SurModics Signs License Agreement with Clinuvel Pharmaceuticals

Saturday 15 June, 2013

SurModics, Inc. (Nasdaq: SRDX), a leading provider of drug delivery and surface modification technologies to the healthcare industry, announced today that it has entered into a license agreement with Clinuvel Pharmaceuticals Limited of Melbourne, Australia. Under the agreement, the Company's SurModics Pharmaceuticals unit has licensed certain of its biodegradable polymer implant technology to Clinuvel for the treatment of sun-induced skin disorders. Terms of the agreement were not disclosed.

"We are very pleased to announce the execution of this important license agreement with Clinuvel" SurModics and Clinuvel have been collaborating on the development of Clinuvel's sustained release SCENESSE® (afamelanotide) implant formulation for several years. The implant is being developed as a prophylactic treatment for a range of UV and light-related skin disorders. Clinuvel's implant is currently being evaluated for a variety of skin disorders in several clinical trials in Europe and Australia. In addition, Clinuvel has recently announced initiation of a Phase II trial in the United States for the treatment of erythropoietic protoporphyria (EPP), an orphan disease which affects around 3,000 Americans. Independent estimates from RBS (Royal Bank of Scotland) place SCENESSE's potential market for all UV-related disorders being investigated by Clinuvel in excess of seven million patients worldwide.

SurModics' biodegradable polymer drug delivery technology enables the drug afamelanotide to be released in a sustained and tightly controlled manner. This elegant release stimulates the production of melanin in the patient's skin, to protect the patient from UV and light exposure.

"We are very pleased to announce the execution of this important license agreement with Clinuvel," said Phil Ankeny, interim CEO of SurModics. "This announcement demonstrates the value of our sustained drug delivery technologies and reinforces how we partner with our customers to develop and bring to market compelling products that leverage our core technologies. It also further validates the progress we are making in securing license agreements with our customers for pharmaceutical products that incorporate technology developed by our SurModics Pharmaceuticals business. Additionally, Clinuvel has become yet another potential customer for our new cGMP manufacturing facility in Alabama."

"Clinuvel is delighted to further our partnership with SurModics through the signing of this agreement," said Philippe Wolgen, M.D., CEO of Clinuvel. "The launch of our clinical trial program for porphyria in the United States is a significant milestone for our company, and our partnership with SurModics reflects not only the company's best-in-class enabling technology, but also their impressive track record of progressing technology through the rigorous regulatory process, from clinical trials to commercialization. We look forward to continuing our work together to develop effective therapies for patients suffering from severe UV-related skin disorders."

"Today's announcement represents a natural progression of our relationship with Clinuvel," said Arthur J. Tipton, Ph.D., senior vice president & chief scientific officer of SurModics. "Together, our teams have solved numerous scientific and technical issues over the years culminating in the signing of this licensing agreement. Clinuvel's product provides a novel way to treat serious skin disorders. We are excited to support Clinuvel as they continue with their U.S. clinical trials, and are also encouraged by the positive clinical results Clinuvel has generated to date."

Clinuvel's Clinical Trials

Clinuvel's SCENESSE (afamelanotide) implant is currently in clinical trials for erythropoietic protoporphyria (EPP, or sun intolerance) – Phase III OUS, Phase II US; actinic keratosis (AK) and squamous cell carcinoma (SCC) in organ transplant recipients (skin cancers) – Phase II OUS; and polymorphous light eruption (PLE, commonly known as sun poisoning) – Phase III OUS. For more information visit www.scenesse.com.

About SurModics, Inc.

SurModics' vision is to extend and improve the lives of patients through technology innovation. The Company partners with the world's foremost medical device, pharmaceutical and life science companies to develop and commercialize innovative products that result in improved diagnosis and treatment for patients. Core offerings include: drug delivery technologies (coatings, microparticles, nanoparticles, and implants); surface modification coating technologies that impart lubricity, prohealing, and biocompatibility

Related Sectors:

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capabilities; and components for in vitro diagnostic test kits and specialized surfaces for cell culture and microarrays. SurModics is headquartered in Eden Prairie, Minnesota and its SurModics Pharmaceuticals subsidiary is located in Birmingham, Alabama. For more information about the Company, visit www.surmodics.com. The content of SurModics' website is not part of this release or part of any filings the Company makes with the SEC.

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Ltd is a leading and innovative Australian company focused on the development of SCENESSE (afamelanotide), its proprietary first-in-class photoprotective drug. Clinuvel has identified five groups of patients with a clinical need for photoprotection. Pending positive clinical results, Clinuvel aims to file SCENESSE for its first market approval for the orphan indication porphyria (EPP). For more information visit www.clinuvel.com.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about beliefs and expectations, such as expectations about our pipeline, and the potential of the SCENESSE product as a treatment for sun-induced skin disorders are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including the following: (1) realizing the full potential benefits of the Company's agreement with Clinuvel requires the successful development of new products and manufacturing processes; (2) our reliance on third parties (including our customers and licensees) and their failure to successfully develop, obtain regulatory approval for, market and sell products incorporating our technologies may adversely affect our business operations, and our ability to realize the full potential of our pipeline, (3) costs or difficulties relating to the integration of SurModics Pharmaceuticals may be greater than expected and may adversely affect the Company's results of operations and financial condition; (4) developments in the regulatory environment, as well as market and economic conditions, may adversely affect our business operations and profitability; and (5) other factors identified under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2009, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at www.surmodics.com and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

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