October 3, 2017

PolarityTE™ Announces FDA Registration of Lead Product - SkinTE™

Controlled limited-market U.S. release underway

SALT LAKE CITY, Oct. 03, 2017 (GLOBE NEWSWIRE) -- PolarityTE™, Inc. (NASDAQ:COOL) today announced that the Company's lead product, SkinTE™, has been registered 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). SkinTE™ is an autologous, minimally manipulated construct intended for homologous uses of skin tissues. As an FDA-registered HCT/P, SkinTE™ may now be made available for appropriate human use in the United States. PolarityTE™ has initiated a controlled, limited-market release of the product to select medical institutions, and expects to accelerate commercialization in 2018 as the company scales up manufacturing efforts.

SkinTE

"The FDA registration of SkinTE™ is an important regulatory step that sets the stage for commercialization and a staged market entry of this revolutionary technology into clinical application," said Denver M. Lough, M.D., Ph.D., Chief Executive Officer of PolarityTE™. "This achievement enables us to deliver an entirely new and pragmatic solution for skin regeneration as well as the ability to change the face and practice of regenerative medicine toward patient-tailored tissue constructs."

In pre-clinical studies, SkinTE™ demonstrated full-thickness regenerative healing, nascent hair follicle formation, cutaneous appendage development, immediate and complete wound coverage, and the progressive regeneration of all skin layers including epidermis, dermis and hypodermal layers. (www.PolarityTE.com/products/SkinTE).

“This progressively-staged market release of SkinTE™ to select institutions will give the Polarity team time to scale manufacturing processes and facilities to meet future demands of SkinTE™ as well as other tissue substrate technologies we have in our translational development pipeline,” said Edward W. Swanson, M.D., Chief Operating Officer of PolarityTE™.

About SkinTE™ and FDA Tissue Establishment Registration
SkinTE™ is regulated by the FDA as an HCT/P solely under Section 361 of the Public Health Service Act and 21 CFR 1271. The FDA has specific regulations governing HCT/Ps. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act and 21 CFR 1271 (361 HCT/Ps) are not subject to pre-market clearance or approval requirements, but are subject to post-market regulatory requirements.

SkinTE™ is processed and marketed in accordance with the FDA’s requirements for human tissue and current good tissue practices (21 CFR 1271) and is manufactured by American Association of Tissue Banks (AATB)- and Foundation for the Accreditation of Cellular Therapy (FACT)-accredited facilities.

Important Safety Information
Poor general medical condition or any pathology that would limit the blood supply and compromise healing, as well as nonvascular surgical sites, should be considered when selecting patients for SkinTE™, as such conditions may compromise successful outcomes or lead to sub-optimal results.

Whenever clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures must be taken. Unused or expired tissue product should be discarded according to local, state, federal and institutional requirements. Utilization of the SkinTE™ construct, process and/or technology is limited to healthcare professionals and facilities that are capable of handling such tissue products.

Proper aseptic procedural and/or surgical handling is mandatory when using SkinTE™. Failure to ensure proper aseptic technique may result in contamination of the tissue product and wound bed. Contamination of the tissue product and/or wound bed due to failure to ensure aseptic technique could result in local, regional, or systemic infection, partial or complete failure of graft take, healing, and/or regeneration, serious injury, and/or death. Failure to follow instructions may lead to sub-optimal outcomes and/or product failure.

Potential adverse effects may include but are not limited to the following: local tissue, wound bed, regional tissue, or systemic infection, hypersensitive, allergic, or other immune response to the product or trace amounts of antibiotic retained from primary harvest, deleterious effects on potential surrounding or adjacent autologous, allogeneic, or xenogenic grafts, skin substitutes, or other reconstructions including infection and/or failure of adjacent grafted material to take and heal, requirement for further surgical operation(s) and/or debridement, or death.

About PolarityTE™
PolarityTE™, Inc. is a regenerative medicine company, and the first to successfully regenerate full-thickness tissue. The Company's novel regenerative medicine platform and proprietary technology employs a patient's own cells for the healing of full-thickness,

functionally-polarized tissues. If clinically successful, the PolarityTE™ platform will provide medical professionals with a truly new paradigm in wound healing and reconstructive surgery by utilizing a patient's own tissue substrates for the regeneration of skin, bone, muscle, cartilage, fat, blood vessels and nerves. The PolarityTE™ platform leverages natural and biologically-sound principles which are readily adaptable to a wide spectrum of organ and tissue systems. This revolutionary technology, paired with the Company's world-renowned clinical advisory board, position PolarityTE™ to drastically change the field and future of translational regenerative medicine. More information can be found online at www.PolarityTE.com.

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. Forward looking statements contained in this release relate to, among other things, the Company's ongoing compliance with the requirements of The NASDAQ Stock Market and the Company's ability to maintain the closing bid price requirements of The NASDAQ Stock Market on a post reverse split basis. They are generally identified by words such as "believes," "may," "expects," "anticipates," "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 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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