Scioderm's SD-101 Receives Breakthrough Therapy Designation from FDA for Treatment of Epidermolysis Bullosa

Breakthrough Therapy designation is based on positive data in patients across inherited EB subtypes

DURHAM, N.C., April 29, 2013 /PRNewswire-iReach/ -- Scioderm announced its investigational product SD-101 has received Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with inherited Epidermolysis Bullosa (EB). SD-101 is Scioderm's investigational therapy that is being evaluated for the treatment of skin blistering and erosions associated with this disease, including facilitation of healing of skin lesions and reduction of the incidence and/or severity of new lesions.

(Photo: http://photos.prnewswire.com/prnh/20130429/CG03170)

"We are truly honored to have received Breakthrough Therapy designation for SD-101 and are pleased with the FDA's decision to place our product in a category that may enable expedited development and review for patients with Epidermolysis Bullosa," said Robert Ryan ., Ph.D., President and Chief Executive Officer of Scioderm. "Given the recent important milestones for Scioderm, including the Series A closing along with this designation, we are looking forward to the opportunity to collaborate more closely with the FDA and potentially expedite the availability of an important new treatment option for patients with a disease that has no current effective treatment."

Breakthrough Therapy Designation was enacted as part of the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA). The designation of an investigational drug as a Breakthrough Therapy is intended to expedite the development and review of a candidate that is planned for use to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A breakthrough therapy designation conveys all of the fast track program features, as well as more intensive FDA guidance on an efficient drug development program. The FDA also has an organizational commitment to involve senior management in such guidance.

The FDA Breakthrough Therapy Designation for SD-101 in EB patents was based on clinical data from a previously conducted open-label Phase II study with topical administration of SD-101 in children with either Simplex, Recessive

Dystrophic (RDEB), or Junctional EB. SD-101 has the potential to facilitate the healing of skin lesions and erosions in this serious and potentially life-threatening disease which has a poor prognosis.

Epidermolysis Bullosa

Epidermolysis Bullosa (EB) is a rare genetic connective tissue condition that, in all of its forms, share the prominent manifestation of extremely fragile skin that blisters or tears with the slightest friction or trauma. This particular manifestation has led to EB patients being known as "Butterfly children" due to the analogous nature of the fragility of the skin to the wings of a butterfly. As of today there is no cure or effective treatment. Daily wound care, pain management and preventative bandaging are the only options available for caregivers, who are usually the parents or other family members. The more severe forms of the disease lead to scarring, disfigurement, disability and early death, usually before the age of 30.

About SD-101

SD-101 is a topical cream that has previously demonstrated potential to provide improvement in treating the severe skin effects seen in patients across all EB subtypes. An open-label Phase II study was conducted previously in children with either Simplex, Recessive Dystrophic (RDEB), or Junctional EB. The primary outcome measurements were assessment of target wound reduction and closure, and reduction in body surface area (BSA) coverage of lesions and erosions. In the clinical trial, SD-101 application resulted in complete closure of 88% of target chronic lesions within one month, in addition to a 57% reduction in BSA coverage of lesions and erosions after 3 months of daily treatment. SD-101 was well tolerated by the children, with daily administration up to 3 months.

About Scioderm

Scioderm is a privately held, clinical-stage pharmaceutical company focused on developing topical products to address critical medical needs in the treatment of chronic skin diseases. The company is headquartered in Durham, North Carolina. Additional information about Scioderm can be found at www.sderm.com.

Scioderm Forward Looking Statement

Except for the historical information contained herein, the matters discussed in this press release are forward-looking statements that involve risks and uncertainties, including: our dependence on third parties for the development, regulatory approval and successful commercialization of our products, the inherent risk of failure in developing product candidates based on new technologies, risks associated with the costs of clinical development efforts, as well as other risks. Actual results may differ materially from those projected. These forward-looking statements represent our judgment as of the date of the release. Scioderm disclaims any intent or obligation to update these forward-looking statements.

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