Mallinckrodt Initiates Rolling Submission of Biologics License Application for StrataGraft® Regenerative Skin Tissue to U.S. Food and Drug Administration

April 6, 2020

- Application is Supported by Data from Pivotal Phase 3 Study for the Treatment of Deep Partial-Thickness Thermal Burns -

- StrataGraft Skin Tissue Could be a Potential New Treatment Option for Deep Partial-Thickness Thermal Burns, if Approved -

STAINES-UPON-THAMES, United Kingdom, April 6, 2020 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a leading global specialty pharmaceutical company, today announced that Stratatech, a Mallinckrodt company, has initiated the rolling submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking approval to market StrataGraft®, a regenerative skin tissue therapy, for the treatment of adult patients with deep partial-thickness thermal burns. StrataGraft skin tissue is an investigational product, and its safety and effectiveness have not yet been established by the FDA.

"This is a significant step forward. Approval of StrataGraft regenerative skin tissue therapy could be a potential new treatment option for patients with deep partial-thickness thermal burns," said **Steven Romano, M.D., executive vice president and chief scientific officer at Mallinckrodt**. "We look forward to working closely with the FDA during its review of the application for StrataGraft skin tissue once the submission is complete."

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 accepted for presentation at the American Burn Association 52nd Annual Meeting, with support from the STRATA2011 clinical trial, previously published in *Burns*.

A rolling submission allows the company to submit portions of the regulatory application to the FDA as they are completed.[1] Mallinckrodt expects to complete the submission of the BLA in the coming months.

The FDA 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.

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.

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 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.[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 extremely 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 future research plans and 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]U.S. Food and Drug Administration. "Guidance for Industry Expedited Programs for Serious Conditions - Drugs and Biologics." Available at https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf. Accessed February 6, 2020.
[2] https://www.gao.gov/assets/590/588738.pdf. Accessed February 12, 2020.

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