Mallinckrodt Announces U.S. FDA Filing Acceptance of Biologics License Application for StrataGraft® Regenerative Skin Tissue for Treatment of Adults with Deep Partial-thickness Thermal Burns

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- StrataGraft® Skin Tissue, If Approved, Could Reduce or Eliminate the Need for Autografting of Healthy Skin to Treat Burn Wounds -

STAINES-UPON-THAMES, United Kingdom, Aug. 10, 2020 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a global biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Stratatech Biologics License Application (BLA) for StrataGraft®, an investigational regenerative skin tissue therapy in development for the treatment of adult patients with deep partial-thickness thermal burns. The FDA granted the application priority review and assigned a Prescription Drug User Fee Act (PDUFA) target date of February 2, 2021.

Autograft, the current standard of care for deep partial-thickness thermal burns, involves the surgical harvesting of healthy skin from an uninjured site on the patient and transplanting the skin graft to the injury, leaving the patient with more wounded areas requiring care. Each year, approximately 40,000 patients in the U.S. require hospitalization for the treatment of severe burns.[1] The Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS), expressed interest in StrataGraft skin tissue as a medical countermeasure in response to large-scale burn incidents, and provided funding and technical support for the continued development of StrataGraft skin tissue.

"Treatment advances are needed that can help minimize or eliminate the need for autografting. The FDA's acceptance of the BLA submission for StrataGraft skin tissue for review takes us one step closer to providing adult burn patients in the United States with a potential new treatment option for deep partial-thickness thermal burns," said **Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt**. "We are focused on delivering solutions to patients with severe and critical conditions, and look forward to working with the FDA during the regulatory review process for StrataGraft skin tissue."

The StrataGraft skin tissue BLA is based on data from the pivotal Phase 3 STRATA2016 clinical trial, previously published as an abstract in the *Journal of Burn Care & Research* and presented via a prerecorded video at the virtual American Burn Association 52nd Annual Meeting, with support from the STRATA2011 clinical trial, previously published in *Burns*. Top-line results from the Phase 3 trial of StrataGraft skin tissue, which met both primary endpoints in adults with deep partial-thickness thermal burns, including autograft sparing and durable wound closure, were announced in September 2019.

The completion of the BLA rolling submission was announced on June 9, 2020. The FDA granted StrataGraft skin tissue orphan drug designation, 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.

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.

The continued development of StrataGraft skin tissue, including the pivotal Phase 3 clinical study (STRATA2016) and the BLA process for StrataGraft skin tissue in the United States, is being supported through a partnership with 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.[2] 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 the anticipated regulatory review process, 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] American Burn Association. Burn Incidence Fact Sheet. http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/. Accessed May 15, 2020.

[2] United States Government Accountability Office. National Preparedness: Countermeasures for Thermal Burns. https://www.gao.gov/assets/590/588738.pdf. Accessed February 12, 2020.

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