Cerapedics Announces Publication of Two-Year IDE Study Follow-Up Data on i-FACTOR™ Bone Graft in the Cervical Spine

Results published in Neurosurgery show peptide enhanced bone graft statistically superior to autograft in ACDF procedures at two years.

WESTMINSTER, Colo., September 12, 2017 - Cerapedics, a privately-held orthobiologics company, today announced the publication of two-year follow-up data from an FDA Investigational Device Exemption (IDE) clinical trial of i-FACTOR™ Peptide Enhanced Bone Graft. The results published in the peer reviewed journal *Neurosurgery* show i-FACTOR Bone Graft is statistically superior in overall clinical success to autograft in anterior cervical discectomy and fusion (ACDF) procedures.

i-FACTOR Bone Graft is based on synthetic small peptide (P-15) technology developed by Cerapedics to support bone growth through cell attachment and activation. In November 2015, Cerapedics received Premarket Approval (PMA) from the FDA for the use of i-FACTOR Bone Graft in ACDF procedures.

"We are pleased that the statistical superiority in overall success for i-FACTOR Bone Graft versus autograft in ACDF procedures was maintained over two years in our IDE trial," said Jeffrey Marx, Ph.D., president and COO of Cerapedics. "The *Neurosurgery* publication is a testament to the hard work and dedication of the clinical investigators who continue to pursue advanced treatment options for patients with degenerative cervical disc disease."

In the IDE clinical trial, patients received either autograft or i-FACTOR Bone Graft in a cortical ring allograft. FDA-mandated success criteria included fusion, improvement in Neck Disability Index (NDI), neurological status, and safety. At two-year follow-up, a responder analysis of combined endpoints for overall success demonstrated 70 percent success for patients receiving i-FACTOR Bone Graft versus 56 percent for patients receiving autograft. This was statistically significant for superiority ($p = 0.0302$).

Fusion success was confirmed radiologically for 97 percent of i-FACTOR Bone Graft patients and 94 percent of autograft patients ($p = 0.2195$). A more than 15-point improvement from baseline NDI was reported for 77 percent of i-FACTOR Bone Graft patients and 69 percent of autograft patients ($p = 0.1804$). Improvement in neurological status was similar in both patient groups (95 percent of i-FACTOR Bone Graft patients and 94 percent of autograft patients, $p = 0.6944$). Safety success measured by the absence of re-operation, device explantation, and device-related serious adverse events was observed in 95 percent of i-FACTOR Bone Graft patients and 91 percent of autograft patients ($p = 0.1379$).

"The publication of the two-year results from this Level I clinical trial further validates previous findings that i-FACTOR™ Bone Graft, with P-15 technology, is statistically superior to autograft," said Paul Arnold, M.D., neurosurgeon at the University of Kansas Hospital Marc A. Asher, M.D. Comprehensive Spine Center and lead author of the study. "we are pleased to be able to offer a new advanced biologic bone graft with outstanding safety and efficacy to our patients."

About Cerapedics

Cerapedics is an orthobiologics company focused on developing and commercializing its proprietary synthetic small peptide (P-15) technology platform. i-FACTOR Peptide Enhanced Bone Graft is the only biologic bone graft in orthopedics that incorporates a small peptide as an attachment factor to stimulate the natural bone healing process. This novel mechanism of action is designed to support safer and more predictable bone formation compared to commercially available bone growth factors. More information can be found at www.cerapedics.com.

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Media contact:
Adam Daley
Berry & Company Public Relations
212-253-8881
adaley@berrypr.com