PRESS RELEASE
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Centauri Therapeutics granted FDA QIDP status for CTX-187 treatment of Gram-negative bacterial infections

- *Lead clinical candidate CTX-187 is a novel antimicrobial immunotherapy developed to treat clinically-prevalent and multi-drug resistant Gram-negative bacterial infections*
- *Qualified Infectious Disease Product designation awarded for the development of antibacterials and antifungals intended to treat serious of life-threatening conditions in humans*

Alderley Park, Cheshire, UK, 10 March 2026: Centauri Therapeutics Limited ('Centauri' or 'the Company'), an immunotherapy company with a unique and proprietary platform technology applicable across a wide range of therapeutic indications, today announced that the Company's lead clinical candidate in the ABX-01 programme, CTX-187, has received Qualified Infectious Disease Product (QIDP) designation from the US Food and Drug Administration (FDA). Currently in pre-clinical development ahead of first in-human trials, CTX-187 provides a novel immunotherapeutic approach to treat Gram-negative bacterial infections and expand therapeutic options for clinically vulnerable patients.

QIDP status is awarded under the US GAIN (Generating Antibiotic Incentives Now) provisions for the development of antibacterials and antifungals intended to treat serious or life-threatening conditions in humans. Drug products receiving QIDP status gain access to several benefits to accelerate the development process, including eligibility for fast-track designation and priority review, and a five-year extension to market exclusivity.

CTX-187 is a novel antimicrobial built on Centauri's proprietary Alphamer® platform, featuring a dual mechanism-of-action that combines immunotherapeutic effects through complement activation and opsonophagocytosis with antibacterial activity. The molecule is currently in development, progressing to first in-human clinical trials later this year as a new treatment for clinically prevalent and multidrug-resistant Gram-negative bacteria.

Dr. Debra Barker, Chief Medical Officer, Centauri Therapeutics, said: "*This designation from the FDA will be invaluable as we continue to advance toward first in-human trials for CTX-187. The recognition of the potential value of our technology further underpins our belief in its potential to transform treatment paradigms for Gram-negative bacterial infections, filling an urgently needed gap in the market for new and effective treatment options for clinically vulnerable patients.*"

The Alphamer® platform is a modularly designed immunotherapeutic that redirects the body's natural antibody repertoire against disease. The unique design is backed by strong proof-of-concept data, demonstrating >99.9% immune-mediated bacterial clearance at sub-therapeutic doses across Gram-negative and multi-drug resistant bacterial strains *in vivo*[1]. This novel immunotherapeutic approach enables Alphamers to be used as a viable treatment option for clinically vulnerable patient groups where current therapies are limited or ineffective, including patients that are immunosuppressed.

Daniel Hynes, VP of Development, Centauri Therapeutics, commented: "*The FDA's QIDP designation is a crucial programme designed to address the healthcare burden of serious and life-threatening infections by accelerating the development of promising therapeutics. We welcome this regulatory endorsement of CTX-187, which will enable us to streamline our route to regulatory approvals, and bring a much-needed treatment option to address serious infections in vulnerable patient groups.*"

The Company has also been supported by CARB-X[2] (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) to undertake research and development studies since 2019, advancing the ABX-01 programme from Lead Optimization to the Preclinical phase.

1) Hairsine, B. et al. (2025) 'Harnessing endogenous anti-glycan antibodies using a novel, bifunctional immunotherapy to treat gram-negative bacterial infections', *The Journal of Immunology*, 00, pp. 1–13. doi:10.1093/jimmun/vkaf055.

2) CARB-X's funding for this project is provided in part with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority; under agreement number: 75A50122C00028, and by awards from Wellcome (WT224842), Germany's Federal Ministry of Research, Technology and Space (BMFTR), and the Novo Nordisk Foundation. The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of CARB-X or any of its funders.

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Notes to Editors

Dr. Debra Barker, Chief Medical Officer, Centauri Therapeutics

Daniel Hynes, VP of Development, Centauri Therapeutics

For high resolution images please contact Zyme Communications.

Media contact
Katie Odgaard
Email: katie.odgaard@zymecommunications.com
Tel: +44 (0) 7787 502 947

Centauri Therapeutics
Jessica Boyle
Email: info@centauritherapeutics.com

About Centauri Therapeutics www.centauritherapeutics.com

Centauri Therapeutics is an immunotherapy company, with a unique and proprietary platform technology applicable across a wide range of therapeutic indications. The Company's initial focus is on infectious diseases, driven by an urgent unmet need for anti-infectives to treat the most vulnerable and at-risk patients. Centauri also has strong initial proof-of-concept data in oncology.

Centauri's Alphamer® platform has a unique mechanism of action, utilising an antibody recruiting molecule to harness the body's natural immune response, and redirect antibodies to target diseases.

Based at Alderley Park, Cheshire UK, Centauri's investors include Animatrix Founders LLP Boehringer Ingelheim Venture Fund, Evotec SE, Novo Holdings REPAIR Impact Fund, Wren Capital LLP and the AMR Action Fund. The Company's anti-infective platform also receives financial and scientific support from CARB-X.

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