May 12, 2023

Acurx Pharmaceuticals

Acurx Pharmaceuticals, Inc. Reports First Quarter 2023 Results and Provides Business Update

STATEN ISLAND, N.Y., May 12, 2023 /PRNewswire/ -- Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("Acurx" or the "Company"), a clinical stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, announced today certain financial and operational results for the first quarter ended March 31, 2023.

Highlights of the first quarter ended March 31, 2023 include:

- Acurx continues to enroll patients in its Phase 2b clinical trial, which now includes 28 U.S. clinical trial sites, for patients with C. *difficile* infection (CDI);
- The Phase 2b clinical trial will compare the efficacy of oral ibezapolstat, the Company's lead antibiotic candidate, to oral vancomycin, the current standard of care for patients with CDI;
- In March 2023, the FDA accepted the Company's protocol amendment to its Investigational New Drug Application (or IND) which will allow an Independent Data Monitoring Committee (or IDMC) to review interim clinical data upon reaching 36 patients enrolled and to then provide its recommendation either to early terminate the Ph2b trial, as the Company had done with the Ph2a trial, or alternatively continue enrolling. We anticipate completing enrollment of the 36 patients in the second half of 2023;
- In April 2023 two presentations were made at the 33rd Annual European Congress of Clinical Microbiology and Infectious Disease (ECCMID) in Copenhagen. First, a scientific poster entitled "Novel Pharmacology and Susceptibility of Ibezapolstat Against C. difficile Isolates with Reduced Susceptibility to C. difficile-directed Antibiotics" was presented by Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy, and Principal Investigator for microbiome aspects of our ibezapolstat clinical trial program. Second, Acurx Executive Chairman, Bob DeLuccia, presented an update regarding the Company's preclinical, systemic oral and IV program for treatment of other gram-positive infections caused by MRSA, VRE and DRSP at the "Pipeline Corner" featured session at ECCMID, organized by Dr. Ursula Theuretzbacher, a world-renowned microbiology expert involved in antibacterial drug research, discovery and development strategies and policies for clinical and public health needs. These presentations are available on the Company's website at www.acurxpharma.com .
- The Company is continuing its R&D collaboration with Leiden University Medical Center (Holland) under a previously awarded grant from the Dutch Government of approximately $500,000 USD to further evaluate the mechanism-of-action of Acurx's inhibitors against the DNA pol IIIC enzyme, which is the bacterial target of our antibiotic pipeline for the systemic treatment (IV and oral) of gram-positive bacterial infections. The Company is currently in active discussions to extend this research program for an additional two-year period;

- Regarding the Company's open application for a non-dilutive grant to CARB-X, the Company was recently informed by CARB-X that its application is in the active review pool and a final decision is to be rendered by CARB-X in or prior to October 2023. We believe that based on our recent development progress and the unique nature of having a new class of antibiotics, we have a strong possibility to obtain CARB-X approval;

First Quarter 2023 Financial Results

- **Cash Position**:
  The Company ended the quarter, with cash totaling $7.2 million compared to $9.1 million as of December 31, 2022.
- **R&D Expenses**:
  Research and development expenses for the three months ended March 31, 2023 were $1.0 million compared to $0.8 million for the three months ended March 31, 2022. The increase was due to an increase in Phase 2b trial related costs.
- **G&A Expenses**:
  General and administrative expenses for the three months ended March 31, 2023 were $1.9 million compared to $1.9 million for the three months ended March 31, 2022.
- **Net Income/Loss**:
  The Company reported a net loss of $2.9 million or $0.25 per diluted share for the three months ended March 31, 2023 compared to a net loss of $2.7 million or $0.26 per diluted share for the three months ended March 31, 2022 for the reasons previously mentioned.

Conference Call

As previously announced, David P. Luci, President and Chief Executive Officer, and Robert G. Shawah, Chief Financial Officer, will host a conference call to discuss the results and provide a business update as follows:

Date:	Friday, May 12, 2023
Time:	8:00 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13738523

About the Ibezapolstat Phase 2 Clinical Trial
The completed multicenter, open-label single-arm segment (Phase 2a) study is now followed by a double-blind, randomized, active-controlled, non-inferiority, segment (Phase 2b) at 28 US clinical trial sites which together comprise the Phase 2 clinical trial (see https://clinicaltrials.gov/ct2/show/NCT04247542). This Phase 2 clinical trial is designed to evaluate the clinical efficacy of ibezapolstat in the treatment of CDI including pharmacokinetics and microbiome changes from baseline and continue to test for anti-recurrence microbiome properties seen in the Phase 2a trial, including the treatment-related changes in alpha diversity and bacterial abundance and effects on bile acid metabolism.

The completed Phase 2a segment of this trial was an open label cohort of up to 20 subjects from study centers in the United States. In this cohort, 10 patients with diarrhea caused by *C. difficile* were treated with ibezapolstat 450 mg orally, twice daily for 10 days. All patients

were followed for recurrence for 28± 2 days. Per protocol, after 10 patients of the projected 20 Phase 2a patients completed treatment (100% cured infection at End of Treatment), the Trial Oversight Committee assessed the safety and tolerability and made its recommendation regarding early termination of the Phase 2a study and advancement to the Ph2b segment. In the currently enrolling Phase 2b, trial segment, patients with CDI will be enrolled and randomized in a 1:1 ratio to either ibezapolstat 450 mg every 12 hours or vancomycin 125 mg orally every 6 hours, in each case, for 10 days and followed for 28 ± 2 days following the end of treatment for recurrence of CDI. The two treatments will be identical in appearance, dosing times, and number of capsules administered to maintain the blind. This Phase 2 clinical trial will also evaluate pharmacokinetics (PK) and microbiome changes and continue to test for anti-recurrence microbiome properties, including the change from baseline in alpha diversity and bacterial abundance, especially overgrowth of healthy gut microbiota Actinobacteria and Firmicute phylum species during and after therapy. In the event non-inferiority of ibezapolstat to vancomycin is demonstrated, further analysis will be conducted to test for superiority.

Phase 2a data demonstrated complete eradication of colonic *C. difficile* by day three of treatment with ibezapolstat as well as the observed overgrowth of healthy gut microbiota, Actinobacteria and Firmicute phyla species, during and after therapy. Very importantly, emerging data show an increased concentration of secondary bile acids during and following ibezapolstat therapy which is known to correlate with colonization resistance against *C. difficile*. A decrease in primary bile acids and the favorable increase in the ratio of secondary-to-primary bile acids suggest that ibezapolstat may reduce the likelihood of CDI recurrence when compared to vancomycin

About the Microbiome in *Clostridioides difficile* Infection (CDI) and Bile Acid Metabolism

C. difficile can be a normal component of the healthy gut microbiome, but when the microbiome is thrown out of balance, the *C. difficile* can thrive and cause an infection. After colonization with *C. difficile*, the organism produces and releases the main virulence factors, the two large clostridial toxins A (TcdA) and B (TcdB). (Kachrimanidou, Microorganisms 2020, 8, 200; doi:10.3390/microorganisms8020200.) TcdA and TcdB are exotoxins that bind to human intestinal epithelial cells and are responsible for inflammation, fluid and mucous secretion, as well as damage to the intestinal mucosa.

Bile acids perform many functional roles in the GI tract, with one of the most important being maintenance of a healthy microbiome by inhibiting *C. difficile* growth. Primary bile acids, which are secreted by the liver into the intestines, promote germination of *C. difficile* spores and thereby increase the risk of recurrent CDI after successful treatment of an initial episode. On the other hand, secondary bile acids, which are produced by normal gut microbiota through metabolism of primary bile acids, do not induce *C. difficile* sporulation and therefore protect against recurrent disease. Since ibezapolstat treatment leads to minimal disruption of the gut microbiome, bacterial production of secondary bile acids continues which may contribute to an anti-recurrence effect.

About *Clostridioides difficile* Infection (CDI)

According to the 2017 Update (published February 2018) of the *Clinical Practice Guidelines for C. difficile Infection by the Infectious Diseases Society of America (IDSA) and Society or Healthcare Epidemiology of America (SHEA),* CDI remains a significant medical problem in

hospitals, in long-term care facilities and in the community. *C. difficile* is one of the most common causes of health care- associated infections in U.S. hospitals (Lessa, et al, 2015, New England Journal of Medicine). Recent estimates suggest *C. difficile* approaches 500,000 infections annually in the U.S. and is associated with approximately 20,000 deaths annually. (Guh, 2020, New England Journal of Medicine). Based on internal estimates, the recurrence rate of two of the three antibiotics currently used to treat CDI is between 20% and 40% among approximately 150,000 patients treated. We believe the annual incidence of CDI in the U.S. approaches 600,000 infections and a mortality rate of approximately 9.3%.

About Acurx Pharmaceuticals, Inc.
Acurx Pharmaceuticals is a clinical stage biopharmaceutical company focused on developing new antibiotics for difficult to treat infections. The Company's approach is to develop antibiotic candidates that target the DNA polymerase IIIC enzyme and its R&D pipeline includes early-stage antibiotic product candidates that target Gram-positive bacteria, including *Clostridioides difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin resistant Enterococcus (VRE) and drug-resistant *Streptococcus pneumoniae* (DRSP). To learn more about Acurx Pharmaceuticals and its product pipeline please visit 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 ibezapolstat will benefit from the QIDP designation; whether ibezapolstat will advance through the clinical trial process on a timely basis; whether the results of the clinical trials of ibezapolstat will warrant the submission of applications for marketing approval, and if so, whether ibezapolstat will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies where approval is sought; whether, if ibezapolstat 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 March 16, 2023. 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.

Forward-Looking Statements

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 ibezapolstat will benefit from the QIDP designation; whether ibezapolstat will advance through the clinical trial process on a timely basis; whether the results of the clinical trials of ibezapolstat will warrant the submission of applications for

marketing approval, and if so, whether ibezapolstat will receive approval from the FDA or equivalent foreign regulatory agencies where approval is sought; whether, if ibezapolstat obtains approval, it will be successfully distributed and marketed; and other risks and uncertainties described in the Company's annual report filed with the Securities and Exchange Commission on Form 10-K for the year ended December 31, 2022, and in the Company's subsequent filings with the Securities and Exchange Commission. Such forward-looking statements speak only as of the date of this press release, and Acurx disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements, except as may be required by law.

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ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM BALANCE SHEETS

	March 31, 2023 (unaudited)	December 31, 2022 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 7,178,820	$ 9,111,751
Prepaid Expenses	206,601	264,955
TOTAL ASSETS	$ 7,385,421	$ 9,376,706
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 2,073,982	$ 2,061,685
TOTAL CURRENT LIABILITIES	2,073,982	2,061,685
TOTAL LIABILITIES	2,073,982	2,061,685
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 11,671,795 and 11,627,609 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	11,672	11,628
Additional Paid-In Capital	46,843,809	45,944,478
Accumulated Deficit	(41,544,042)	(38,641,085)
TOTAL SHAREHOLDERS' EQUITY	5,311,439	7,315,021
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 7,385,421	$ 9,376,706

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2023	**2022**
	(unaudited)	**(unaudited)**
OPERATING EXPENSES		
Research and Development	$ 1,015,583	$ 818,888
General and Administrative	1,887,374	1,851,250
TOTAL OPERATING EXPENSES	2,902,957	2,670,138
NET LOSS	$ (2,902,957)	$ (2,670,138)
LOSS PER SHARE		
Basic and diluted net loss per common share	$ (0.25)	$ (0.26)
Weighted average common shares outstanding basic and diluted	11,639,395	10,232,843

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