StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat) – New orphan drug approval

- On June 15, 2021, the FDA announced the approval of Mallinckrodt's StrataGraft (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat), for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

- For many deep burns, treatment frequently involves the removal of the damaged, burned skin and replacement with a skin graft. Skin grafts are often the patient's own healthy skin taken from their body and moved to the burned area to help it heal. This procedure, called an autograft, leaves a new wound where the healthy skin was removed.

    - StrataGraft is produced from two kinds of human skin cells (keratinocytes and dermal fibroblasts) grown together to make a bi-layered construct (a cellularized scaffold).

- The efficacy of StrataGraft was established in two randomized, open-label, intrapatient-controlled studies in 101 adult patients with thermal burns. In both studies, two comparable wound sites of each patient were selected and randomized to receive either topical application of StrataGraft or autograft. Autografts served as the intrapatient control.

    - In study 1, the difference in the percent area of StrataGraft and control autograft treatment sites that required autografting by 3 months was 98% ± 17% ($p < 0.0001$). The proportion of patients achieving durable closure of the StrataGraft treatment site at 3 months without autograft placement was 83% (95% CI: 74, 92). The proportion of patients achieving durable closure of the autograft control treatment site at 3 months without additional autograft placement was 86% (95% CI: 78, 94).
    - In study 2, no StrataGraft treatment site required autografts by 28 days. At 3 months, 93.1% of StrataGraft treatment sites and 100% of autograft treatment sites achieved complete wound closure. All StrataGraft treatment sites that achieved complete wound closure at 3 months remained closed when evaluated at 6 months and 12 months after treatment.

- StrataGraft is contraindicated in patients with known allergies to murine collagen or products containing ingredients of bovine or porcine origin.

- Warnings and precautions for StrataGraft include potential sensitivity; hypersensitivity reactions; transmission of infectious diseases; and donation of blood, organs, tissues, or cells.

- The most common adverse reactions (≥ 2%) with StrataGraft use were itching, blisters, hypertrophic scar, and impaired healing.

- StrataGraft is for topical application to a prepared wound bed (excision/debridement). A StrataGraft construct may be trimmed to fit the shape and size of the wound area. The surface area of StrataGraft to be applied should be equal to the surface area of the wound to be treated.

    - StrataGraft is applied in appropriate aseptic conditions by a trained healthcare provider.

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- Mallinckrodt's launch plans for StrataGraft are pending. StrataGraft will be available as a rectangular sheet of approximately 100 cm^2.