Cerapedics Receives FDA Approval for i-FACTOR™ Peptide Enhanced Bone Graft in Cervical Spine Surgery

Orthobiologics company positioned to begin commercial distribution in the U.S. following successful Premarket Approval application.

WESTMINSTER, Colo., Nov. 3, 2015 - Cerapedics, a privately-held orthobiologics company, announced today the U.S. Food and Drug Administration (FDA) has approved the company's Premarket Approval (PMA) application for i-FACTOR™ Peptide Enhanced Bone Graft for use in anterior cervical discectomy and fusion (ACDF) procedures in patients with degenerative cervical disc disease. i-FACTOR bone graft is the first bone graft to be approved for use in the cervical spine and only the second PMA-approved bone graft in the spine.

"This is an historic milestone for us at Cerapedics and also for the surgical treatment of cervical disc degeneration," said Jeffrey G. Marx, Ph.D., president and COO of Cerapedics. "It is the culmination of years of seamless cooperation with our clinical investigators to support PMA approval. With our transition to a commercial stage company, all of us at Cerapedics look forward to bringing an important new biologic bone graft option, the only backed by significant level-1 clinical evidence, to surgeons and patients across the U.S."

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. It may be used as a substitute for autologous bone in ACDF procedures.

The PMA approval is driven by data from a pivotal clinical trial comparing i-FACTOR bone graft to autograft in ACDF procedures. In the trial, i-FACTOR bone graft met all four pre-specified primary endpoints (fusion rate, NDI score, neurological outcomes, and safety success), demonstrating non-inferiority to autograft with p-values of < 0.0005 for each. 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. The proportion of i-FACTOR bone graft subjects with overall success was significantly higher than that of the autograft subjects ($p = 0.0382$).

"We are extremely pleased and excited about the FDA's approval of i-FACTOR bone graft for cervical spinal fusions, a large and growing market segment that, up until now, has been lacking the optimal product solution," said Glen Kashuba, CEO of Cerapedics. "Now for the first time spine surgeons in the U.S. will have access to a biologic bone graft based on our proprietary P-15 technology platform, providing a safe and effective alternative to a patient's own bone and other less studied products that are being marketed for cervical spine procedures. The approval will allow for the immediate U.S. commercial release of i-FACTOR bone graft and represents a significant achievement for Cerapedics."

As a result of the FDA approval, Cerapedics has begun to engage a number of top-tier distributors, and is preparing to recruit a number of direct sales representatives, to support the U.S. commercial launch of

i-FACTOR bone graft. The U.S. surgical market for biologic bone substitutes is estimated to be about $500 million.

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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