# Acurx Pharmaceuticals to Enter Clinical Trials with First-In-Class Antibiotics to Treat Selected Gram-Positive Bacterial Infections

## Acurx and WuXi AppTec enter collaboration to advance Acurx's pipeline of novel DNA polymerase-inhibiting antibiotic candidates

WHITE PLAINS, N.Y., Oct. 4, 2018 /PRNewswire/ -- Acurx Pharmaceuticals, LLC ("Acurx" or the "Company") announced today that it has entered into a scientific collaboration with the Research Service Division of WuXi AppTec ("WuXi") to further advance the Company's pipeline of novel DNA polymerase-inhibiting antibiotic candidates. Under the agreement, Acurx will engage WuXi for certain research and development activities and WuXi will enable the progression of Acurx's discovery pipeline of novel DNA polymerase IIIC inhibitors.

Acurx is a privately held clinical-stage biopharmaceutical company that focuses on developing new antibiotics for difficult-to-treat bacterial infections. Acurx's lead product candidate, ACX-362E, is an oral antibiotic which targets the treatment of *Clostridium difficile* Infection (CDI). AXC-362E is expected to enter a Phase 1 clinical trial in Q4 2018 and has been granted QIDP (Qualified Infectious Disease Product) designation by FDA as an oral treatment for *Clostridium difficile* bacteria. Acurx's new class of antibiotics inhibit DNA polymerase IIIC and replication of selected Gram-positive bacteria.

Initially, WuXi will focus on advancing the Company's second discovery project of optimized derivatives of ACX-375C, for the treatment of VRE (vancomycin-resistant enterococci) infections such as UTI (Urinary Tract Infections), Intraabdominal Infections and SSTI (Skin and Soft Tissue Infection), into pre-clinical studies by the end of 2019. Acurx intends to apply for QIDP designation by mid-2019 for use of ACX-375C derivatives to treat infections caused by VRE which is on FDA's priority pathogens list used to determine the granting of QIDP designation by FDA.

Additionally, the collaboration will utilize WuXi's state-of-the-art expertise in structure-based drug design, computational chemistry, chemistry synthesis and antibacterial biology to generate a series of novel compounds with potent activity against polymerase IIIC-dependent Gram-positive bacteria to build the Company's pipeline of new antibiotics.

"We are very pleased to be working with WuXi to build upon decades of research into pol IIIC inhibitors and the means of inhibiting pathogenesis through inhibition of this critical bacterial enzyme. WuXi's state-of-the-art computational chemistry and molecular design tools have the potential to refine the activity and improve the utility of this class of molecules," said Robert J. DeLuccia, Co-Founder & Managing Partner of Acurx.

"The Research Service Division of WuXi AppTec is very enthusiastic about working with the Acurx team as a strategic collaborator. We are pleased to provide mission-critical scientific support to an early-stage biopharmaceutical company in the discovery and preclinical development of new molecular entities in a disease area with challenging unmet medical needs," said Steve Yang, Executive Vice President and Chief Business Officer of WuXi AppTec.

### 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 would be active against bacteria by DNA polymerase IIIC (pol IIIC) inhibition. In addition to its lead product candidate, ACX-362E, an oral antibiotic which targets the treatment of *Clostridium difficile* Infection (CDI), its R&D pipeline includes early stage antibiotic candidates that target other Gram-positive bacteria, including Methicillin-Resistant *Staphylococcus Aureus* (MRSA), Vancomycin-Resistant *Enterococcus* (VRE) and Penicillin-Resistant *Streptococcus Pneumoniae* (PRSP), that are active parenterally. For more information, please visit our website at <a href="https://www.acurxpharma.com">www.acurxpharma.com</a>.

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 Acurx's collaboration with WuXi will result in any viable antibiotic candidates that would be granted market approval by FDA; 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.

#### About WuXi AppTec

WuXi AppTec is a leading pharmaceutical and medical device open-access capability and

technology platform company with global operations. As an innovation-driven and customer-focused company, WuXi AppTec provides a broad and integrated portfolio of services to help our customers and partners worldwide shorten the discovery and development time and lower the cost of drug and medical device R&D through cost-effective and efficient solutions. With its industry-leading capabilities such as small molecule R&D and manufacturing, cell therapy and gene therapy R&D and manufacturing, and medical device testing, the WuXi platform is enabling over 3,000 innovative collaborators from more than 30 countries to bring innovative healthcare products to patients, and to fulfill WuXi's dream that "every drug can be made and every disease can be treated." Please visit: <a href="http://www.wuxiapptec.com">http://www.wuxiapptec.com</a>

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