probiodrug

News

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Osi Pharmaceuticals' Subsidary Prosidion Acquires Dipeptidyl Peptidase IV Platform From Probiodrug / Includes Phase II Development Candidate P93/01

Melville, New York, USA // Oxford, United Kingdom // Halle (Saale), Germany
OSI Pharmaceuticals, Inc. (Nasdaq: OSIP), Prosidion Limited, a subsidiary of OSI focused on the discovery and development of diabetes and obesity therapeutics, and Probiodrug AG announced today that Prosidion has agreed to purchase a platform of Dipeptidyl Peptidase IV (DP-IV) technology from Probiodrug for $35 million in cash plus future milestones. The milestone payments are contingent upon the successful development of P93/01, Probiodrug's DP-IV inhibitor, which is set to enter Phase II clinical trials for the treatment of Type 2 diabetes. Probiodrug, based in Halle (Saale), Germany, has pioneered much of the research and development that has led to the characterization of DP-IV as an important target in diabetes drug development today. Included in the assets to be acquired by Prosidion is the portfolio of medical use patents around the target. These include issued and pending patents with claims covering DP-IV as a target, and use of combinations of DP-IV inhibitors with other oral anti-diabetes drugs such as Metformin. Three non-exclusive license agreements to that patent estate and future potential milestones and royalties arising from this intellectual property will also be transferred to Prosidion upon the closing. Prosidion will also enter a three-year funded research agreement with Probiodrug.

"The acquisition of P93/01 and the associated intellectual property estate will allow us to assume development of an exciting Phase II development candidate in a prominent area of diabetes research and development," stated Anker Lundemose, Chief Executive Officer of Prosidion. "This combination of a clinical candidate and the DP-IV medical use patent estate will add significant value to the growing Prosidion asset base."

The Board of OSI has authorized a further investment of $50 million in Prosidion, in addition to the $10 million invested in April 2004, in order to finance the acquisition and fund the ongoing research and development efforts at Prosidion. OSI will own 96% of Prosidion following the closing of the deal. The Company anticipates the cost to acquire the DP-IV technology will be accounted for as in-process R&D and reflected in the FY2004 financial statements of OSI.

"The acquisition of the DP-IV platform and our follow-on investment positions Prosidion as an important business unit within OSI," stated Colin Goddard, Ph.D., Chief Executive Officer at OSI Pharmaceuticals and Chairman of the Board at Prosidion. "Although the focus on the core business will continue to be on the filing, approval and launch of Tarceva™ and on our growing oncology franchise, a strong second disease area is an important part of a long-term strategy for sustained value creation for our shareholders."

OSI's investment in Prosidion will be effective upon closing of the transaction, which is estimated to occur later in the summer and is subject to customary closing conditions.

Konrad Glund, Ph.D. and Hans-Ulrich Demuth, Ph.D., Probiodrug's founders and majority shareholders, see significant potential in the transaction: "Contributing our promising program in a prominent area of metabolic research and our broad portfolio of intellectual property into a leading transatlantic biotechnology pioneer with a proven track record in delivering tangible value creates an attractive metabolic biotechnology company in Europe with exciting prospects. The structure of the transaction offers Probiodrug the opportunity to replicate its success by focusing on our innovative and internationally recognized research centering on gastrointestinal, neuronal and autoimmune disorders."

Dr. Konrad Glund, co-Chief Executive Officer at Probiodrug will join Prosidion as Vice President of Corporate Development, while Dr. Hans-Ulrich Demuth will continue as Chief Executive Officer at Probiodrug and join the Prosidion Scientific Advisory Board.

About DP-IV and P93/01

Dipeptidyl Peptidase IV cleaves and inactivates Glucagon-like Peptide-1 (GLP-1) an important mediator of blood glucose levels. Inhibition of DP-IV leads to increased GLP-1 activity and inhibitors of DP-IV have demonstrated significant effects on mean blood glucose and post-prandial blood glucose and HbA1C levels (a reference marker widely used in the monitoring of diabetes patients) in pre-clinical and clinical trials. The field is competitive with the Novartis DP-IV inhibitor, LAF237 currently entering Phase III trials and competitors from Merck and Bristol- Myers Squibb in Phase II trials. P93/01 is an orally active, competitive inhibitor of DP-IV that is designed as a shorter-acting inhibitor. P93/01 has been shown to lower glucose in Type 2 diabetics in early clinical trials. Prosidion will fund an ongoing research program at Probiodrug focused on a P93/01 back-up program and some early leads discovered for a related target, the Glucose-dependent Insulinotropic Peptide Receptor (GIP-R).

About OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company focused on the discovery, development, and commercialization of high-quality, next-generation oncology products that both extend life and improve the quality of life for cancer patients worldwide. OSI has a balanced pipeline of oncology drug candidates that includes both novel mechanism-based, gene-targeted therapies focused in the areas of signal transduction and apoptosis and next-generation cytotoxic chemotherapy agents. OSI's most advanced drug candidate, Tarceva™, a small-molecule inhibitor of the HER1 gene, has successfully completed Phase III clinical trials for lung cancer and is subject to an ongoing rolling submission of an NDA. OSI has a commercial presence in the U.S. oncology market where it exclusively markets Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications and Gelclair® for the relief of pain associated with oral mucositis. OSI has also established Prosidion Ltd., an independently operated diabetes and obesity subsidiary based in the United Kingdom. For additional information about the company, please visit *www.osip.com (URL: http://www.osip.com)* .

About Prosidion

Prosidion Limited is a research and development stage biotechnology company which is committed to the discovery and early-development of novel high-quality, next-generation small molecule compounds to treat Type 2 diabetes and obesity. Prosidion has established a strong preclinical pipeline in diabetes and obesity with its most advanced programmes in late-preclinical development. Prosidion is headquartered in Oxford, UK and has a research, development and management team possessing extensive experience within diabetes and obesity research, development, commercialisation and licensing. Prosidion is a majority-owned subsidiary of OSI Pharmaceuticals, Inc. Prosidion has full and continued access to OSI's small-molecule discovery platform and R & D infrastructure.

About Probiodrug AG
Probiodrug is a drug discovery company with a focus on distinct proteins as drug targets. The company endeavors to identify new orally active compounds for selectively modifying enzymatic activity in order to derive therapeutic effects in gastrointestinal, neuronal and autoimmune disorders. Probiodrug actively pursues patent protection for its lead and back-up compounds as well as for fundamental treatment technologies in various indications.

This news release contains forward-looking statements. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Factors that might cause such a difference include, among others, the completion of clinical trials, the FDA review process and other governmental regulation, OSI's and its collaborators' abilities to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, the ability to effectively market products and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission. Tarceva™ and P93/01 are investigational compounds and have not yet been approved as safe or efficacious in humans for their ultimate intended use.

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