



Allegra Therapeutics and Acino Sign Exclusive Licensing and Supply Agreement for Allegra's Novel Antibiotic EXBLIFEP® in Gulf Cooperation Council countries and South Africa

- Acino gains commercial rights for EXBLIFEP® (cefepime/enmetazobactam) within the member states of the Gulf Cooperation Council (GCC) and South Africa.
- EXBLIFEP® has been approved by the U.S. Food and Drug Administration (FDA) and the European Commission (EC) for the treatment of severe infections earlier in 2024.

Saint-Louis, France and Weil am Rhein, Germany and Zurich, Switzerland, 24 June

2024: Allegra Therapeutics ("Allegra") and Acino today announced the signing of an exclusive licensing agreement under which Acino gains the rights to commercialise Allegra's antibiotic drug EXBLIFEP® (cefepime/enmetazobactam) within the Republic of South Africa and the member states of the GCC alliance, which includes Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates, effective from 12 June 2024. In addition, the companies have signed a supply agreement under which Allegra will supply the cefepime/enmetazobactam finished product in the above territories.

"Acino has established itself as a leader in South Africa and the GCC region. They are an ideal partner to support us as we build towards commercialisation of EXBLIFEP® following our regulatory approvals in the US and EU," stated Andreas Kranzusch, Chief Financial Officer and Managing Director at Allegra Therapeutics. "This agreement reflects the understanding that there remains a significant global need to address the dangerous increase of resistance to standard-of-care antibiotics, and we look forward to working with Acino to address this."

"At Acino, we are dedicated to providing novel healthcare solutions to physicians and patients, aiming to alleviate the health burden in emerging markets. We are incredibly excited to partner with Allegra to offer access to this innovative product in two key geographic regions and, potentially, beyond," said Andrew Bird, CEO (ai) at Acino. "We are committed to expediting the registration process in these designated markets to ensure hospitals' swift access to EXBLIFEP® as they continue to fight against high-risk infectious diseases in patients."

About EXBLIFEP® (cefepime/enmetazobactam)

EXBLIFEP® is an intravenous antibiotic fixed-dose combination of enmetazobactam, a novel extended-spectrum β -lactamase inhibitor belonging to the penicillanic acid sulfone class, with the fourth-generation cephalosporin cefepime. Enmetazobactam has been shown to restore the efficacy of cefepime against some multi-drug resistant bacteria, including ESBL-producing pathogens alone or in combination with some resistant β -lactamase mutations as OXA-48 or AmpC, which are increasing in Europe and for which there are few therapeutic alternatives.

EXBLIFEP® demonstrated statistically significant superior overall treatment success in Allegra's pivotal Phase III ALLIUM trial, which compared 1034 randomized patients receiving

either cefepime 2 g/enmetazobactam 0.5 g or piperacillin 4 g/tazobactam 0.5 g every 8 h as 2 h continuous intravenous infusion in a multi-centre, randomized, controlled, double-blind, global study in 112 sites within nineteen countries.

In February 2024, the U.S. Food and Drug Administration (FDA) approved EXBLIFEP® as a treatment for complicated urinary tract infections (cUTI), including pyelonephritis, in patients 18 years and older. In March 2024 the European Commission (EC) granted marketing authorisation for EXBLIFEP® for the treatment of adult patients with cUTI, including pyelonephritis; hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP); and bacteraemia that occurs in association with, or is suspected to be associated with any of the infections listed previously.

About Allecra Therapeutics

Allecra Therapeutics, founded in 2013, is a private, clinical-stage biopharmaceutical company developing novel therapies to combat antibiotic resistance by overcoming emergent resistance mechanisms. Lead product candidate EXBLIFEP® (cefepime/enmetazobactam), has successfully completed a randomized, controlled, double-blind, global Phase 3 trial compared to standard of care in patients with complicated urinary tract infections (cUTIs). Based on these results, the company has received FDA marketing approval in the U.S. and announced approval in the European Union for EXBLIFEP® earlier this year.

Allecra has significant patent protection covering proprietary enmetazobactam in major territories. Allecra's investors include Forbion, Andera Partners, Delos Capital, Xeraya Capital, EMBL Ventures, and BioMedPartners. Allecra's wholly owned French subsidiary is a beneficiary of financial support from Bpifrance and the Région Alsace. Please visit www.allecra.com for further information.

About Acino

Acino is a Swiss pharmaceutical company headquartered in Zurich with a clear focus on selected markets in the Middle East, Africa, Ukraine, the CIS Region, and Latin America. We deliver quality pharmaceuticals to promote affordable healthcare in these emerging markets and leverage our high-quality pharmaceutical manufacturing capabilities and network to supply leading companies through contract manufacturing and out-licensing. For more information, please visit www.acino.swiss.

Acino is part of Arcera, a global company in the life sciences sector headquartered in Abu Dhabi, United Arab Emirates. Arcera was established by ADQ, an Abu Dhabi-based investment and holding company, to build a global life sciences powerhouse poised to make significant contributions to realising the UAE's aspiration to emerge as a frontrunner in science and technology. To learn more about Arcera, please visit www.arceralifesciences.com.

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References:

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