Stem Cell Therapy Regenerates Jaw Bone, Enables Dental Implants

Ann Arbor, Mich.-based Aastrom Biosciences, Inc. (Nasdaq: ASTM) said on August 10 that “compassionate use treatments” using its Bone Repair Cells (BRCs) in patients suffering from severe craniofacial defects regenerated bone and other tissues and enabled dental implants.

In an oral presentation at the 2nd Annual Congress of Regenerative Medicine & Stem Cells in Dalian, China, Dr. Jose Mendonza, director of the head and neck surgery unit of Hospital POLUSA in Lugo, Spain, reviewed the results of treatment with BRCs in three patients with craniofacial defects.

BRCs are derived from a small sample of the patient’s bone marrow that is processed using Aastrom’s proprietary Tissue Repair Cell (TRC) technology to generate larger numbers of stem and early progenitor cells with enhanced therapeutic potential.

The results are as follows:

– The first patient was treated for severe mandibular osteoradionecrosis, or osteonecrosis of the jaw caused by radiation, and presented with pathological fracture and complete numbness of the lower lip. At 12 months post-BRC treatment, the patient displayed restored vascular function, new bone formation, fracture consolidation and total recovery of lip numbness.

– The second patient was treated for post-traumatic mandibular osteomyelitis and presented with massive bone loss, chronic infection, chronic pain and total impairment of function of both mandibular nerves. At 12 months post-BRC treatment, the patient experienced complete functional nerve recovery and the formation of new bone.

– The third patient was treated for iatrogenic massive bone loss in the posterior maxilla and presented with severe oral function impairment. At 12 months post-BRC treatment, the patient had new bone formation in atrophic areas.

– All patients underwent a minor surgery to insert a dental implant into the newly regenerated jaw bone. Eight weeks later, the dental prosthesis (teeth) was attached to the implant completing the treatment objectives with the restoration of oral function.

“We observed early bone formation in the afflicted areas that eventually resulted in complete healing,” Mendonza said. “Unexpected therapeutic results from treatment with BRCs include peripheral nerve regeneration or repair, new skin formation and proliferation in blood vessels in ischemic areas. The results open a promising pathway for the treatment of some patients where conventional therapies fail or do not exist.”

Compassionate use of TRC-based products was authorized by the Spanish Ministry of Health.

In May 2008, Aastrom announced the reprioritization of its clinical development programs to focus primarily on cardiovascular applications, thus discontinuing further patient enrollment into the U.S. Phase III ON-CORE bone regeneration clinical trial.

The Company does not anticipate new clinical bone activity or reactivating the Phase III ON-CORE trial.
at the present time but has continued to treat patients on a compassionate use basis in Spain.

“Our bone program remains open for partnering. Encouraging compassionate use treatments such as those noted by Dr. Mendonça strengthen our bone program portfolio, especially in the EU,” said Sheldon A. Schaffer, Ph.D., vice president of corporate development & intellectual property.

Aastrom’s proprietary Tissue Repair Cell (TRC) technology involves the use of a patient’s own cells to manufacture products to treat a range of chronic diseases and serious injuries.

The company is focused on cardiovascular regeneration through a Phase II clinical trial with dilated cardiomyopathy (DCM) patients (the IMPACT-DCM trial) and a Phase IIb clinical trial with critical limb ischemia (CLI) patients (the RESTORE-CLI trial).

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