First of a New Class of Antibiotics Targeting "Priority Pathogens"

Preparing for the Next Pandemic: Antimicrobial Resistance

Robert J. DeLuccia
Executive Chairman

World Antimicrobial Resistance Conference
September 7, 2023

Disclosure

Acurx

Forward-Looking Statements

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AMR: GLOBAL CHALLENGE

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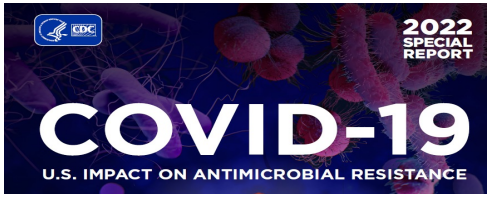


RE-EMPHASIZED PRIORITY PATHOGENS

C. diff remains one of the most common healthcare-associated infections, affecting thousands of people every year

We must prepare our public health systems to fight multiple threats, simultaneously. Because antimicrobial resistance will not stop, we must meet the challenge. Now is the time to address our current antimicrobial-resistant threats, while simultaneously preparing for unknown emerging threats in the future.*

Because of pandemic impacts, 2020 data are delayed or unavailable for 9 of the 18 antimicrobial resistance threats.

- *Clostridioides difficile (C. diff)*
- Drug-resistant *Neisseria gonorrhoeae*
- Drug-resistant *Campylobacter*
- Drug-resistant nontyphoidal *Salmonella*
- Drug-resistant *Salmonella* serotype Typhi
- Drug-resistant *Shigella*
- Drug-resistant *Streptococcus pneumoniae*
- Erythromycin-resistant group A *Streptococcus*
- Clindamycin-resistant group B *Streptococcus*

Available data show an alarming increase in resistant infections starting during hospitalization, growing at least 15% from 2019 to 2020.

- Carbapenem-resistant *Acinetobacter* (↑78%)
- Antifungal-resistant *Candida auris* (↑60%)*
- Carbapenem-resistant Enterobacterales (↑35%)
- Antifungal-resistant *Candida* (↑26%)
- ESBL-producing Enterobacterales (↑32%)
- Vancomycin-resistant Enterococcus (↑14%)
- Multidrug-resistant *P. aeruginosa* (↑32%)
- Methicillin-resistant *Staphylococcus aureus* (↑13%)

- ***Panel:*** Bruce Lee, Forbes: *Can We Push AMR to the Forefront*
- ***Keynote Panel****: What if a pandemic were to happen tomorrow*
- ***Investor Panel:*** *Funding Investments in the AMR Desert*
- ***MRSA highlighted: newly released YouTube video****:*
  Race Against Resistance; TIMEBOMB WAITING TO EXPLODE!
- ***MRSA highlighted****: NAIAD /Antibacterial Resistance Leadership Group; Gymnast Duke Medical Student Tori Kinamon with a catastrophic MRSA skin infection undergoing* eight surgeries, over a month in the hospital, partly in the intensive care unit, and faced the possibility of losing her leg

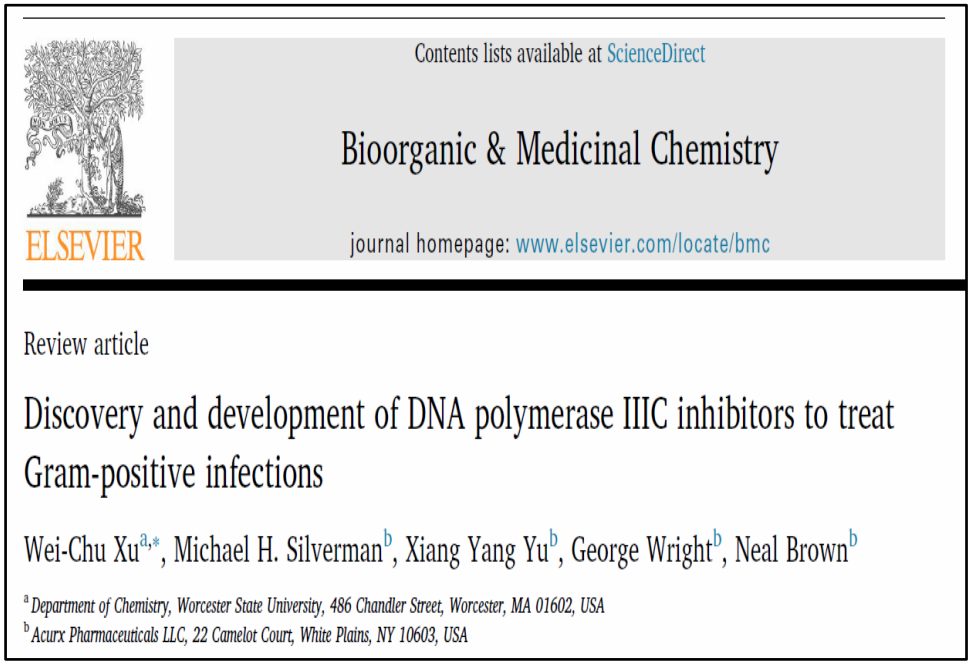
**Excerpted from: CDC. COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report 2022. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/drugresistance/covid19.html

Company Mission and Key Publications

Acurx

- Develop new class of antibiotics for difficult-to-treat bacterial infections
- Lead DNA pol IIIC Inhibitor discovered by Wright/Brown, Professors Emeritus, UMass; Acurx acquired in 2018*
- First of a new class of antimicrobials addresses global crisis of AMR in certain Gram-positive bacteria; novel mechanism not expected to share any cross-resistance with existing classes
- Previously unexploited scientific target – DNA pol IIIC – critical for DNA replication of certain Gram-positive bacteria

THE UNTOLD STORY UNFOLDING



Contents lists available at ScienceDirect

Bioorganic & Medicinal Chemistry

journal homepage: www.elsevier.com/locate/bmc

Review article

Discovery and development of DNA polymerase IIIC inhibitors to treat Gram-positive infections

Wei-Chu Xu[a,*], Michael H. Silverman[b], Xiang Yang Yu[b], George Wright[b], Neal Brown[b]

[a] Department of Chemistry, Worcester State University, 486 Chandler Street, Worcester, MA 01602, USA
[b] Acurx Pharmaceuticals LLC, 22 Camelot Court, White Plains, NY 10603, USA

Clin Infect Dis. 2022 Feb 4;ciac096. doi: 10.1093/cid/ciac096. Online ahead of print.

Efficacy, Safety, Pharmacokinetics, and Microbiome Changes of Ibezapolstat in Adults with Clostridioides difficile Infection: A Phase 2a Multicenter Clinical Trial

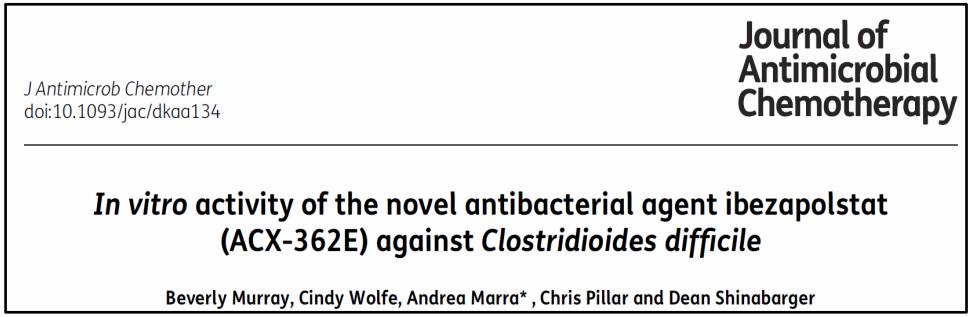
Kevin W Garey [1 2], Jacob McPherson [1], An Q Dinh [2], Chenlin Hu [1], Jinhee Jo [1], Weiqun Wang [1], Chris K Lancaster [1], Anne J Gonzales-Luna [1], Caroline Loveall [1], Khurshida Begum [1], M Jahangir Alam [1], Michael H Silverman [3], Blake Hanson [2]

J Antimicrob Chemother
doi:10.1093/jac/dkaa364

Journal of Antimicrobial Chemotherapy

A randomized, double-blind, placebo-controlled, single and multiple ascending dose Phase 1 study to determine the safety, pharmacokinetics and food and faecal microbiome effects of ibezapolstat administered orally to healthy subjects

Kevin W. Garey [1]*†, Khurshida Begum[1]†, Chris Lancaster[1], Anne Gonzales-Luna[1], Dinh Bui[1], Julie Mercier[2], Corinne Seng Yue[3], Murray P. Ducharme[3], Ming Hu[1], Bradley Vince[2], Michael H. Silverman[4], M. Jahangir Alam[1] and Martin Kankam[2]



J Antimicrob Chemother
doi:10.1093/jac/dkaa134

Journal of Antimicrobial Chemotherapy

In vitro activity of the novel antibacterial agent ibezapolstat (ACX-362E) against *Clostridioides difficile*

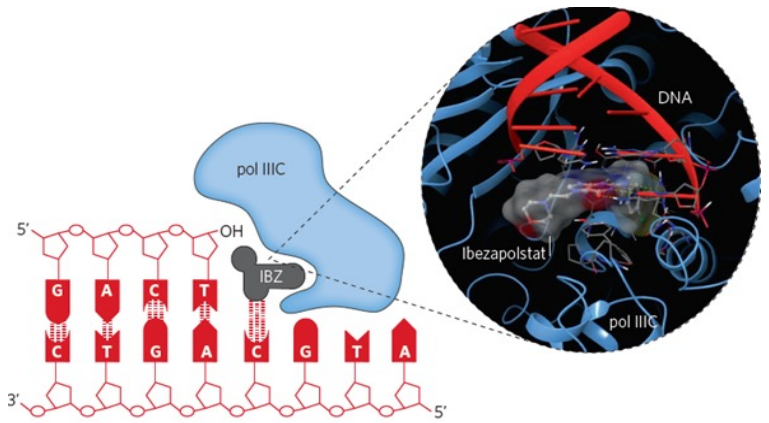
Beverly Murray, Cindy Wolfe, Andrea Marra* , Chris Pillar and Dean Shinabarger

*Patented to May 2032 with 10 years regulatory exclusivity from FDA approval (QIDP and NCE)

Acurx Snapshot

Novel Mechanism of Action:

- Previously unexploited scientific target
- Lead pol IIIC Inhibitor discovered by Wright/Brown Professors Emeriti, UMass; Acurx acquired in 2018[1]
- Innovation criteria[2]:
  - ✓ New chemical class
  - ✓ New target (Gram+; now clinically validated)
  - ✓ New MOA (Unique)
  - ✓ No cross-resistance
- Ibezapolstat (oral) potential for first-line treatment for *C. difficile* Infection (CDI)- FDA QIDP/Fast Track
- Gram-Positive Selective Spectrum (GPSS™) oral and IV antibiotics target all low G + C bacterial pathogens (including MRSA, VRE, DRSP) - QIDP/Fast Track eligible



Acurx compounds block the active site of the Gram+ specific bacterial enzyme DNA polymerase IIIC (pol IIIC), inhibiting DNA replication

Unmet Medical Need: CDC classifies CDI as an ***urgent threat*** requiring new antibiotic development; CDC classifies MRSA, VRE, PRSP as ***serious threats***

Ibezapolstat Phase 2a Success/Phase 2b Enrolling: Ph2a *demonstrated 100% cure rate and 100% sustained clinical cure 30 days after EOT. Microbiome restoration/sparing and bile acid ratio may inhibit recurrence.*[3]

Upcoming Interim Analysis of Ph2b data: Independent Data Monitoring (IDMC) committee to review unblinded data from 36 enrolled patients and recommend early termination (as was done in Phase 2a) or continue enrollment.

[1]Patented to May 2032 with 10 years regulatory exclusivity from FDA approval (QIDP and NCE); [2]*Theuretzbacher, WHO, 2017;* [3] *Garey ,CID, 2022*

Ibezapolstat: Phase 2a Success

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- Patients with mild to moderate CDI treated with orally administered ibezapolstat given 450mg twice daily for 10 days
- All 10 patients (100%) met the study's primary and secondary efficacy endpoints of Initial Cure and Sustained Cure
- Ibezapolstat very well tolerated; no SAEs
- Compelling evidence of efficacy and safety allowed early termination of Segment 2A and advancement to Segment 2B
- Phase 2a efficacy results (*Clinical Infectious Diseases, 2022*) **provide clinical validation for targeting pol IIIC to kill resistant gram-positive bacteria, including *C. difficile*, MRSA, VRE and DRSP**

Ibezapolstat Phase 2b Clinical Trial Design

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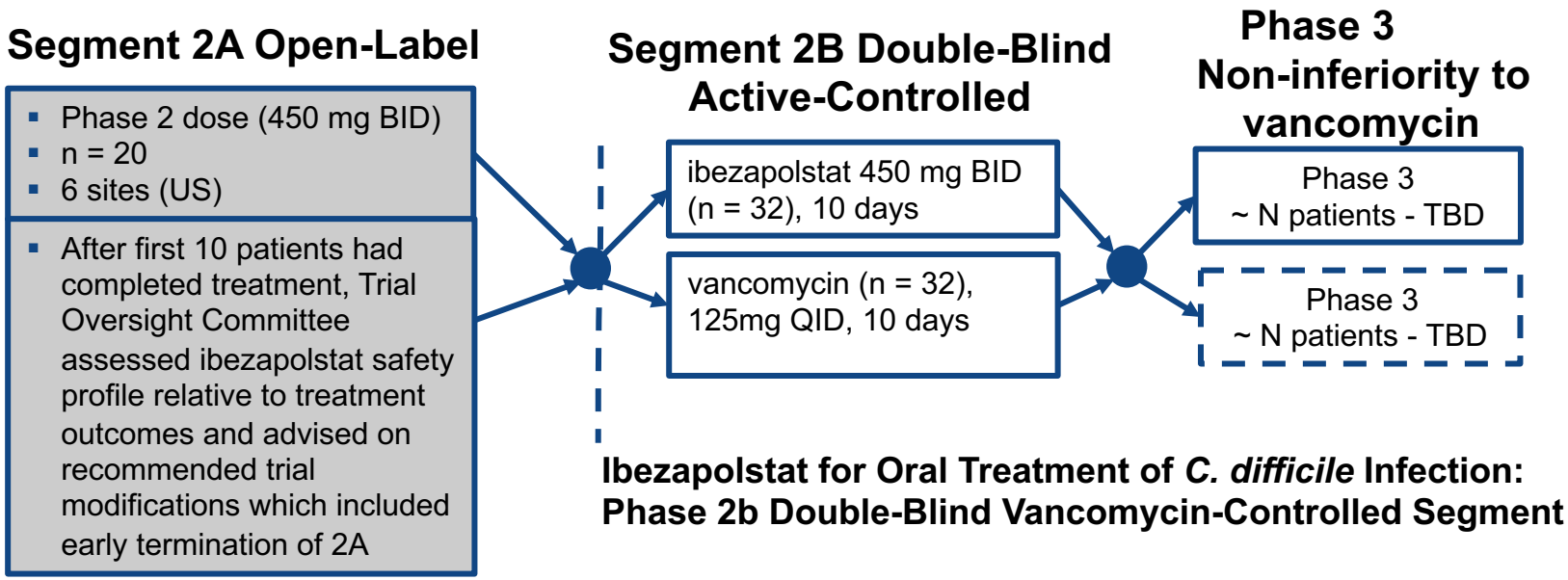

- Management will continue to pursue non-dilutive grants for late-stage clinical trials.

Management Expects Ph2b success. Why?

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Factors that will provide confidence in successful outcomes of future clinical trials:

- Invitro potency vs *C. difficile (+100x concentration needed)*
- Excellent human safety profile
- High human fecal concentrations (>100-fold above MIC_{50} in patient samples)
- Favorable microbiome effects
- 100% cure at EOT in Ph2a
- 100% sustained cure at Ph2a follow up
- Rapid eradication (by Day 3) of *C. difficile* in patients
- Does not trigger sporulation or toxin release
- Favorable effect on bile acids

Systemic GPSS™ Antibiotic: Program Highlights

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Systemic Pol IIIC Inhibitor Program: Oral and IV formulations to target systemic treatment of *Staphylococcus, Streptococcus and Enterococcal* infections, including MRSA, VRE, and other resistant G+ bacterial infections; WHO/CDC Priority Pathogen Lists[1]

- Novel mechanism of action, inhibiting DNA pol IIIC, present in G+ and not G- bacteria or mammals[2]
- Bacteria resistant to current antibiotics, including daptomycin, telavancin, ceftaroline, new tetracyclines & linezolid-resistant bacteria
- In hospitalized patients in the United States, MRSA accounted for 52% of all infections, almost twice as many as MDR Gram-negative infections[3]
- VRE hospital infections exceeded carbapenem-resistant (CR) Acinetobacter, MDR *Pseudomonas aeruginosa* and CR Enterobacteriaceae infections combined[3]

Potential Clinical Indications: ABSSSI (MRSA + other G+). Follow-on: community-acquired bacterial pneumonia, hospital and/or ventilator-associated bacterial pneumonia; bacteremia with or w/o infectious endocarditis, bone/joint infections & diabetic foot infections

[1] CDC Antibiotic Resistance Threats in the U.S., 2019, Atlanta, U.S. Department of Health and Human Services, CDC, Nov. 2019; [2] Xu, et al., Bioorganic & Medicinal Chemistry https://doi.org/10.1016/j.bmc.2019.06.017; [3]Jernigan, et al., Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012–2017, *N Engl J Med* 382:1309-19; (2020)

Systemic GPSS™ Antibiotic: Program Goal / Progress

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- **Hit-to-Lead testing of >500 novel compounds** resulted in significant improvements in:
  - Cytotoxicity, solubility, plasma protein binding
  - In vitro & in vivo safety
  - Oral and IV efficacy in mouse infection models including in neutropenic mice (MRSA systemic & thigh, VRE thigh, and PRSP lung)

- **Lead Optimization**: Further improve drug-like properties through:
  - Streamlined chemical synthesis and testing paradigm
  - Advanced molecular modeling based on improved leads
  - Stepwise core modifications to expand chemical selections
  - Collaboration with LUMC (Leiden University Medical Center):
    - High-throughput measurement of pol IIIC inhibition: MRSA, VRE, & PRSP
    - 3D structure elucidation of pol IIIC enzyme alone & bound to Acurx inhibitors
    - Design of new compounds based on 3D target binding site data
  - Prodrug approaches for IV & oral delivery (Preliminary prodrug approach validated)
  - ***Current focus: development of oral antibiotic first to speed advance into clinic***

LUMC Collaboration: Developing High-Throughput IC_{50} Assay and 3D Crystal Structures of Acurx compounds bound to Pol IIIC

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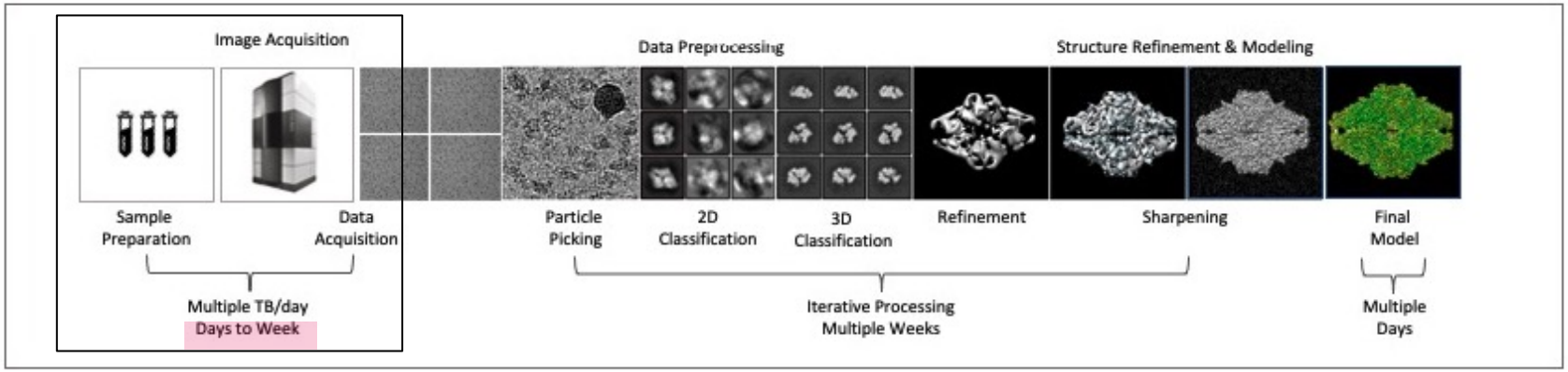
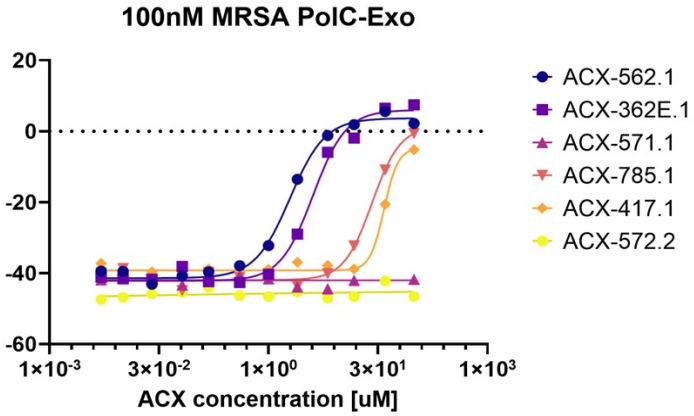
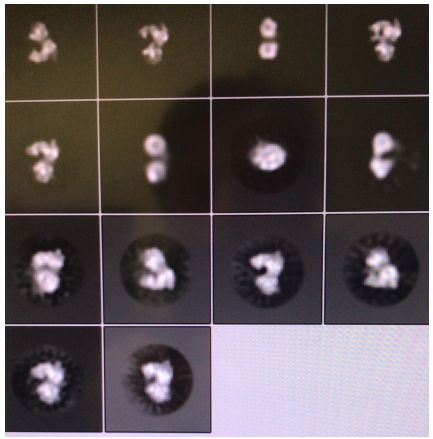
The Cryo-EM Workflow



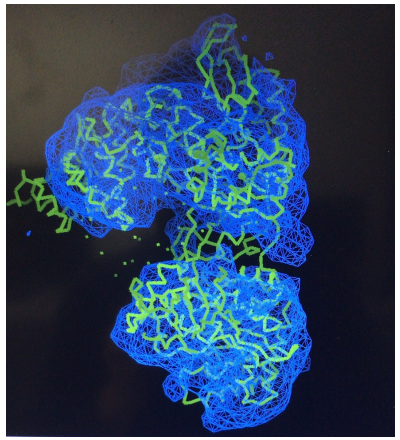
IC_{50} Inhibition Assay



Multiple 2D Images: VRE Pol IIIC



Early 3D Image Map: VRE Pol IIIC



Experienced Senior Executive Management

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- **David P. Luci, CPA, Esq., CEO,** Former CEO Dipexium Pharmaceuticals (Nasdaq:DPRX); Abeona Therapeutics, MacroChem, Bioenvision. Raised capital in several public offerings and private placements; sold 3 public companies from “C” suite

- **Robert J. DeLuccia, Executive Chairman,** Former Chairman Dipexium Pharmaceuticals (Nasdaq: DPRX); Former President Sanofi U.S.and Pfizer, Sr. Executive; Former CEO Immunomedics (Nasdaq: IMMU) and MacroChem Corporation (OTC BB: MACM); Lead Director BOD, IBEX Pharmaceuticals (IBT-TSX)

Management Team

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Michael Silverman, MD, FACP: Acurx Medical Director (Independent consultant)

>30 years' experience clinical research/product development; KPMG Health Care Consulting; Biopure Corp, Sandoz, Sterling-Winthrop (Kodak-Sanofi) and clinical practice of medicine

Xiang Yu, PhD, Pre-Clinical Development Director (Independent Consultant)

>27 years' industry experience advancing new compounds from discovery to clinical development; Accellient Partners, Ironwood Pharmaceuticals, Epix Pharmaceuticals, **Cubist**

Larry Mortin, PhD, Acurx Director, Pharmacology (Independent Consultant)

>25 years' experience advancing new compounds into clinical testing; designing/optimizing efficacy screens/animal models, PK/PD drivers, mechanism of action, and dose optimization;13 years leading **Cubist** In Vivo Pharmacology Group

Les Johnson, Acurx Manufacturing Director (Independent consultant,)

>30 years' experience in manufacture of products for advanced therapeutics (cell therapies), biologics, pharmaceuticals and devices; Clear Path Development, Salamandra, Celsis, Cambrex, Biosynexus, Baxter Bioscience, Protein Polymer Technologies, Bayer Biologics, Cetus/Codon/Berlex

Jeff Alder, PhD, Clinical Research and Development (Independent Consultant)

>30 years' experience infectious disease research and clinical development; Abbott, Bayer, **Cubist** Pharmaceuticals, Scriptgen

Judith Steenbergen, PhD, Director of Microbiology (Independent Consultant)

>20 years' experience medical affairs and clinical development; **Cubist**, Paratek

Michael Barbachyn, PhD, Medicinal Chemistry (Independent Consultant)

>27 years' experience antibacterial drug discovery; Upjohn, Pharmacia/Upjohn, Pharmacia, **Pfizer**, and AstraZeneca

Scientific / Corporate Advisors

Acurx

SCIENTIFIC

- **Jack H. Dean, Ph.D.,** Former Director, Worldwide Pre-Clinical Research at Sanofi; Research Professor, Univ of Arizona (Pharmacology & Toxicology)
- **Richard Ellison, MD**, Professor of Medicine, UMass Medical School (Microbiology
- **Kevin Garey, PharmD*,** Professor, University of Houston College of Pharmacy (Microbiology & Microbiome)
- **Mark Goldberger, MD, MPH**, Former Director Office of Antimicrobial Products, U.S. Food and Drug Administration
- **Ellie Goldstein, MD,** Clinical Professor of Medicine, UCLA (Infectious Disease)
- **Stuart Johnson, MD*,** Professor of Medicine, Loyola University (Infectious Disease)
- **Ciaran Kelly, MD*,** Professor of Medicine, Harvard Medical School (Gastroenterology)
- **Brad Spellberg, MD**, Professor Clinical Medicine USC (Infectious Disease)
- **George Wright, Ph.D.,** Professor Pharmacology, UMass Medical School (Discoverer of pol IIIC inhibitors)

CORPORATE

- **Fred Hassan,** Director, Warburg Pincus; Previously Chairman & CEO of Schering-Plough and of Pharmacia, prior EVP of American Home Products (Wyeth) and CEO of Sandoz US Pharmaceuticals; Board of Directors of Precigen (formerly Intrexon) and Time Warner, Bausch & Lomb and Amgen

**Co-authors of Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). April 2018*

No new classes of antibiotics discovered or approved in decades

*Have foresight **NOW** not to repeat history with inadequate pipeline of novel antibiotics to treat infections caused by MRSA and other* Gram^{+} *organisms*

Please visit our website: www.acurxpharma.com
ACXP: Nasdaq

Contact: Bob DeLuccia 914-949-3898 - Dave Luci 917-533-1469