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17 June 2026, London UK

***Utebzi* (tebipenem pivoxil) approved in the US for adults with complicated urinary tract infections (cUTIs)**

- First and only oral carbapenem antibiotic approved in the US
- Approval based on PIVOT-PO trial demonstrating non-inferiority compared to intravenous treatment¹
- More than 3 million cases of cUTIs are treated annually in the US² with up to a third of patients impacted by resistant infections³

GSK plc (LSE/NYSE: GSK) and Spero Therapeutics (Nasdaq: SPRO) today announced that the US Food and Drug Administration (FDA) has approved *Utebzi*, an oral antibiotic for the treatment of complicated urinary tract infections (cUTIs) including pyelonephritisⁱ, caused by certain susceptible pathogensⁱⁱ in adult patients who have limited or no alternative oral treatment options. This is the first and only oral carbapenem antibiotic approved for these patients. This approval is a result of GSK's development and exclusive global licensing agreement (excluding select Asian territories) with Spero Therapeutics.⁴

There are more than 3 million cases of cUTI in the US annually and treatment failure impacts up to 34% of patients.^{2,3} Often caused by multidrug-resistant pathogens,⁵ these infections account for over \$6 billion per year in healthcare costs.⁶ Carbapenems are the standard treatment for severe or resistant infections, but until now have only been available through intravenous administration⁷, increasing hospital resource use and reducing patients' quality of life.⁸ Tebipenem pivoxil offers the potential for an effective oral alternative taken outside of a hospital setting.

Tony Wood, Chief Scientific Officer, GSK, said: "With antibiotic resistance continuing to rise, patients and healthcare professionals need new treatment options. The approval of *Utebzi* provides the first and only oral carbapenem antibiotic for appropriate adults with complicated UTIs, a solution that could help reduce reliance on hospital-based intravenous care and support efforts to address resistant infections."

Dr. Bilal Chughtai, Chief of Urology at Plainview Hospital, Northwell Health and Associate Professor of Urology at the Zucker School of Medicine at Hofstra/Northwell, said: "For patients with complicated urinary tract infections (cUTIs) and their caregivers, this approval is a major milestone as today's standard of care places a serious burden on them and hospitals. A new effective oral treatment offering an alternative option to intravenous care has the potential to enable more treatment in the outpatient settings with the ambition to improve their experience."

Esther Rajavelu, President and Chief Executive Officer, Spero Therapeutics added: "The FDA approval of tebipenem pivoxil marks the culmination of more than a decade of dedication from our team, partners, and, most importantly, the patients who placed their trust in this program. We are proud to reach this important milestone. Through our partnership with GSK, we look forward to this much-needed oral treatment option reaching cUTI patients to help reduce the burden of the disease."

This approval is supported by positive results from the PIVOT-PO phase III trial, which demonstrated non-inferiority of tebipenem pivoxil compared to intravenous imipenem-cilastatin in hospitalised patients with cUTI, including pyelonephritis, based on the overall response (composite of clinical cure plus microbiological eradication) at the test of cure visit. Tebipenem pivoxil (oral, 600 mg) achieved a 58.5% overall success rate (261/446 participants)

ⁱ Pyelonephritis is a specific type of UTI that has travelled up the urinary tract to infect one or both kidneys.

ⁱⁱ *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae* species complex, *Klebsiella oxytoca*, and *Enterococcus faecalis*.

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compared to 60.2% overall success rate (291/483 participants) for imipenem-cilastatin (intravenous, 500 mg) (adjusted treatment difference: -1.3%; 95% CI: -7.5%, 4.8%).

The safety profile of tebipenem pivoxil was generally similar to that of imipenem-cilastatin and other carbapenem antibiotics. The most frequently reported adverse events (in $\geq 3\%$ of patients) were diarrhoea and headache; these events were all mild or moderate and non-serious.¹

Tebipenem pivoxil is anticipated to be made available to US patients by the end of 2026. With this approval, GSK builds on recent advances in its growing anti-infectives portfolio.

This approval confirms the successful and productive collaboration between GSK and Spero Therapeutics. The development of tebipenem pivoxil has been supported in part with federal funds from the US Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract numbers HHSO100201800015C and HHSO100201300011C.

About tebipenem pivoxil

Tebipenem pivoxil was developed in collaboration with Spero Therapeutics⁴ for the treatment of cUTIs, including pyelonephritis. In September 2022, GSK entered into an exclusive license agreement with Spero Therapeutics for the development and commercialisation in all markets, except certain Asian territories. Under this agreement, GSK sub-licensed back to Spero Therapeutics the rights and responsibility to conduct certain development work, including the PIVOT-PO phase III study. The sponsorship of the New Drug Application has been transferred to GSK. As part of the license agreement, tebipenem pivoxil has received Qualified Infectious Disease Product and Fast Track designations from the US FDA.

The US Prescribing Information will be available [here](#)

[https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Utebzi/pdf/UTEBZI-PI-PIL.PDF]

About the PIVOT-PO trial

The PIVOT-PO trial was a global, randomised, double-blind, pivotal, non-inferiority (NI margin: -10%) phase III trial evaluating the potential of oral tebipenem pivoxil compared to IV imipenem-cilastatin, in hospitalised adult patients with complicated urinary tract infections, including acute pyelonephritis. Patients were randomised 1:1 to receive tebipenem pivoxil (600 mg) orally every six hours, or imipenem-cilastatin (500 mg) IV every six hours, for a total of seven to ten days. Dose adjustments were made for patients with reduced renal function. Matching placebos were used to maintain blinding. The primary efficacy endpoint was composite response (combined per-patient clinical cure and microbiological response) at the test-of-cure visit (about 17 days from first dose administration of study drug) in patients with qualifying pathogens susceptible to imipenem. The trial enrolled a total of 1,690 patients, with randomisation stratified by age, baseline diagnosis (cUTI or acute pyelonephritis), and the presence or absence of urinary tract instrumentation. For further details on the trial, refer to clinicaltrials.gov identifier NCT06059846.⁹

About complicated urinary tract infections (cUTIs)

cUTIs are broadly described as any UTI that carries an increased risk of morbidity and mortality.⁵ Definitions of cUTIs are not currently uniform among international societies and regulatory agencies. cUTIs encompass a heterogeneous patient population due to the wide range of host factors, comorbidities and urological abnormalities associated with cUTIs. Risk factors for cUTIs include indwelling catheters, ureteric stents, neurogenic bladder, obstructive uropathy, urinary retention, urinary diversion, kidney stones, diabetes mellitus, immune deficiency, urinary tract modification and UTIs in renal transplant patients.^{10,11,12,13}

GSK in infectious diseases

GSK has pioneered innovation in infectious diseases for over 70 years, and the Company's pipeline of medicines and vaccines is one of the largest and most diverse in the industry, with a goal of developing preventive and therapeutic treatments for multiple disease areas or diseases with high unmet need globally. Our expertise and capabilities in infectious disease strongly position us to help prevent and treat disease and potentially mitigate the challenge of antimicrobial resistance. The approval of tebipenem pivoxil continues the momentum for our anti-infectives portfolio.

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About Spero Therapeutics

Spero Therapeutics, headquartered in Cambridge, Massachusetts, is a clinical-stage biopharmaceutical company focused on identifying and developing novel treatments for rare diseases and diseases with high unmet need. For more information, visit www.sperotherapeutics.com.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together. Find out more at gsk.com.

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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2025, and GSK's Q1 Results for 2026.

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⁴ GSK press release, GSK and Spero Therapeutics announce exclusive licence agreement for tebipenem HBr, a late-stage antibiotic that may treat complicated urinary tract infections, 22 September 2022.

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