Mallinckrodt Announces Enrollment of First Patient in Phase 1/2a StrataSOMA Clinical Trial of StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat) for Investigating the Treatment of Full-Thickness Burns

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-- Company pursuing additional indication for FDA-approved product as part of clinical development program --

DUBLIN, Dec. 16, 2021 /PRNewswire/ -- Mallinckrodt plc (OTCMKTS:MNKKQ), a global biopharmaceutical company, today announced enrollment of the first patient in StrataSOMA, a Phase 1/2a clinical trial that is assessing StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen – dsat) for the investigational treatment of adults with third-degree full-thickness thermal burns.

In June 2021, the U.S. Food and Drug Administration (FDA) approved StrataGraft for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns). Development of StrataGraft has been funded in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201500027C. The StrataSOMA trial is not BARDA-supported. Please see Important Safety Information below.

"As we launch StrataGraft commercially, we are continuing our clinical development activities, which includes the StrataSOMA clinical trial, with the goal of seeking to expand the approved indication to include other patient populations with severe burns," said **Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt**. "For patients with full-thickness thermal burns, treatment options that may help reduce the amount of skin required for autografting are needed to help clinicians improve care and treatment management."

Each year, approximately 40,000 patients in the United States require hospitalization for the treatment of severe burns.[1] Third-degree full-thickness burns – skin injuries that destroy the epidermis (outermost layer of skin) and dermis (innermost layer of skin) – are treated with autografting.[2] This 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.[2]

About the StrataSOMA Clinical Trial

The open-label randomized, within-patient controlled multicenter Phase 1/2a clinical trial is evaluating the efficacy, safety and tolerability of StrataGraft overlay of meshed autograft in the investigational treatment of patients with full-thickness thermal burns. The study is expected to enroll 40 adults ages 18 to 75 with a 2% to 49% total body surface area (TBSA) thermal burn, including areas of full-thickness injury clinically indicated for surgical excision and autografting appropriate for protocol-defined treatment areas.[3] All study participants will serve as their own control. On each participant, similar wounds will be identified as treatment sites and will be randomized to receive either meshed autograft or meshed autograft with StrataGraft. Primary outcomes include complete wound closure without additional autografting at Month 2 and durable wound closure without additional autografting at Month 12. The trial is underway in several locations in the U.S. and additional sites may be added.[3]

Additional study details can be found at clinicaltrials.gov (NCT04765202).

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).

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

- StrataGraft contains glycerin. Avoid glycerin in patients with known sensitivity (irritant reaction) to glycerin.
- 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.
- 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 an 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 not used in the manufacture of StrataGraft; however, these measures do not entirely eliminate the risk of transmitting infectious diseases and disease agents.

  Transmission of infectious diseases or agents by StrataGraft has not been reported.
- Because StrataGraft is a xenotransplantation product, StrataGraft recipients should not donate whole blood, blood components, plasma, leukocytes, tissues, breast milk, ova, sperm, or other body parts for use in humans.

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 see full Prescribing 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, 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, including clinical trial plans and potential outcomes, 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.

CONTACTS

Media Inquiries
Ben Rickles
Real Chemistry
404-502-6766
brickles@realchemistry.com

Investor Relations
Daniel J. Speciale
Vice President, Finance and Investor Relations
daniel.speciale@mnk.com

[1] American Burn Association. Burn Incidence Fact Sheet. http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/. Accessed November 24, 2021.

[2] Sinha S, Schreiner AJ, Biernaskie J, Nickerson D, Gabriel VA. Treating pain on skin graft donor sites: review and clinical recommendations. *J Trauma Acute Care Surg*. 2017;83(5):954-964

[3] ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04765202. Accessed December 13, 2021.

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