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Acurx Pharmaceuticals

Acurx Receives FDA Fast Track Designation for ACX-362E for the Treatment of C. difficile infection

- Innovative New Molecule Recognized as a Potential Treatment for CDI, a Life-threatening Condition with Persistent Unmet Medical Need

- Phase 1 clinical study underway - anticipated completion second quarter 2019

- FDA Fast Track Designation marks significant milestone for Acurx's R&D pipeline

WHITE PLAINS, N.Y., Jan. 16, 2019 /PRNewswire/ -- Acurx Pharmaceuticals, LLC ("Acurx" or the "Company"), a clinical stage, privately-held biopharmaceutical company focused on developing new antibiotics for difficult-to-treat bacterial infections, announced today that the U.S. Food and Drug Administration has granted Fast Track designation for ACX-362E, an investigational new treatment for *Clostridium difficile* Infection (CDI). ACX-362E is a novel, oral antibiotic that recently entered Phase 1 development.

"The FDA's decision to grant Fast Track Designation for ACX-362E corroborates our effort to develop a new, highly innovative treatment option for patients with CDI, an area of significant unmet need," said Robert J. DeLuccia, Co-Founder & Managing Partner of Acurx. "If approved, we believe our new antibacterial, ACX-362E, will be an important therapeutic alternative for patients with CDI. The Fast Track designation will allow Acurx to work more closely with the FDA to bring ACX-362E to physicians and patients as soon as possible."

David P. Luci, Co-Founder & Managing Partner of Acurx, stated, "FDA's granting of Fast Track designation for our lead antibiotic program validates our business model which includes a pipeline of DNA polymerase IIIC Inhibitors we are currently developing to treat other resistant bacterial infections."

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 its portfolio of DNA polymerase IIIC inhibitors 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 inhibitor and targets the oral treatment of CDI (*Clostridium 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 enterococcus, staphylococcus, and streptococcus. 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.

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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