Cerapedics Announces FDA Advisory Committee Panel Is Not Required for i-FACTOR™ PMA Approval

Orthobiologics company has submitted response to remaining items from PMA review of i-FACTOR™ Peptide Enhanced Bone Graft

WESTMINSTER, Colo., June 16, 2015 - Cerapedics, a privately-held orthobiologics company, announced today that the U.S. Food and Drug Administration has informed the company that an advisory committee panel meeting will not be required for the final review of the Premarket Approval (PMA) application for i-FACTOR™ Peptide Enhanced Bone Graft. Furthermore, the company has filed a comprehensive response to the last few remaining items from the PMA review of i-FACTOR Peptide Enhanced Bone Graft, including those from a recently completed pre-approval facility inspection.

"We were pleased to receive notice from the FDA that we can move forward in the PMA review process without a panel meeting. We appreciate the interactive nature of the FDA review process, which has streamlined our application," said Jeffrey G. Marx, Ph.D., president and COO of Cerapedics.

i-FACTOR Peptide Enhanced Bone Graft is based on P-15 technology developed by Cerapedics to support bone growth through cell attachment and activation. The PMA application is supported by data from a pivotal clinical trial comparing i-FACTOR bone graft to autograft in anterior cervical discectomy and fusion (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. This was statistically significant for superiority ($p = 0.038$).

"Leading with this excellent clinical profile and what we believe will become the only biologic bone graft approved for cervical fusion, we think that i-FACTOR bone graft will be an important product for patients and clinicians. We are excited to be advancing i-FACTOR bone graft through the regulatory process and are now shifting our focus toward planning for U.S. commercialization," said Glen Kashuba, CEO of Cerapedics. "We would like to thank all of our clinical investigators and other contributors. Without their efforts, we would not be in this position today."

Cerapedics is leading efforts to identify and develop innovative biologic bone graft products for orthopedic procedures including spinal fusion, traumatic fracture treatment, and joint reconstruction.

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.

CAUTION: i-FACTOR bone graft is currently not approved for commercial use in any indication in the United States and is limited by U.S. Federal Law to investigational use only.

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