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Independent Studies Demonstrate that NellOne Therapeutics' Protein Has Potential to Heal Damaged Skeletal and Heart Muscle

Results show treatment can promote restoration of injured tissue, taking company closer to preclinical testing and toxicology studies

KNOXVILLE, Tenn., March 25, 2010 – Two key, independent proof-of-concept studies conducted for NellOne Therapeutics, Inc. (NellOne) demonstrate the potential efficacy of the company's lead therapeutic candidate for both skeletal muscle wound healing and myocardial infarction.

The regenerative medicine company, which was spun out of the U.S. Department of Energy's Oak Ridge National Laboratory (ORNL) in 2008, is developing novel [therapeutic treatments](#) that restore both mass and function to damaged human tissues, such as heart and skeletal muscle. These treatments are based on the discoveries of company founder [Dr. Cymbeline Culiat](#), who, as an ORNL systems genetics researcher, identified the [role that the Nell1 pathway plays](#) in tissue growth and maturation.

The two efficacy studies, *in vivo* for skeletal muscle and *in vitro* for heart muscle, sought to establish the Nell1 protein therapeutic's promise to effectively improve wound healing and to restore cardiac tissue while also preventing further damage to heart cells, explained Dr. Culiat, who also is chair of the NellOne Scientific Advisory Board.

"Evaluation of the protein for skeletal muscle wound healing in a murine diabetic model showed that Nell-1 significantly increased new blood-vessel formation and muscle regrowth," she said, adding that the results were consistent with earlier genetic and genomic studies she conducted at ORNL—that Nell1 triggers the production of several extracellular matrix (ECM) proteins that support cell proliferation and maturation in muscle and the blood-vessel network.

The cardiac study evaluated the protein as a treatment for myocardial infarction by testing if Nell1 can protect cardiomyocytes (heart muscle cells) in a low-oxygen (hypoxic) environment. "These conditions mimic what heart-muscle cells are subjected to during a heart attack," Dr. Culiat continued.

The data showed that the Nell1 protein significantly protects cells exposed to low-oxygen conditions and prevents them from dying, she said.

(more)

NellOne CEO [Tracy Warren](#) said that the results “are important milestones on NellOne’s path to create and commercialize protein therapeutics that can be delivered to damaged tissue with the unique potential to restore both tissue mass AND function in patients recovering from heart attacks.”

“The studies are early positive indications that the Nell1 protein may be an effective therapy for restoration of functioning tissue, both in healing injured skeletal muscle after trauma or immobility, or following a heart attack. Annually, more than 1.2 million Americans suffer new or recurrent coronary attacks, with a greater-than-30-percent mortality rate,” she noted.

Warren, who also is a general partner of [Battelle Ventures](#), which financially made possible the [spinout from ORNL](#) to commercialize the technology, added, “Following further proof-of-concept studies this year, we hope to be ready to commence preclinical testing and toxicology studies for both protein treatments derived from the Nell1 platform.”

Warren discusses these studies today, along with an overview of NellOne’s technology and business strategy, in a presentation around 3 P.M., at the venture showcase of the [2010 Global Venture Challenge](#) hosted by Oak Ridge National Laboratory in Oak Ridge, Tenn.

About NellOne

NellOne is an early stage regenerative medicine company developing protein therapeutics for restoring cardiac muscle mass and function in patients recovering from myocardial infarction and congestive cardiac failure. It was spun out of Oak Ridge National Laboratory in 2008 by Battelle Ventures and its Knoxville-based affiliate fund, Innovation Valley Partners (IVP). In January 2010, the company exclusively [licensed patents](#) from ORNL contractor UT-Battelle on inventions based on the Nell1 gene. If successful, the protein therapy being developed from the Nell1 protein platform could improve the lives of victims of heart attacks and severe muscle wounds. For more information, visit: www.nell-one.com

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