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PolarityTE registers OsteoTEÃ¢â??Â¢ with USFDA

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PolarityTE, Inc., a commercial-stage biotechnology company focused on transforming the lives of patients by discovering, designing and developing a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences has announced that it registered OsteoTE™ with the U.S. Food and Drug Administration (FDA) pursuant to applicable regulations governing human cells, tissues and cellular and tissue-based products (HCT/Ps).

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In pre-clinical studies, OsteoTE demonstrated the capacity to regenerate bone with function and composition similar to natural bone. Pre-clinical animal studies suggest the product is a viable alternative to bone grafts and bone substitutes in treating long bone, craniomaxillofacial, spine, dental, hand and foot/ankle defects.

Denver M. Lough, Chairman and Chief Executive Officer of PolarityTE said, "With the registration of OsteoTE with the FDA, we remain on track to meet our goal of commercialization through a phased release starting in early 2019. OsteoTE is the second product from our platform technology which is based on understanding how cells across the body work and how they can be deployed to regrow where needed. Through OsteoTE, we are giving providers an advanced regenerative solution that challenges current standards of care and improves patient outcomes."

OsteoTE is a human cellular and tissue-based product derived from a patient's own bone intended for the repair, reconstruction, and replacement of bone tissue. OsteoTE preclinical results have shown the regeneration of full-thickness corticocancellous, functionally-polarized bone.