**Cerapedics Announces Publication of Results from Pivotal IDE Clinical Trial of i-FACTOR™ Bone Graft in the Cervical Spine**

*Results published in peer-reviewed journal Spine show peptide enhanced bone graft is safe and effective when compared to local autograft in ACDF procedures.*

**WESTMINSTER, Colo., Feb. 4, 2016** - Cerapedics, a privately-held orthobiologics company, announced today results from a pivotal FDA Investigational Device Exemption (IDE) clinical trial for i-FACTOR™ Peptide Enhanced Bone Graft in anterior cervical discectomy and fusion (ACDF) procedures have been electronically published in the peer-reviewed journal *Spine*.[i]

The research effort led by principal investigator Michael Janssen, DO, Spine Education Research Institute showed that i-FACTOR bone graft demonstrated safety and efficacy while meeting all four U.S. Food and Drug Administration (FDA) mandated non-inferiority success criteria when compared to local autograft in single-level ACDF for cervical radiculopathy.

“The results of this landmark IDE study further reinforce our belief that i-FACTOR bone graft represents an important advance in ACDF procedures and may offer an alternative to autograft harvesting or other growth factor technologies,” said Jeffrey G. Marx, Ph.D., president and COO of Cerapedics. “We are pleased to have these data published by such a prominent and well-respected journal in the field of spine surgery.”

In the prospective, randomized, single-blinded study patients received either autograft (N=154) or i-FACTOR bone graft (N=165) in a cortical ring allograft. Success was determined by non-inferiority in fusion, Neck Disability Index (NDI) and Neurological Success endpoints, and adverse events at 12 month follow-up.

Both i-FACTOR bone graft and autograft demonstrated a high fusion rate (88.97% and 85.82%, respectively, non-inferiority $p=0.0004$), significant improvements in NDI (28.75 and 27.40, respectively, non-inferiority $p<0.0001$) and high Neurological Success rate (93.71% and 93.01%, respectively, non-inferiority $p<0.0001$). There was no difference in the rate of adverse events (83.64% and 82.47%, respectively, $p=0.8814$).

In addition, a responder analysis for overall success in all four primary outcomes demonstrated 69 percent success for i-FACTOR bone graft versus 57 percent for autograft. This was statistically significant for superiority ($p = 0.0382$).

“Until now alternatives to autograft bone for use in ACDF procedures had not been evaluated in rigorous randomized, controlled studies,” said co-investigator and lead author of the *Spine* paper Paul M. Arnold, MD, professor of neurosurgery at University of Kansas Medical Center. “This study demonstrates that treatment with i-FACTOR bone graft resulted in similar and on some metrics superior outcomes compared to local autograft bone.”

i-FACTOR bone graft is based on synthetic small peptide (P-15) technology and supports bone growth through cell attachment and activation. In November 2015 Cerapedics received FDA approval for the use of i-FACTOR bone graft in ACDF procedures in patients with degenerative cervical disc disease.

**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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[i] Arnold, Paul M. "Efficacy of i-Factor™ Bone Graft versus Autograft in Anterior Cervical Discectomy and Fusion: Results of the Prospective Randomized Single-blinded Food and Drug Administration Investigational Device Exemption Study." *Spine*. Publish Ahead of Print. January 27, 2016. http://journals.lww.com/spinejournal/Fulltext/publishahead/Efficacy_of_i_Factor_TM__Bone_Graft_versus.96262.aspx.