NEWS RELEASE

Cerapedics Announces FDA Approval of PearlMatrix™ P-15 Peptide Enhanced Bone Graft, The First and Only Proven Bone Growth Accelerator for Lumbar Fusion

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ASPIRE pivotal Level-1 PMA IDE study evaluated PearlMatrix vs. local autograft in single-level TLIF procedures:
- Demonstrated statistically superior fusion speed;
- Achieved over twice as many patients fused at six months;
- Included ~60% high-risk patients

WESTMINSTER, Colo., June 23, 2025 /PRNewswire/ -- Cerapedics Inc., a global, commercial-stage orthopedics company dedicated to redefining the path to bone repair, today announced the U.S. Food and Drug Administration (FDA) premarket approval (PMA) of PearlMatrix™ P-15 Peptide Enhanced Bone Graft as a Class III drug-device combination product for use in single-level transforaminal lumbar interbody fusion (TLIF) surgery in adult patients with degenerative disc disease (DDD). Despite the availability of over 350+ spinal bone grafts, none have demonstrated a substantial improvement in fusion speed until now. Powered by a proprietary P-15 Osteogenic Cell Binding Peptide, PearlMatrix Bone Graft is the first and only bone growth accelerator (BGA) proven to accelerate lumbar fusion.

TLIF is a complex surgical procedure aiming to reduce or eliminate pain in the lumbar spine because of degenerative disc disease (DDD) by removing a damaged disc and then uniting (fusing) the spinal vertebral bones above and below the damaged disc to create spinal stability along with decompression of the spine. The fusion is

achieved using a bone graft which, over time, grows together with the vertebrae to form one bone.1 In 2023, an estimated 465,000 spinal fusion cases utilizing a bone graft replacement were performed in the U.S.1 Additionally, despite recent advances, spinal fusion procedures have become more complex due to an increase in the prevalence of patients with one or more risk factors.2

"As it can take up to 12 months for bones to fully fuse following a TLIF procedure, there remains a critical unmet need for new treatment options that accelerate fusion, especially for high-risk patients who are more prone to complications following surgery," said Michael Steinmetz, M.D., Chairman, Department of Neurosurgery, Cleveland Clinic and Study Investigator, ASPIRE Study.* "The majority of patients included in the ASPIRE study had one or more comorbidities, which is rare for these types of trials, although it's more representative of the patients I see in daily practice. The efficacy data of the ASPIRE study demonstrate faster fusion compared to local autograft."

FDA approval is supported by data from ASPIRE, a prospective, single-blinded, multi-center, randomized, controlled pivotal PMA IDE study, evaluating the safety and efficacy of PearlMatrix Bone Graft compared to use of local autologous bone graft and cancellous allograft when applied in TLIF surgery.3 The ASPIRE trial included 33 U.S. centers and 293 patients, including approximately 60 percent of patients that were considered high risk for non-union (i.e., patients with Type 2 diabetes, BMI ≥ 30 and/or nicotine users). The study met the primary endpoint of 24-month Composite Clinical Success (CCS) and further demonstrated statistical superiority versus local autograft in CCS which was comprised of five components: fusion, function (ODI), neurological, no serious device-related adverse events, and no index-level secondary surgical interventions. ASPIRE is the first study of its kind to show substantially higher fusion rates achieving statistically superior fusion speed at 24 months with more than twice as many patients fused at six months versus local autograft. Complete results of the ASPIRE study are expected to be published in the coming months.

"The FDA approval of PearlMatrix Bone Graft is a significant achievement for Cerapedics as we're the only company with two PMA-approved products for use in spinal fusion. This is a testament to our dedication to investing in high-quality clinical evidence in our pursuit to have a positive impact on the practice of spine surgery and the lives of patients," said Valeska Schroeder, Chief Executive Officer of Cerapedics. "Differentiated by its unique P-15 Osteogenic Cell Binding Peptide, PearlMatrix Bone Graft is the first and only bone growth accelerator proven to substantially increase lumbar fusion speed, giving surgeons a new option to better meet patient needs and treat them more efficiently."

PearlMatrix Bone Graft was approved through the FDA PMA pathway and was **granted a Breakthrough Device designation** in April 2021. This designation is offered by the FDA for a product that could provide more effective treatment of a life-threatening disease, is a novel technology or offers significant advantages over existing approved or cleared alternatives. Premarket approval is the most stringent type of device marketing application required by

the FDA and approval is based on a determination by the FDA that the PMA application contains sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use. Of the more than 350 spinal bone grafts in the U.S. market, Cerapedics has two of only three spinal bone grafts that have received PMA approval.

About PearlMatrixTM P-15 Peptide Enhanced Bone Graft

PearlMatrix P-15 Peptide Enhanced Bone Graft is the first and only bone growth accelerator proven to accelerate lumbar fusion with demonstrated statistically superior fusion speed in single level TLIF procedures. P-15 Peptide, the active component of PearlMatrix, provides a distinct and proven mechanism of action to attach and activate osteogenic cells to accelerate new bone formation. P-15 Peptide is a 15-amino acid sequence found naturally in Type-1 collagen, the predominant protein in bone. It serves a crucial role in the bone regeneration process as a powerful cell attachment factor. Cerapedics' pharmaceutically manufactured P-15 Peptide is bound onto calcium phosphate particles, creating a P-15-enhanced scaffold that provides an abundance of attachment sites for osteogenic, bone-forming, cells. Cell attachment activates pathways that release cell-signaling growth factors and allow bone growth through natural cellular processes.

Indications for use

PearlMatrix™ Bone Graft is indicated for intervertebral body fusion of the spine in skeletally mature patients. PearlMatrix is intended to be used in conjunction with a PEEK TLIF Fusion Device and supplemental internal spinal fixation systems cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. PearlMatrix is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back and/or radicular pain of discogenic origin with degeneration of the disc confirmed by history, physical exam, and radiographic studies.

PearlMatrix is contraindicated in situations where there is an absence of load-bearing structural support at the graft site, sensitivity to components or the product, active infection at the operative site, or an operative site subject to excessive impact or stress.

The effect of PearlMatrix on pregnant or nursing patients has not been evaluated. Care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure such as individuals with bleeding disorders of any etiology, long-term steroidal therapy, immunosuppressive therapy or high dosage radiation therapy. PearlMatrix in a TLIF procedure was associated with a higher rate of secondary surgical interventions compared to local autograft.

PearlMatrix should only be used by physicians who are experienced with TLIF procedures and in surgical procedures where it can be adequately contained at the bony void or defect.

To learn more about PearlMatrix, its indications, contraindications, warnings, precautions and potential adverse events, visit our website at **www.cerapedics.com** or refer to the PearlMatrix Instructions for Use for complete safety and risk information.

About Cerapedics

Cerapedics is a global, commercial-stage orthopedics company that is dedicated to redefining the path to bone repair by healing bones faster and at higher rates, so all patients can get back to living their fullest lives. Bone grafts, including Cerapedics' products, are used in over four million annual spine, orthopedics, trauma, and interventional procedures worldwide. Cerapedics has two products approved by the FDA: PearlMatrixTM Bone Graft for single-level transforaminal lumbar interbody fusion (TLIF) in the lumbar spine and i-FACTOR® Bone Graft for single-level anterior cervical discectomy and fusion (ACDF) in the cervical spine. Cerapedics is headquartered in Westminster, CO.

For more information, visit us at **www.cerapedics.com** and follow us on **LinkedIn**.

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* Dr. Michael Steinmetz has provided consulting, advisory, and speaking services to Cerapedics, Inc.; he has not been paid for any media work.

1 Clarivate | Decision Resources Group. Bone Graft Substitutes. December 2022.

2 Haik H, et al. Population-Based Trends in Complexity of Hospital Inpatients JAMA Intern Med. 2024;184(2):183-192. doi:10.1001/jamainternmed.2023.7410

3 **ClinicalTrials.gov**. P-15L Bone Graft in Transforaminal Lumbar Interbody Fusion With Instrumentation. Accessed August 2024. Available at: **https://clinicaltrials.gov/study/NCT03438747**

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