



SurModics and Edge Therapeutics Collaborate on Development of Sustained-Release Neurological Product

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Site-Specific Product Designed to Prevent Delayed Complications After Subarachnoid Hemorrhage

EDEN PRAIRIE, Minn. & NEWARK, N.J., Nov 03, 2010 (BUSINESS WIRE) --

[SurModics, Inc.](#) (Nasdaq: SRDX), a leading provider of drug delivery and surface modification technologies to the healthcare industry, and Edge Therapeutics, Inc., a specialty biopharmaceutical company that transforms proven, off-patent drugs into targeted, locally delivered therapies for neurological disorders, announced today that the companies have entered into a licensing agreement for drug delivery technology.

On July 21, 2010, Edge announced a feasibility collaboration with SurModics to develop a novel biodegradable, site-specific, sustained-release formulation (NimoGel(TM), EG-1961) for the potential treatment of delayed cerebral ischemia (DCI). DCI is a complication that often occurs hours to days following subarachnoid hemorrhage (SAH), which is typically the result of a ruptured brain aneurysm or head trauma.

Under the licensing agreement, Edge will lead and fund development and commercialization of the program. SurModics will provide Edge access to certain proprietary technologies as well as technical and manufacturing expertise at its cGMP facility in Birmingham, Alabama. SurModics will be eligible to receive licensing fees and milestone payments in the event of the successful development and commercialization of the product. SurModics will also receive royalties on product sales.

The license agreement covers NimoGel, Edge's lead drug program that combines the FDA-approved calcium channel blocker nimodipine and SurModics' proprietary biodegradable delivery system. NimoGel is designed to be delivered directly to the injury and is expected to provide consistent and appropriate local concentrations of nimodipine while minimizing systemic side effects.

"SurModics' proprietary biodegradable drug delivery system is an ideal match for brain injury clinical applications, as generating high local drug levels is critical for achieving optimal clinical outcomes," said Philip D. Ankeny, SurModics' interim chief executive officer, senior vice president and chief financial officer. "We are very impressed with the thought leaders and clinical advisors that Edge has assembled and the drive that Edge executives have demonstrated to rapidly advance this program. The promising data that our teams generated in the feasibility phase was a compelling reason for executing this licensing agreement. We look forward to continued progress in developing and commercializing this important product for patients suffering brain hemorrhages."

"We are excited to have SurModics as our development and commercialization partner on NimoGel given the company's technical experience, depth of capabilities, and world-class cGMP manufacturing facility," said Brian A. Leuthner, president and chief executive officer of Edge Therapeutics. "We are confident in our ability to advance our research and development and ultimately commercialize this potentially life-saving product."

"There is an urgent need for better treatments to address complications resulting from SAH. The current treatment, oral nimodipine, is only marginally effective in part because it fails to provide adequate drug concentrations at the injury site in the brain. Higher oral doses that may be more effective cause side effects outside the brain and are unsafe," said R. Loch Macdonald, M.D., co-founder and chief scientific officer of Edge Therapeutics. "Importantly, NimoGel has the potential to dramatically improve patient outcomes where other drugs have failed."

About Delayed Cerebral Ischemia (DCI)

Following SAH, brain neurons die acutely due to trauma and lack of blood flow; however, even greater neuronal damage may occur in the first several weeks following SAH due to DCI. DCI is caused by a series of biochemical processes that occur hours to days after SAH, which provides a unique opportunity to initiate protective therapy while the patient is hospitalized and under the care of a neurosurgeon and prior to the onset of secondary injury. The time-dependent progression of damage presents a window of opportunity to prevent DCI; however despite substantial research and clinical efforts with oral and intravenous therapies, DCI continues to cause irreversible brain injury and remains a significant contributor to death and disability.

About NimoGel(TM) (EG-1961)

NimoGel is a locally delivered, sustained-release formulation of the calcium channel blocker nimodipine designed to provide consistent and sufficiently high local nimodipine concentrations in the brain to prevent a catastrophic condition called delayed cerebral ischemia. Of note, NimoGel is delivered during surgery required to secure the bleeding artery, so NimoGel administration does not require a special surgery or an additional procedure to administer.

About SurModics

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 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 Edge Therapeutics

Edge Therapeutics is a privately held specialty biopharmaceutical company founded in 2009 and funded by private investors and the New Jersey Economic Development Authority. Edge believes that local, sustained-release delivery of medicine directly to the injury site will improve patient outcome and reduce healthcare costs in unmet conditions in the central nervous system. By transforming well-established off-patent drugs, Edge streamlines the development path and dramatically reduces both risk and cost. Edge's lead product, NimoGel, will soon enter into its IND-enabling study for the treatment of delayed cerebral ischemia and has the potential to generate annual sales exceeding \$500 million. For more information on Edge Therapeutics, please visit www.edgetherapeutics.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 potential applications of SurModics' proprietary technologies, the potential of NimoGel(TM) as a possible treatment of delayed cerebral ischemia or other neurological disorders, and our ability to successfully develop and commercialize our technologies, 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 SurModics' agreement with Edge 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, our ability to realize the full potential of our pipeline, and our ability to achieve our corporate goals; (3) costs or difficulties relating to the integration of the businesses of SurModics Pharmaceuticals and BioFX Laboratories, and the drug delivery assets and collaborative programs acquired from PR Pharmaceuticals, Inc., with SurModics' business 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.

SOURCE: SurModics, Inc.

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