January 18, 2022

PolarityTE Announces U.S. FDA Approval of IND for Pivotal Phase 3 Study of SkinTE® to Support Chronic Cutaneous Ulcer Indication

SALT LAKE CITY, Jan. 18, 2022 /PRNewswire/ --**PolarityTE, Inc. (Nasdaq: PTE),** a biotechnology company developing regenerative tissue products and biomaterials, today announced that the U.S. Food and Drug Administration (FDA) has approved its investigational new drug (IND) application for the evaluation of SkinTE for the treatment of chronic cutaneous ulcers. This follows the Company satisfactorily addressing clinical hold items that the FDA had previously identified. The approval enables PolarityTE to commence the first of two expected pivotal studies needed to support a biologics license application (BLA) seeking a chronic cutaneous ulcer indication for SkinTE.

Richard Hague, Chief Executive Officer and President of PolarityTE, commented, "The clearance of our IND is a critical milestone for PolarityTE and a testament to the talent and hard work of our entire team. It is important to note that our strategy to pursue a complex chronic cutaneous ulcer indication, which includes the most challenging and cost-intensive wounds, is based on the learnings from our prior commercial experience as a 361 HCT/P and from our previous non-IND DFU and VLU RCTs, which gives us a great deal of confidence as we look forward to commencing our first pivotal study in the very near future."

The first planned pivotal study is a multi-center, randomized controlled trial evaluating SkinTE in the treatment of Wager 2 DFUs entitled "Closure Obtained with Vascularized Epithelial Regeneration for DFUs with SkinTE," or "COVER DFUs." The Company plans to enroll up to 100 patients at up to 20 sites in the U.S. in COVER DFUs, which will compare treatment with SkinTE plus the standard-of-care to the standard-of-care alone. The primary

endpoint is the incidence of DFUs closed at 24 weeks. Secondary endpoints include percent area reduction (PAR) at 4, 8, 12, 16, and 24 weeks, improved quality of life, and new onset of infection of the DFU being evaluated. The Company expects enrollment to begin later in Q1 or in early Q2 and looks forward to providing updates as this study progresses and as PolarityTE engages FDA in discussions around the second pivotal study design and implementation.

FDA Guidance defines chronic cutaneous ulcers as those wounds that have "failed to proceed through an orderly and timely series of events to produce a durable structural, functional, and cosmetic closure," and specifically include DFUs, venous leg ulcers and pressure injuries. With respect to DFUs alone, the annual cost to the U.S. health care system ranges between $9 Billion and $13 Billion. The five-year mortality and direct costs of care for people with DFU complications are comparable to cancer.

About PolarityTE®
PolarityTE is 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. Rather than manufacturing with synthetic and foreign materials within artificially engineered environments, PolarityTE manufactures products from the patient's own tissue and uses the patient's own body to support the regenerative process. From a small piece of healthy autologous tissue, the company creates an easily deployable, dynamic and self-propagating product designed to regenerate the target tissues. PolarityTE's innovative methods are intended to promote and accelerate growth of the patient's tissues to undergo a form of effective regenerative healing. PolarityTE's products, including SkinTE, are in the development stage, and when clinical studies commence, SkinTE will be available for investigational use only. Learn more at www.PolarityTE.com – Welcome to the Shift®.

Forward Looking Statements
Certain statements contained in this release are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. They are generally identified by words such as "believes," "may," "expects," "anticipates," "intend," "plan," "will," "would," "should" and similar expressions. Readers should not place undue reliance on such forward-looking statements, which are based upon the Company's beliefs and assumptions as of the date of this release. The Company's actual results could differ materially due to the impact of the COVID-19 pandemic, future clinical studies, and FDA regulatory matters, which cannot be predicted, and the risk factors and other items described in more detail in the "Risk Factors" section of the Company's Annual Reports and other filings with the SEC (copies of which may be obtained at www.sec.gov). Subsequent events and developments may cause these forward-looking statements to change. The Company specifically disclaims any obligation or intention to update or revise these forward-looking statements as a result of changed events or circumstances that occur after the date of this release, except as required by applicable law.

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