

Promising clinical results of OrgaNext' Recovery Booster therapy for older patients

Arnhem, The Netherlands – June 30, 2014 - OrgaNext Research, a Dutch biopharmaceutical company¹, announced the results of the first clinical studies in older people with its novel Recovery Booster therapy². The studies showed that the innovative therapy is safe and well tolerated by older women (65-79 years) and that biomarker data are indicative of early anabolic response in all treated individuals.

Hospitalized elderly patients can lose up to 10% of lean leg muscle mass in only three days³. As muscle mass plays a key role in recovery from illness or trauma, there is an urgent unmet medical need to support the recovery of older patients.

OrgaNext is pursuing a novel approach to restore muscle strength and battle post-surgery muscular atrophy in older patients. The aim of OrgaNext's Recovery Booster therapy NDD is to reverse the catabolic state, mitigate the disuse atrophy and support functional recovery of older patients for a period of 6 months. In-vitro studies on human skeletal muscle demonstrated that the novel Recovery Booster activates the sleeping beauties in aged muscles: the muscle stem cells.

Lenus Kloosterboer, PhD. presented the clinical data on June 21 at the joint meeting of the International Society of Endocrinology and the Endocrine Society, June 21-24 in Chicago. *"This is the first time a Recovery Booster therapy for elderly has been clinically tested and the results are very promising. Multiple injections with NDD are safe and well tolerated, and biomarkers are indicative of an early therapeutic effect in elderly. This is good news for patients aged 65 years or older who struggle to regain their strength"*, Kloosterboer said. *"We soon hope to start pivotal clinical Phase 2b studies in older women recovering after a hip fracture⁴."*

Marjanne Prins, Founder and CEO of OrgaNext Research, presented the novel Recovery Booster therapy last week at the 2014 BIO International Convention⁵ in San Diego.

"This is exiting news; activation of elderly muscle stem cells is an important step forward in the independent aging battle. With the promising results of the first clinical studies, we have come one step closer to making a difference in the lives of many," Marjanne Prins said. *"This is very good news for elderly patients and those who care for them."*

"I have seen too many elderly struggling to regain their physical strength after illness or hospitalization. The loss of independence, dignity, and possessions that accompanies the move from living in your own home to living in a nursing home has a detrimental effect on quality of life. As a nutritionist with 23 years of experience in the pharmaceutical industry and a global network of clinical and biopharmaceutical experts I felt compelled to make a difference. That was why I launched OrgaNext Research in 2009!"

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1) OrgaNext Research BV is a privately owned biopharmaceutical company, founded by former Organon executives in 2009, based in Arnhem, the Netherlands. The company focuses exclusively on recovery of physical strength after hospitalization and injury.

2) Recovery Booster therapies are a new class of prescription drugs that provide systemic support for the rehabilitation efforts of elderly hospitalized patients through mitigation of disuse atrophy and stimulation of the proliferation of satellite cells, also known as muscle stem cells. In other words: Recovery Boosters are expected to give patients 'More Bang for their Sweat' and increase their chance to regain independence and return to pre-hospitalization living conditions. It is expected that Recovery Booster therapies will lower the costs of care.

3) Muscle mass plays a key role in recovery from illness or trauma. Muscle strength and function is vital to the physical recovery process. Satellite cells, the stem cells of skeletal muscle, are activated upon injury or exercise, but the process of activation gradually comes to almost a stand still as we age. While bedridden young and healthy people lose only 2% of muscle mass in 28 days, recent studies demonstrated that elderly hospitalized patients could lose up to 10% of muscle mass in only three days.

4) 353,000 hip fractures occurring annually in the USA and over 800,000 in Europe and these numbers are expected to increase as the population ages. Hip fractures are a persistent cause of excessive morbidity, reduced life quality, and premature mortality among older people. Among survivors, 50% need assistance to walk and 90% need assistance to climb stairs after 1 year. Among women who lived independently before hip fracture, about half remain in long term care or need help with the activities of daily living one year after the event. The annual costs of hip fractures are estimated at 21 billion EURO in Europe and 12.6 billion US\$ in the USA (International Osteoporosis Foundation and US Pharm. 2011;36(10)). Currently there is no drug intervention therapy available to address the debilitating consequences of slow and/or partial recovery of hip fracture patients.

5) The 2014 BIO International Convention, is the global event for biotechnology hosted by the Biotechnology Industry Organization (BIO) and took place June 23-26, 2014 at the San Diego Convention Center in San Diego, California. Keynote speakers of the 2014 Convention included Richard Branson and Hillary Rodham Clinton.