February 27, 2019 Acurx Pharmaceuticals

Acurx Announces First-In-Man Clinical Trial Data of ACX-362E for CDI

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

- Phase 1 Clinical Trial provides first evidence of human safety and favorable PK profile

- Fecal concentrations of ACX-362E exceeded concentrations known to inhibit C. difficile by factors of several hundred-fold.

WHITE PLAINS, N.Y., Feb. 27, 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 32-subject, double-blinded, placebo-controlled, single-ascending dose portion of this first-in-man Phase 1 clinical trial. ACX-362E is a novel, oral antibacterial agent for the treatment of *Clostridioides difficile* infection (CDI), an acute, serious, potentially life-threatening, intestinal infection. ACX-362E is Acurx's lead compound in a pipeline of molecules that target a previously unexploited mechanism of action, namely, inhibition of the bacterial enzyme DNA polymerase IIIC (pol IIIC). Pol IIIC is required for DNA replication of many Gram-positive pathogens, including not only *Clostridioides* but also *Enterococcus*, *Staphylococcus*, and *Streptococcus*. Although the trial data remain blinded, ongoing monitoring of the data show dose levels up to 600mg have been generally well tolerated. Blood levels of ACX-362E show low systemic exposure, as predicted by prior animal studies and desirable in treating CDI. Additionally, fecal concentrations of ACX-362E at higher dose levels have exceeded the concentrations known to inhibit *C. difficile* by several hundred-fold.

"We are very encouraged by these initial data which corroborate our nonclinical findings, showing that at well-tolerated doses ACX-362E reaches concentrations in the colon that are projected to be therapeutically relevant for patients with CDI" said Robert J. DeLuccia, Co-Founder and Managing Partner of Acurx. "This gives us confidence that the ongoing multiple-dose segment of the trial will 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 planned to start later this year."

Dr. Kevin Garey, Professor, University of Houston College of Pharmacy and the Principal Investigator for microbiomic aspects of the Phase 1 clinical trial said: "The emerging fecal concentration data are comparable to those observed with precedent products that have advanced to demonstrate clinical success. I look forward to the multiple-dose safety data and to the results of the microbiomic analyses that our laboratory is performing which will form a template for a new paradigm in microbiome studies associated with drug discovery and development of CDI-directed antibiotics."

About the Phase 1 Clinical Trial
This Phase 1 trial, conducted in the U.S., is a double-blinded, placebo-controlled study to determine safety, tolerability, pharmacokinetics and fecal concentrations of ACX-362E in healthy volunteers. It is being conducted in two parts; first, single ascending doses are administered to four cohorts of 8 subjects each, and second, multiple ascending doses are given that simulate the anticipated clinical treatment regimen. Safety information is analyzed through assessment of adverse events and other standard safety measures, while concentrations of ACX-362E are determined in both the blood and the feces, the latter being the critical site of drug delivery for treating CDI. In addition, Acurx has partnered with the laboratory of Dr. Kevin Garey at the University of Houston to perform state-of-the-art microbiomic testing of gastrointestinal flora in trial subjects.

About ACX-362E, FDA QIDP and Fast Track Designation
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 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. 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 anticipates completing the Phase 1 clinical trial in the second quarter of 2019 and is planning to advance ACX-362E into a Phase 2 clinical trial in the fourth quarter of 2019. 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 *Clostridium 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, 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 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 June 20, 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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