes. Specifically, vancomycin treatment resulted in a 3-4 log reduction in *Bacteroides* while ACX-362E doses of 300 or 450 mg BID showed minimal effect.

Dr. Garey stated, "The safety data are impressive with fecal concentrations comparable to those observed with precedent products that have advanced to demonstrate clinical success. For example, *Bacteroides* is one of the predominant species in the normal gut microbiome, and one of the most important in preventing colonization with *C. difficil*e. *Bacteroides* represents the Bacteroidetes family of bacteria, which along with Firmicutes comprise the predominant portion of the normal gut flora often reported to exceed 80% of the microbiome." He stated further, "The minimal disruption to the healthy gut microbiome identified in this Phase 1 study population should offer advantages over other therapeutic options for an initial episode of CDI if these salutary effects on the gut microbiome translate into the clinical benefit of reducing recurrent infection."

"We are very encouraged by these data showing that at well-tolerated doses ACX-362E reaches concentrations in the colon that are anticipated to have a highly favorable therapeutic index for patients with CDI," said Robert J. DeLuccia, Co-Founder and Managing Partner of Acurx. "The safety, fecal concentration, low systemic exposure and, most importantly, the minimal impact on the healthy gut microbiome provide data to guide selection of our Phase 2 dose and improve the probability of success and timeline efficiency of our Phase 2 clinical trial program."

About the Phase 1 Clinical Trial

The Phase 1 trial was a double-blind, placebo-controlled study to determine safety, tolerability, pharmacokinetics and fecal concentrations of ACX-362E in healthy volunteers conducted in the U.S. A total of 68 subjects, of which 44 were given active drug, were enrolled in 3 parts: Part 1, Single-ascending dose (n = 32); 6 active/2 placebo per dose cohorts of 150, 300, 600, and 900 mg; Part 2: Food-effect crossover at 300 mg (n = 8); Part 3: Multiple-ascending dose (n = 22); 6 active/2 placebo per dose cohort; BID dosing x10 days; 30-day follow-up visit for microbiome sampling; dose cohorts of 300 and 450 mg. Additionally, it included an "Active" control group for microbiome studies, oral vancomycin q6H x10 days (n = 6)

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. In addition, Acurx partnered with Dr. Kevin Garey's laboratory at the University of Houston to perform state-of-the-art microbiome testing of gastrointestinal flora in trial subjects.

About ACX-362E, FDA QIDP and Fast Track Designation

FDA granted Fast Track Designation to ACX-362E in January, 2019. 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.

ACX-362E is a Qualified Infectious Disease Product (QIDP) for the oral treatment of patients with Clostridium difficile infection (CDI). Under QIDP designation, ACX-362E will 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)
Building on the mechanism of action of ACX-362E, Acurx's lead product candidate, which acts as a DNA polymerase IIIC inhibitor and targets the oral treatment of CDI (*C. difficile* Infection), Acurx has identified additional potential therapeutic candidates to add to its pipeline. 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 August 28, 2018. 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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