Stock-exchange announcement

For media and investors only

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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 treatment[1]
- More than 3 million cases of cUTIs are treated annually in the US[2] with up to a third of patients impacted by resistant infections[3]

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 pyelonephritis[i], caused by certain susceptible pathogens[ii] 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 administration[7], 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 hospitalized 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) 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%).

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[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*.

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 ≥3% of patients) were diarrhea 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 Therapeutics[4] for the treatment of cUTIs, including pyelonephritis. In September 2022, GSK entered into an exclusive license agreement with Spero Therapeutics for the development and commercialization 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.

Please see accompanying US Prescribing Information, including Patient Information, here.

UTEBZI (tebipenem pivoxil) tablets, for oral use

Professional Indication and Important Safety Information (ISI)

Indication for UTEBZI

UTEBZI is indicated for the treatment of adults with complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae* species complex, *Klebsiella oxytoca*, and *Enterococcus faecalis,* who have limited or no alternative oral treatment options.

Usage to Reduce Development of Drug-Resistant Bacteria

To reduce the development of drug-resistant bacteria and maintain effectiveness of UTEBZI and other antibacterial drugs, UTEBZI should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Important Safety Information for UTEBZI

CONTRAINDICATIONS

UTEBZI is contraindicated in patients with hypersensitivity to UTEBZI or other beta-lactam drugs.

UTEBZI is contraindicated in patients with primary or secondary carnitine deficiency or inborn errors of metabolism that may result in clinically significant carnitine deficiency.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam and carbapenem drugs. Before initiating UTEBZI, assess patients for previous hypersensitivity to carbapenems, penicillins, cephalosporins or other beta-lactams. If an allergic reaction to UTEBZI occurs, discontinue, and institute appropriate supportive measures.

Seizures and Other Central Nervous Systems (CNS) Adverse Reactions

- Seizures and other CNS adverse reactions have been reported in patients receiving therapy with beta-lactam and carbapenem drugs, including UTEBZI. These reactions occurred most commonly in patients with CNS disorders and/or compromised renal function. Monitor patients at risk for convulsive activity. If CNS adverse reactions including seizures occur, evaluate neurologically to determine whether UTEBZI should be discontinued.

Interactions with Valproic Acid

- Concomitant use of carbapenems, including UTEBZI, with valproic acid or divalproex sodium may reduce the plasma concentration of valproic acid, potentially increasing the risk of breakthrough seizures. Avoid concomitant use of UTEBZI with valproic acid or divalproex sodium.

Carnitine Depletion

- Clinical manifestations of carnitine deficiency may occur with pivalate-containing compounds, including UTEBZI. UTEBZI is contraindicated in patients with primary and secondary carnitine deficiency or inborn errors of metabolism that may result in clinically significant carnitine deficiency. Do not use UTEBZI beyond the recommended treatment duration. Consider alternative antibacterial therapy in patients at risk of carnitine depletion (eg, patients with significant renal impairment or decreased muscle mass). Concomitant use with valproic acid, valproate, or other pivalate-generating drugs is generally not recommended due to the increased risk of carnitine depletion.

***Clostridioides difficile* (CDI) Infection**

- *Clostridioides difficile* infection has been reported with nearly all systemic antibacterial agents, including UTEBZI. Evaluate patients who develop diarrhea.

Interference with Newborn Screening Test

- Treatment of a pregnant individual with UTEBZI prior to delivery may cause a false positive test for isovaleric acidemia in newborn screening. Prompt follow-up of a positive result is recommended.

Development of Drug-Resistant Bacteria

- Prescribing UTEBZI in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

- The most common adverse reactions occurring in ≥1% of patients are diarrhea, headache, nausea, abdominal pain, hepatic enzyme increased, and *Clostridioides difficile* infection.

DRUG INTERACTIONS

- Organic anion transporter 1 (OAT1) and OAT3 inhibitors: Concomitant use is generally not recommended due to increased tebipenem plasma concentrations. If concomitant use is necessary, monitor more frequently for adverse reactions associated with UTEBZI.
- Valproic acid and divalproex sodium: Avoid concomitant use as it may reduce valproic acid plasma concentrations, increasing the risk of breakthrough seizures. If concomitant use is necessary, monitoring of valproic acid serum concentrations is recommended and consider supplemental anticonvulsant therapy.
- Other pivalate-generating drugs: Concomitant use is generally not recommended due to decreased carnitine plasma concentrations which may increase the risk of carnitine depletion-associated adverse reactions. If concomitant use is necessary, counsel patients to monitor adverse reactions associated with carnitine depletion.

- Treatment of a pregnant individual with UTEBZI prior to delivery may cause a false positive test for isovaleric acidemia in the newborn as part of newborn screening. Prompt follow-up of a positive result is recommended.

USE IN SPECIFIC POPULATIONS

- Pregnancy: There are insufficient data on the use of UTEBZI in pregnant women. There is a pregnancy safety study for UTEBZI. Healthcare providers or patients may report UTEBZI exposure while pregnant by contacting GSK at 1-825-825-5249. Treatment of a pregnant individual with UTEBZI prior to delivery may cause a false positive test for isovaleric acidemia in the newborn as part of newborn screening.

- Renal Impairment: Tebipenem plasma concentrations increase with decreasing renal function. Dosage adjustments for UTEBZI are recommended for patients with renal impairment (eGFR 15 mL/min to < 60 mL/min). Use in adults with eGFR >150 mL/min is not recommended because it is predicted to decrease tebipenem exposure, which may reduce UTEBZI efficacy. If use is necessary, monitor clinical response closely and counsel patients to promptly report lack of improvement or worsening of their condition.

About the PIVOT-PO trial
The PIVOT-PO trial was a global, randomized, double-blind, pivotal, non-inferiority (NI margin: -10%) phase III trial evaluating the potential of oral tebipenem pivoxil compared to IV imipenem-cilastatin, in hospitalized adult patients with complicated urinary tract infections, including acute pyelonephritis. Patients were randomized 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 randomization 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.

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 us.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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