# The Madonna Minute

A briefing about the programs and innovations at Madonna Rehabilitation Hospital

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# New investigational clinical study to begin in acute spinal cord-injured patients

Madonna Rehabilitation Hospital is pleased to be one of 60 selected research sites in the U.S. and Canada for an investigational clinical study for persons with newly-diagnosed acute spinal cord injury (ASCI). The research will evaluate the safety and effectiveness of an investigative new drug called SUN13837 to determine whether the drug improves neurological function in this catastrophic injury. At present there is no drug approved by the FDA or Health Canada to treat the paralysis and sensory loss which occurs after ASCI.

In nonclinical studies, SUN13837 mimics the potentially therapeutic properties of basic fibroblast growth factor (bFGF), such as neuroprotection and neuroregeneration, without the detrimental effect of cell proliferation that is seen with bFGF. Moreover, bFGF is a large protein molecule, which is difficult to administer to humans and, therefore, replicate any of the positive results seen with bFGF in nonclinical studies. In contrast SUN13837 is a small molecule with good blood-brain barrier penetration that can be given intravenously.

The study, sponsored by Asubio Pharmaceuticals, Inc., a Daiichi Sankyo Group Company, is expected to enroll 164 patients. Patients will be selected based on baseline spinal cord level of injury (American Spinal Cord Injury AssociationImpairment Scale A, or complete injury,cervical spine levels 4 to 7). In this blinded, randomized trial, the patient will be randomly assigned to receive a placebo or SUN13837 within 12 hours of injury and then daily for 28 days.

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Researchers will determine if subjects receiving SUN13837 are more likely to respond to the treatment (and to what extent) compared to those in the placebo group. A person who has responded to treatment is viewed as someone who has a greater potential to perform typical activities of daily living, such as eating or bathing, independently (or with minimal assistance). Moreover, the drug level in the blood stream will be compared to the response to determine the relationship between dose, effect (efficacy or clinical symptoms) and safety.

An added benefit of the study design is the collaboration between trauma centers and rehabilitation and spine centers. Typically, these centers do not participate together in clinical programs and this study design will enhance cooperation in future clinical programs.

This scientific study is intended to investigate a potential treatment option for acute spinal cord injured patients and to assess the safety and efficacy of this investigational new drug for an unmet medical need. SUN13837 may provide a therapeutic option that will offer these patients a greater opportunity to live independently and lessen the impact of this life-altering trauma on the person, their family and society.

For more information on this ASCI research study in patients, please call Diane Ulmer, OTR/L, Program Manager, Spinal Cord Injury Rehabilitation Program, at 402-483-9617 or dulmer@madonna.org.

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