GSK and Spero Therapeutics announce exclusive licence agreement for tebipenem HBr, a late-stage antibiotic that may treat complicated urinary tract infections

PUBLISHED SEP 22, 2022
BY GSK

For media and investors only

The exclusive licence allows GSK to commercialise tebipenem HBr in all regions except for Japan and certain other Asian countries

Spero Therapeutics receives $66 million upfront, with potential for future milestone payments and tiered royalties

GSK to purchase $9 million in shares of Spero common stock

GSK plc (LSE/NYSE: GSK) and Spero Therapeutics, Inc. (Nasdaq: SPRO) today announced they have entered into an exclusive licence agreement for tebipenem pivoxil hydrobromide (tebipenem HBr), a late-stage antibiotic being developed by Spero, as the first oral carbapenem antibiotic to potentially treat complicated urinary tract infections (cUTI), including pyelonephritis, caused by certain bacteria.

Luke Miels, Chief Commercial Officer, GSK, said:

> There is a high unmet medical need for a novel oral antibiotic as an alternative to intravenous hospital therapy for drug-resistant complicated urinary tract infections. Tebipenem HBr complements GSK's infectious disease strategy and is consistent with our commitment to find value-enhancing opportunities to build a strong late-stage portfolio. Tebipenem HBr has a clear US FDA regulatory path to potential approval, which could significantly benefit patients with complicated

urinary tract infections.

> Spero's agreement with GSK provides a critical step towards fully realising the value tebipenem HBr can potentially provide to physicians, payors, and patients," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero. "We are thrilled to collaborate with GSK on developing tebipenem HBr for patients suffering from complicated urinary tract infections. With their antibiotic expertise and global commercial reach, GSK is ideally positioned to launch tebipenem HBr following regulatory approval as the first oral treatment for complicated urinary tract infections, providing patients with an alternative to in-hospital intravenous therapy. Tebipenem HBr's potential as an at-home, oral option can potentially be of significant benefit by reducing hospital resource utilisation. In addition, our partnership with GSK strengthens our balance sheet and shareholder base.

Spero will start a new phase III clinical trial in 2023, following encouraging US FDA regulatory feedback on the proposed clinical trial design.

GSK will receive an exclusive licence to develop and commercialise tebipenem pivoxil HBr in all countries except Japan and certain other Asian countries that Spero partner Meiji Seika will retain. Under the licence agreement, Spero will be responsible for the execution and costs of the remaining phase III clinical trial of tebipenem HBr. GSK will be responsible for the execution and costs of additional clinical development, including regulatory submission and commercialisation activities for tebipenem HBr in the countries mentioned above.

Under the terms of the licence agreement, GSK will make an upfront initial payment to Spero of $66 million to secure rights to the medicine. Remaining potential payments are milestone-based, as follows.

| Event | Milestone payments (up to) |

| Delivery of phase III programme | $150m |

| Total commercial milestone payments based on first sale (US/EU) | $150m |

| Sales milestone events | |

| Net sales greater than $200m | $25m |

| Net sales greater than $300m | $25m |

| Net sales greater than $400m | $25m |

| Net sales greater than $500m | $50m |

| Net sales greater than $750m | $50m |

| Net sales greater than $1,000m | $50m |

| Total sales milestone payments: | $225m |

| Royalties | Low-single digit to low-double digit (if sales exceed $1bn) tiered royalties on net product sales. |

In connection with the licence agreement and under a stock purchase agreement between GSK and Spero, GSK has agreed to make a $9 million investment in Spero common stock, purchasing 7,450,000 shares at a purchase price of approximately $1.20805 per share, not to exceed 19.99% beneficial ownership of Spero by GSK and its affiliates.

The transactions are expected to close in the fourth quarter of 2022, subject to customary closing conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. The closing of the equity investment is conditioned upon the effectiveness of the licence following Hart-Scott-Rodino clearance.

Tebipenem HBr (tebipenem pivoxil hydrobromide; formerly SPR994) is Spero's novel late-stage development asset, an oral formulation of tebipenem pivoxil, a carbapenem antibiotic of the β-lactam class marketed by Meiji Seika Pharma Co. Ltd. (Meiji) in Japan as Orapenem® since 2009 for paediatric infections limited to pneumonia, otitis media and sinusitis. Carbapenems are an important subclass of antibiotics because they have been observed to be safe and effective in treating drug-resistant Gram-negative bacterial infections. Tebipenem HBr is being developed to treat cUTIs, including acute pyelonephritis caused by certain bacteria. If approved, tebipenem HBr would be the first oral carbapenem antimicrobial to receive marketing approval in the United States. Tebipenem HBr has been granted

Qualified Infectious Disease Product (QIDP) and Fast Track designations by the US FDA for cUTI and acute pyelonephritis treatment. Following feedback from the US FDA at Spero's recent Type A meeting, Spero will conduct an additional phase III trial to support the regulatory submission.

Tebipenem HBr research support

Select tebipenem HBr trials have been funded in part with federal funds from the Department of Health and Human Services; Office of the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number HHSO100201800015C.

Spero Therapeutics, headquartered in Cambridge, Massachusetts, is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing, and commercializing novel treatments for bacterial infections, including multi-drug resistant bacterial infections and rare diseases.

- Spero Therapeutics is developing SPR720 as a novel oral therapy candidate for the treatment of a rare, orphan pulmonary disease caused by non-tuberculous mycobacterial infections.

- Spero Therapeutics also has an IV-administered next-generation polymyxin product candidate, SPR206, developed from its potentiator platform, which is in development to treat multi-drug resistant Gram-negative infections in the hospital setting.

- Tebipenem HBr is an investigational drug in the United States being developed for the treatment of cUTI, including pyelonephritis, caused by certain bacteria, in adult patients with limited treatment options; tebipenem HBr is not FDA-approved.

For more information, visit https://www.sperotherapeutics.com.

GSK has been developing and supplying antibiotics for more than 70 years. Research and development continue to investigate new tools to prevent and mitigate infectious disease – and get ahead of antimicrobial resistance. GSK is already a leader on the Antimicrobial Resistance Benchmark of the Access to Medicine Foundation and participates in the AMR Action Fund, which aims to bring 2-4 new antibiotics to patients by 2030 through sustainable investment in the

antibiotic pipeline.

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/company.

GSK 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 Company's Annual Report on Form 20-F for 2021, GSK's Q2 Results for 2022 and any impacts of the COVID-19 pandemic.

Spero forward-looking statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about the timing of the closing of the license and equity investment transactions, the regulatory path forward for tebipenem HBr and potential FDA approval, the potential commercialization of tebipenem HBr and its future value, and the potential receipt of milestone payments, and royalties on future sales under the license agreement. In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intent," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including Spero's and GSK's ability to obtain antitrust clearance and close the proposed transactions in a timely manner; whether tebipenem HBr will advance through the clinical trial process on a timely basis, or at all, taking into account the effects of possible regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, clinical trial design and clinical outcomes; whether the results of such trials will warrant submission for approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether the FDA will ultimately approve tebipenem HBr and, if so, the timing of any such approval; whether the FDA will require any additional clinical data or place labeling restrictions on the use of tebipenem HBr that would delay approval

and/or reduce the commercial prospects of tebipenem HBr; whether a successful commercial launch can be achieved and market acceptance of tebipenem HBr can be established; and other factors discussed in the “Risk Factors” set forth in filings that Spero periodically makes with the U.S. Securities and Exchange Commission. The forward-looking statements included in this press release represent Spero’s views as of the date of this press release. Spero anticipates that subsequent events and developments will cause its views to change. However, while Spero may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Spero’s views as of any date subsequent to the date of this press release.

Press release distributed by Wire Association on behalf of GSK, on Sep 22, 2022. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-and-spero-therapeutics-announce-exclusive-licence-agreement-for-tebipenem-hbr-a-late-stage-antibiotic-that-may-treat-complicated-urinary-tract-infections-1818

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
Website: https://www.gsk.com/
Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/