Acurx Pharmaceuticals

FDA Grants QIDP Designation to Acurx's Lead Antibiotic Product Candidate, ACX-362E for *Clostridium Difficile* Infection

WHITE PLAINS, NY.—June 20, 2018 --Acurx Pharmaceuticals, LLC ("Acurx" or the "Company"), a privately held clinical stage biopharmaceutical company focused on developing new antibiotics for difficult to treat infections, today announced that the U.S. Food and Drug Administration (FDA) has designated the Company's lead antibiotic product candidate, ACX-362E, as a Qualified Infectious Disease Product (QIDP). The QIDP designation was granted by the FDA 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 is planning to advance ACX-362E into a Phase 1 clinical trial in the fourth quarter of this year and anticipates completing the Phase 1 clinical trial in the second 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."

Acurx intends to file for Fast Track status with the FDA in Q4 2018.

"We are very pleased that our lead antibiotic product candidate meets the FDA criteria and has been designated as a QIDP for oral use in patients with CDI, a life-threatening disease" said Robert J. DeLuccia, Co-Founder and Managing Partner of Acurx. In an era of emerging bacterial threats where development of new antibiotics is needed, our new therapeutic approach has a novel mechanism of action and molecular target that qualifies it as a truly innovative anti-infective agent".

David P. Luci, Co-Founder and Managing Partner of Acurx, said "our ability to advance this antibiotic product candidate through clinical development and commercialize it, if approved, would constitute a significant advance for patients with CDI and treating physicians."

About The GAIN Act

The GAIN Act, Title VIII (Sections 801 through 806) of the FDA Safety and Innovation Act, seeks to provide pharmaceutical and biotechnology companies with incentives to encourage the development of new drugs to treat, prevent, detect and diagnose antibiotic-resistant infections. Qualifying pathogens are defined by the GAIN Act to include multi-drug resistant Gram-negative bacteria, including *Pseudomonas, Acinetobacter, Klebsiella,* and *Escherichia coli* species; resistant Gram-positive pathogens, including *methicillin-resistant Staphylococcus aureus* (MRSA), *vancomycin-resistant Staphylococcus aureus* and *vancomycin-resistant Enterococcus*; multi-drug resistant tuberculosis; and *Clostridium difficile*. It extends the length of time an approved drug is free from competition and clarifies the regulatory pathway for new antibiotics.

About *Clostridium Difficile* Infection

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 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.

Contacts

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