CERAPEDICS FILES PREMARKET APPROVAL APPLICATION WITH US FDA FOR I-FACTOR™ PEPTIDE ENHANCED BONE GRAFT

Application is supported by data from a pivotal clinical trial demonstrating that i-FACTOR bone graft can be used as an alternative to autograft harvesting in certain procedures.

WESTMINSTER, Colo. - September 4, 2014 – Cerapedics, a privately-held orthobiologics company, today announced that the company has filed a Premarket Approval Application (PMA) with the U.S. Food & Drug Administration for i-FACTOR™ Peptide Enhanced Bone Graft. The application is supported by data from a pivotal clinical trial demonstrating that i-FACTOR bone graft can be used as an alternative to autograft harvesting in anterior cervical discectomy and fusion (ACDF) procedures. Cerapedics submitted the PMA for i-FACTOR bone graft in modules, and pivotal clinical data was the final module required to complete the application.

"The PMA filing is an important milestone in our effort to advance our proprietary synthetic small peptide (P-15) technology platform, which has the potential to provide significant benefits to patients and surgeons in the U.S. who currently rely on autograft and other less-studied bone graft products on the market today," said Glen Kashuba, CEO at Cerapedics. "This filing is supported by robust clinical data and analysis from a pivotal trial in which i-FACTOR bone graft successfully met all four pre-specified primary endpoints. We look forward to completing the final phases of the regulatory review process."

Jeff Marx, Ph.D., president and COO of Cerapedics, said, "We are excited to advance i-FACTOR toward becoming only the second PMA-approved bone graft and the first to be approved for use in the cervical spine. We look forward to leveraging the reimbursement and commercial potential of our Level I data and unique regulatory position, which are key factors supporting success in today's healthcare environment."

In March 2014, Cerapedics presented preliminary outcomes data from an FDA Investigational Device Exemption (IDE) clinical trial for i-FACTOR bone graft in New Orleans. With the PMA filing, final data from this trial have been submitted. The study randomized 319 patients to either i-FACTOR bone graft or autograft inside of a structural allograft ring for single-level instrumented ACDF procedures. The use of i-FACTOR bone graft resulted in an 89% fusion rate after one year as compared to an 86% fusion rate with autograft, meeting the pre-specified non-inferiority endpoint ($p = 0.0004$). i-FACTOR also met the pre-specified non-inferiority criteria for the other three primary endpoints of the study (neck disability index [NDI], neurological success, and safety), and in a responder analysis for all primary outcomes combined i-FACTOR was superior to autograft with statistical significance. The occurrence of complications was similar for i-FACTOR bone graft and autograft, and there were no reported incidents of ectopic bone formation or immunological response during the study.

About Cerapedics

Cerapedics is an orthobiologics company focused on developing and commercializing its proprietary synthetic small peptide (P-15) technology platform with over 10,000 treated patients worldwide. i-FACTOR Peptide Enhanced Bone Graft is the only biologic bone graft 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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