GSK and Spero Therapeutics Announce Exclusive License Agreement for Late-Stage Antibiotic Asset, Tebipenem HBr

The exclusive license allows GSK to commercialize tebipenem HBr in all territories, except 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

LONDON and CAMBRIDGE, Mass., Sept. 22, 2022 (GLOBE NEWSWIRE) -- GSK (LSE/NYSE: GSK) and Spero Therapeutics, Inc. (Nasdaq: SPRO) today announced they have entered into an exclusive license agreement for Spero's late-stage antibiotic asset, tebipenem HBr. Tebipenem HBr is being developed as the first oral carbapenem antibiotic for the treatment of 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 realizing 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 cUTI. 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 cUTI, providing patients with an alternative to in-hospital intravenous (IV) therapy. Tebipenem HBr's potential as an at-home, oral option can potentially be of significant benefit by reducing hospital resource utilization. In addition, our partnership with GSK strengthens our balance sheet and shareholder base."

Spero expects to start a new phase 3 clinical trial in 2023, following encouraging US FDA regulatory feedback on the proposed clinical trial design.

Financial Terms

GSK will receive an exclusive license to develop and commercialize tebipenem pivoxil and tebipenem pivoxil HBr in all territories, except Japan, and certain other Asian countries, territories which will be retained by Spero partner, Meiji Seika. Under the license agreement, Spero will be responsible for the execution and costs of the follow-up Phase 3 clinical trial of tebipenem HBr. GSK will be responsible for the execution and costs of additional development, including Phase III regulatory filing and commercialization activities for tebipenem HBr outside of the Meiji Seika territory.

Under the terms of the license agreement, Spero will receive an upfront payment of $66 million for GSK to secure rights to the medicine. Remaining potential payments are milestone based, and are 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

<table>
<thead>
<tr>
<th>Event</th>
<th>Amount</th>
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<tbody>
<tr>
<td>Net sales greater than $200m</td>
<td>$25m</td>
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<tr>
<td>Net sales greater than $300m</td>
<td>$25m</td>
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<tr>
<td>Net sales greater than $400m</td>
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<td>Net sales greater than $500m</td>
<td>$50m</td>
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<tr>
<td>Net sales greater than $750m</td>
<td>$50m</td>
</tr>
<tr>
<td>Net sales greater than $1,000m</td>
<td>$50m</td>
</tr>
<tr>
<td>Total sales milestone payments:</td>
<td>$225m</td>
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</tbody>
</table>

### Royalties

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

In connection with the license agreement and pursuant to a stock purchase agreement between GSK and Spero, GSK has agreed to make a $9 million common stock investment in Spero, purchasing 7,450,000 shares of Spero's common stock 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 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 license following Hart-Scott-Rodino clearance.

As of June 30, 2022, Spero had cash, cash equivalents, and marketable securities of $45.4 million. Based on the previously announced restructuring and the cessation of commercialization activities for the tebipenem HBr program, along with the initial cash payment of $66 million from the GSK licensing transaction, Spero believes that its current cash runway will be sufficient to fund the company beyond 2024.

### About Tebipenem HBr

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 pediatric 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 the treatment of drug-resistant Gram-negative bacterial infections. Tebipenem HBr is being developed for the treatment of complicated urinary tract infections, including acute pyelonephritis (AP), 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 Food and Drug Administration (FDA) for the treatment of cUTI and AP. Following feedback from the FDA, at Spero's recent Type A meeting, Spero will conduct an additional Phase 3 trial to support the regulatory file.

### Tebipenem HBr Research Support

Select tebipenem HBr studies 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.

### 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/company

**GSK in Antibiotics**

GSK has been developing and supplying antibiotics for more than 70 years, and research and development continues 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.

**About Spero Therapeutics**

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 who have limited treatment options; tebipenem HBr is not FDA-approved.

For more information, visit [https://sperotherapeutics.com](https://sperotherapeutics.com).

**GSK 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 Therapeutics 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, the potential receipt of milestone payments, and royalties on future sales under the license agreement and Spero’s cash runway. In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "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 FDA 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; whether Spero's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; 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.

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