March 16, 2023

Acurx Pharmaceuticals

Acurx Pharmaceuticals, Inc. Reports Fourth Quarter and Full Year 2022 Results and Provides Business Update

STATEN ISLAND, N.Y., March 16, 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 fourth quarter and full year ended December 31, 2022.

Highlights of the fourth quarter and full year ended December 31, 2022 include:

- Acurx continues to enroll patients in its Phase 2b clinical trial, which includes 28 U.S. sites (up from the initial 12 clinical trial sites), in patients with C. *difficile* infection (CDI) with an interim review of clinical data anticipated in mid-2023;
- 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 CDI;
- Based on the blinded observed data from the ongoing Ph2b clinical trial to date, in January 2023, the Company filed a protocol amendment to its Investigational New Drug Application (IND) with FDA to allow for an Independent Data Monitoring Committee (IDMC) to review interim clinical data. If acceptable to FDA, the IDMC will review the clinical data upon enrollment of 36 patients in the Ph2b clinical trial. The Company currently has enrolled 25 patients in the Ph2b clinical trial. The IDMC will determine and recommend to the Company whether the most appropriate course of action forward is to early terminate the Ph2b clinical trial (as the Company had done with the Ph2a clinical trial) or to continue patient enrollment. The Company intends to report available data promptly after the IDMC conducts this interim review. The Company assembled its IDMC during this first quarter of 2023 for this purpose.
- The Company has continued its R&D collaboration with Leiden University Medical Center (Holland) 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 product pipeline for the systemic treatment (IV and oral) of other gram-positive bacterial infections. Data generated from this program was critical to include in a recent grant application for $11.3 million of non-dilutive funding (described below) with a decision anticipated in April 2023. Based on this successful collaboration, LUMC has proposed a second-stage, two-year project to further analyze chemical structure relationships of new Acurx compounds with a propensity for reduced antimicrobial resistance. At this point, this new project proposal is subject to review, approval and funding by the Dutch government for an additional $500,000 and the Company anticipates a decision by mid-2023;
- The Company completed certain portions of its laboratory study at the University of Houston comparing the killing effect of ibezapolstat to vancomycin, fidaxomicin and metronidazole using both in vitro and ex vivo analyses. Certain results were presented at the Anaerobe Society of America annual scientific conference and results

demonstrated that ibezapolstat has favorable killing kinetics compared to vancomycin to treat *C. difficile* infection at standard and high bacterial concentrations, supporting continued development of this first-in-class antibiotic to treat *C. difficile* Infection. Comparisons of the killing effect of ibezapolstat to fidaxomicin and metronidazole are ongoing. These reported clinical results support the expectation that microbiome effects may be predictive of beneficial patient outcomes including low rates of recurrence;

- In October 2022, the Company filed for a non-dilutive grant of up to $11.3 million which, if approved, would provide funding for ACX-375, our second antibiotic program targeting the treatment of MRSA infections, for a period of 5 years up to the start of Ph2 clinical trials. The Company is now in the third and final round of consideration for this non-dilutive grant and a decision is expected in April 2023. If approved, the Company would need to pay approximately $5 million of the approximate $16 million program total cost over a five-year period with approximately $11.3 million paid by the grant provider;
- Next month, the European Congress of Clinical Microbiology and Infectious Disease (commonly referred to as ECCMID), one of the most comprehensive and influential scientific conferences in clinical microbiology and infection, will hold its 33rd session in Copenhagen. An abstract entitled "Novel pharmacology and susceptibility of ibezapolstat against *C. difficile* isolates with reduced susceptibility to *C. difficile*-directed antibiotics" has been accepted. Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy and the Principal Investigator for microbiome aspects of our ibezapolstat clinical trial program, will present on our behalf;
- Additionally, our Executive Chairman, Robert J. DeLuccia, has been invited to present the Company's preclinical, systemic oral and IV program for treatment of other gram-positive infections caused by MRSA, VRE and DRSP in their "Pipeline Corner" featured session at ECCMID, organized by Dr. Ursula Theuretzbacher, a world-renowned microbiology expert for antibacterial drug research, discovery and development strategies and policies for clinical and public health needs. More details on these presentations will be announced prior to the meeting date.

Fourth Quarter and Full Year 2022 Financial Results

- **Cash Position**:
  The Company ended the year, with cash totaling $9.1 million compared to $13.0 million as of December 31, 2021.
- **R&D Expenses**:
  Research and development expenses for the three months ended December 31, 2022 were $1.4 million compared to $0.7 million for the three months ended December 31, 2021. The increase was due to an increase in Phase 2b trial related costs. For the twelve months ended December 31, 2022, research and development expenses were $4.8 million versus $2.0 million for the twelve months ended December 31, 2021. This increase was due primarily to Phase 2b trial related costs.
- **G&A Expenses**:
  General and administrative expenses for the three months ended December 31, 2022 were $1.8 million compared to $1.9 million for the three months ended December 31, 2021. The decrease was primarily due to a decrease in professional fees. For the twelve months ended December 31, 2022, general and administrative expenses were $7.3 million versus $10.8 million for the twelve months ended December 31, 2021. The

decrease was primarily attributable to a decrease in professional fees and stock-based compensation, partially offset by an increase in insurance costs.

- **Net Income/Loss**:
  The Company reported a net loss of $3.3 million or $0.28 per diluted share for the three months ended December 31, 2022 compared to a net loss of $2.6 million or $0.26 per diluted share for the three months ended December 31, 2021, and a net loss of $12.1 million or $1.12 per share for the twelve months ended December 31, 2022, compared to a net loss of $12.7 million or $1.49 per diluted share for the twelve months ended December 31, 2021 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:	Thursday, March 16, 2023
Time:	8:00 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13736887

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.

Investor Contact:

Acurx Pharmaceuticals, Inc.
David P. Luci, President & Chief Executive Officer
Tel: 917-533-1469
Email: davidluci@acurxpharma.com

ACURX PHARMACEUTICALS, INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2022 AND 2021

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash	$ 9,111,751	$ 12,958,846
Prepaid Expenses	264,955	295,304
TOTAL ASSETS	$ 9,376,706	$ 13,254,150
LIABILITIES AND MEMBERS' AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 2,061,685	$ 843,909
TOTAL CURRENT LIABILITIES	2,061,685	843,909
TOTAL LIABILITIES	2,061,685	843,909
COMMITMENTS AND CONTINGENCIES		
MEMBERS' AND SHAREHOLDERS' EQUITY		
Members' Equity, Class A	—	—
Members' Equity, Class B	—	—
Common Stock; $.001 par value, 200,000,000 shares authorized, 11,627,609 and 10,215,792 shares issued and outstanding at December 31, 2022 and 2021, respectively	11,628	10,216
Additional Paid-In Capital	45,944,478	38,948,334
Accumulated Deficit	(38,641,085)	(26,548,309)
TOTAL MEMBERS' AND SHAREHOLDERS' EQUITY	7,315,021	12,410,241
TOTAL LIABILITIES AND MEMBERS' AND SHAREHOLDERS' EQUITY	$ 9,376,706	$ 13,254,150

ACURX PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2022 AND 2021

	2022	2021
OPERATING EXPENSES		
Research and Development	$ 4,754,271	$ 2,030,177
General and Administrative	7,338,505	10,784,023
TOTAL OPERATING EXPENSES	12,092,776	12,814,200
Gain on Forgiveness of Paycheck Protection Program Loan	—	66,503
NET LOSS	$ (12,092,776)	$ (12,747,697)
LOSS PER SHARE		
Basic and diluted net loss per common share	$ (1.12)	$ (1.49)
Weighted average common shares outstanding basic and diluted	10,816,412	8,535,873

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