Mallinckrodt to Present Phase 3 StrataGraft® Regenerative Skin Tissue Clinical Trial Results on Severe Burns During the Virtual American Burn Association 52nd Annual Meeting

June 15, 2020

-- Phase 3 Clinical Trial Selected Among "Top Five Abstracts" --

-- Additional Abstracts on Health Economics and Outcomes Research and Other Data Accepted as Poster Presentations --

STAINES-UPON-THAMES, United Kingdom, June 15, 2020 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a global biopharmaceutical company, today announced it will present data from the pivotal Phase 3 clinical trial (STRATA2016) of its investigational product StrataGraft®, a regenerative skin tissue therapy in development for the treatment of deep partial-thickness thermal burns, as well as health economics and outcomes research (HEOR) and other data on the treatment of burns as part of the virtual American Burn Association (ABA) 52nd Annual Meeting. The virtual meeting begins today and is accessible online for attendees during the next 90 days. StrataGraft skin tissue is an investigational product, and its safety and effectiveness have not yet been established by the U.S. Food and Drug Administration (FDA).

The preliminary analysis of data from the Phase 3 trial will be presented by Dr. James H. Holmes, IV, via a prerecorded video, and available for attendees as part of the virtual meeting. The video presentation is part of the Education Forum as one of the "Top Five Abstracts," after receiving one of the top scores by blinded reviewers. The abstract from the Phase 3 trial was previously published in the *Journal of Burn Care & Research.*

"We are pleased to be sharing the results from our pivotal Phase 3 clinical trial of StrataGraft regenerative skin tissue, as well as data that provides insights into the implications of autografting during this year's virtual ABA Annual Meeting," said **Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt**. "At Mallinckrodt, we are committed to research in support of patients with severe burns. If approved, StrataGraft skin tissue would be a potential new treatment option for deep partial-thickness thermal burns to help reduce or eliminate the need to harvest healthy skin tissue from an uninjured site through autografting."

Phase 3 Clinical Trial Data

Title:	Preliminary Analysis of a Phase 3 Open-Label, Controlled, Randomized Trial Evaluating the Efficacy and Safety of a Bioengineered Regenerative Skin Construct in Patients with Deep Partial-thickness Thermal Burns
Virtual Location:	Part of the Education Forum
Session:	Top 5 Abstracts
Presentation #:	T5

Other Poster Presentations

Title:	Skin Graft Donor-Site Morbidity – A Systematic Literature Review
Virtual Location:	Exhibit Hall
Session:	Poster Session – R-123 Clinical Sciences: Wounds and Scars 1
Poster #:	522

Title:	Healthcare Resource Utilization and Costs of Care Among Pediatric Patients with Thermal Burns Undergoing Inpatient Autografting in a US Managed Care Population
Virtual Location:	Exhibit Hall
Session:	Poster Session – R-125 Public Health/Epidemiology 1
Poster #:	540

Title:	Establishing Thresholds for Clinically Significant Donor Skin Reduction – Initial Findings from a Physician Delphi Panel
Virtual Location:	Exhibit Hall
Session:	Poster Session – R-224 Clinical Sciences: Wounds and Scars 4
Poster #:	730

About StrataGraft
StrataGraft regenerative skin tissue is an investigational treatment being developed to reduce autograft in patients with severe thermal burns. An engineered, bilayer tissue, StrataGraft skin tissue is designed to mimic natural human skin with both inner dermis-like and outer epidermis-like layers. StrataGraft skin tissue can be sutured, stapled or secured with an adhesive. StrataGraft skin tissue is cryopreserved in order to deliver viable cells upon application.

Mallinckrodt is currently conducting a StrataGraft skin tissue continued access clinical trial (StrataCAT, NCT04123548) under an Expanded Access Program (EAP). The trial sites involved in the pivotal Phase 3 trial (STRATA2016, NCT03005106) have the opportunity to participate in this multicenter, open-label study. The company is planning to evaluate StrataGraft skin tissue for the treatment of adults with full-thickness burns (also

referred to as third-degree burns). Additionally, Mallinckrodt plans to conduct a study evaluating StrataGraft skin tissue in treatment of pediatric populations.

StrataGraft skin tissue is an investigational product, and its safety and effectiveness have not yet been established by the FDA.

Mallinckrodt announced the completion of the rolling submission of a Biologics License Application to the FDA for StrataGraft skin tissue for the treatment of adult patients with deep partial-thickness thermal burns on June 9, 2020. The FDA has granted StrataGraft skin tissue orphan drug status, and it was among the first products designated by the Agency as a Regenerative Medicine Advanced Therapy (RMAT) under the provisions of the 21st Century Cures Act.

Funding and technical support for the continued development of StrataGraft skin tissue, including the pivotal Phase 3 clinical study (STRATA2016) and the Biological Licensing Application process for StrataGraft skin tissue in the United States, is being provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under Project BioShield Contract No. HHSO100201500027C. These efforts are part of BARDA's strategy to build emergency preparedness in response to mass casualty events involving trauma and thermal burns by developing novel medical countermeasures for adult and at-risk populations. In the case of a mass casualty thermal burn event, the Government Accountability Office estimates that more than 10,000 patients might require thermal burn care.[1] The limited number of specialized burn centers and related medical infrastructure in the United States creates a public health need for therapies that could be deployed quickly for use in these and other care sites.

About Deep Partial-Thickness Thermal Burns
Deep partial-thickness thermal burns are complex skin injuries in which the damage extends through the entire epidermis (outermost layer of skin) and into the lower part of the dermis (innermost layer of skin).

Autograft is considered to be a standard of care by many for deep partial-thickness thermal burns. It involves the surgical harvesting of healthy skin tissue from an uninjured site on the patient and transplanting the skin graft to the injury. While this process can be effective in providing closure of the original wound, it has significant limitations related to the donor site wounds created during surgical removal of the skin tissue for grafting. Donor site wounds are painful and can create risks of additional scarring and infection. In addition, the amount of healthy skin available for harvesting is frequently limited in those patients with large burns, necessitating sequential re-harvesting of available donor sites. As a result, there is a need for alternatives to donor site harvesting for the treatment of severe burns.

About Mallinckrodt
Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission (SEC) disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

Cautionary Statements Related to Forward-Looking Statements
This release includes forward-looking statements concerning StrataGraft regenerative skin tissue, including expectations with regard to related regulatory filings, its potential impact on patients, and anticipated benefits associated with its use. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; issues with product quality, manufacturing or supply, or patient safety issues; and other risks identified and described in more detail in the "Risk Factors" section of Mallinckrodt's most recent Annual Report on Form 10-K and other filings with the SEC, all of which are available on its website. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

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[1] https://www.gao.gov/assets/590/588738.pdf. Accessed February 12, 2020.

View original content to download multimedia:http://www.prnewswire.com/news-releases/mallinckrodt-to-present-phase-3-stratagraft-regenerative-skin-tissue-clinical-trial-results-on-severe-burns-during-the-virtual-american-burn-association-52nd-annual-meeting-301076557.html

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