Mallinckrodt Receives U.S. Food and Drug Administration Label Update for StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen – dsat) Reducing Xenotransplantation Requirements

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– The FDA no longer restricts donation of human cells, tissues, cellular or tissue-based products, human milk, ova, sperm, or organs for transplantation for patients who receive StrataGraft –

– The FDA no longer requires Mallinckrodt, and ultimately hospitals, to collect or store blood samples or patient information –

DUBLIN – September 5, 2023 – Mallinckrodt plc (OTCMKTS: MNKTQ), a global specialty pharmaceutical company, today announced that after working with the U.S. Food and Drug Administration (FDA), the label for StrataGraft® has been updated to reflect FDA's determination that several xenotransplantation-related requirements are no longer warranted for commercially sold product and have been removed. StrataGraft is used for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated – known as deep partial-thickness (DPT) burns.

Please see Important Safety Information below.

The StrataGraft label update reflects FDA's acknowledgement of reduced xenotransplantation risks allowing recipients who otherwise meet donor requirements to be eligible to donate human cells, tissues, cellular or tissue-based products, human milk, ova, sperm, or organs for transplantation. In addition, Mallinckrodt's requirement to collect patient information and blood samples and to maintain a patient database has been waived, alleviating the patient burden of additional testing.

"We thank the FDA for working with us to update the StrataGraft label. This update will now allow burn surgeons to treat patients without many of the previous concerns around the xenotransplantation risks," said **Peter Richardson, MRCP UK, Executive Vice President & Chief Scientific Officer at Mallinckrodt**. "Burn surgeons will be able to provide StrataGraft as a potentially effective and less-invasive treatment option for more eligible patients with DPT burns."

Each year, more than 40,000 people in the U.S. require hospitalization as a result of a severe burn. Autologous skin grafting is the most common inpatient treatment for burns, and involves the surgical harvesting of healthy skin from an uninjured site on the patient and transplanting the skin graft to the injury, creating a donor site wound and leaving the patient with more wounded areas requiring care. Mallinckrodt's Evidence Generation and Data Sciences team estimates that of those requiring in-patient care annually, 6,000 – 10,000 are treated with autograft.

StrataGraft received FDA approval in 2021 as an innovative treatment option for appropriate patients who suffer DPT burns and is the first approved alternative to autograft for DPT burns that is donor site-free at application and handles like an autograft,1, taking a novel approach as a first-of-its-kind technology that supports the body's own ability to heal without harvesting.1 By avoiding the use of autografting, the patient circumvents the risk of donor site complications, including pain, itching, increased risk of infection and scarring.

For more information about StrataGraft, please visit StrataGraft.com.

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About StrataGraft
StrataGraft is a viable, bioengineered, allogeneic, cellularized scaffold product derived from keratinocytes grown on gelled collagen containing dermal fibroblasts. StrataGraft is designed to deliver viable cells to support the body's own ability to heal. StrataGraft contains metabolically active cells that produce and secrete a variety of growth factors and cytokines. Growth factors and cytokines are known to be involved in wound repair and regeneration. The product is designed with both dermal and epidermal layers composed of well-characterized human cells. StrataGraft is intended to be applied in appropriate aseptic conditions, such as the operating room, and can be sutured, stapled or secured with a tissue adhesive.

The FDA granted StrataGraft 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. At the time of approval, the FDA awarded Stratatech Corporation, a Mallinckrodt company, a Priority Review Voucher (PRV). The Biomedical Advanced Research and Development Authority (BARDA), which is part of the Office of the Assistant Secretary for Preparedness and Response under contract HHSO100201500027C has funded in part the development of StrataGraft.

INDICATION

StrataGraft is an allogeneic cellularized scaffold product indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

IMPORTANT SAFETY INFORMATION

Contraindications

- Do not use in patients with known allergies to murine collagen or products containing ingredients of bovine or porcine origin.

Warnings and Precautions

- **Potential Sensitivity:** StrataGraft contains glycerin. Avoid glycerin in patients with known sensitivity (irritant reaction) to glycerin.
- **Hypersensitivity Reactions:** Severe hypersensitivity reactions may occur. Monitor for both early and late symptoms and signs of hypersensitivity reaction following StrataGraft application, and treat according to standard medical practice.
- **Transmission of Infectious Diseases:** StrataGraft contains cells from human donors and may transmit infectious diseases or infectious agents, eg, viruses, bacteria, or other pathogens, including the agent that causes transmissible spongiform encephalopathy (TSE, also known as Creutzfeldt-Jakob disease [CJD] or variant CJD).

  StrataGraft is a xenotransplantation product because of a historic exposure of the keratinocyte cells to well-characterized mouse cells. The cell banks have been tested and found to be free of detectable adventitious agents, and mouse cells are no longer used in the manufacture of StrataGraft.

  StrataGraft was established to be free of detectable pathogens using FDA-recommended characterization procedures and tests including molecular and analytical testing. Transmission of infectious diseases or agents by StrataGraft has not been reported.

- **Donation of Blood, Organs, Tissues, or Cells:** Recipients of xenotransplantation products such as StrataGraft are generally not eligible to donate whole blood or blood components, including source plasma and source leukocytes. However, individual blood collection establishments may request an exception.

  StrataGraft recipients who otherwise meet donor requirements are eligible to donate human cells, tissues, cellular or tissue-based products (HCT/Ps), human milk, ova, sperm, or organs for transplantation.

Adverse Reactions

- The most common adverse reactions (incidence ≥2%) were itching (pruritus), blisters, hypertrophic scar, and impaired healing. Other adverse events reported are included in the full Prescribing Information.

Pediatric Use

- The safety and effectiveness of StrataGraft in pediatric patients (<18 years) have not been established.

Please click here to see full Prescribing Information for additional Important Safety Information.

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, hepatology, nephrology, pulmonology, ophthalmology, and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes 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 contains forward-looking statements, including with regard to StrataGraft, the expected benefits of its updated label and its potential impact on patients. 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: the impact of Mallinckrodt's pending Chapter 11 cases; satisfaction of, and compliance with, 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; competition; pricing pressure on Mallinckrodt's products; 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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