Paradigm Therapeutics, Inc. Announces First Patient Enrolled in Phase 3 Trial for SD-101 (Zorblesiaâ?¢) in Epidermolysis Bullosa

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SD-101 (Zorblesiaâ?¢) is the First Topical Therapy Being Developed to Treat Wounds and Lesions Across the Entire Skin Surface in Patients with Three Major Subtypes of Epidermolysis Bullosa

MOUNT PLEASANT, S.C., Oct. 22, 2026 /PRNewswire/ â?? Paradigm Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on developing innovative treatments for rare diseases, today announced that the first patient has been enrolled in its Phase 3 clinical trial (SD-007) evaluating SD-101 (Zorblesiaâ?¢), an investigational topical cream for the treatment of chronic wounds and skin lesions associated with epidermolysis bullosa (EB).

EB is a rare genetic disorder characterized by fragile skin that blisters and tears easily, often beginning at birth or during early childhood. The condition can cause chronic wounds, pain, itching, infections, and scarring, placing a substantial burden on patients and their families.

The SD-007 study is a multicenter, prospective, randomized, double blind, placebo-controlled trial designed to evaluate the efficacy and safety of SD-101 in patients with EB simplex (EBS), recessive dystrophic EB (RDEB), and junctional EB (JEB). The study will assess the closure of selected chronic target wounds, changes in the body surface area affected by wounds and lesions, and improvements in itching.

Approximately 80 patients aged 28 days to 12 years old are planned for enrollment at 17 clinical sites across 14 countries, spanning North America, South America, Europe, Asia, and Australia. Participants will apply SD-101 cream or the study comparator daily over the entire body for two months, according to the study protocol. Patients who complete SD-007 will be eligible to participate in a subsequent study, SD-008, providing an opportunity for continued treatment.

Additional information about the SD-007 study is available at www.paradigmtherapeutics.com.

â??People living with EB can experience skin blistering, chronic wounds, persistent pain and itching, infections, and scarring,â?• said Robert Ryan, Ph.D., President and Chief Executive Officer of Paradigm Therapeutics. â??Available treatment options have important limitations, and there remains a significant unmet need for therapies designed to address the widespread skin involvement associated with EB. We believe SD-101 has the potential to offer a different approach by targeting wounds and lesions across the skin surface in patients with EB simplex, recessive dystrophic EB, and junctional EB.â?•

Dr. Ryan added, â??Initiating this Phase 3 study is an important milestone in the development of SD-101 (Zorblesiaâ?¢). Results from our completed Phase II and Phase III clinical studies support continued evaluation of daily, whole-body application, including its potential to promote target-wound closure and reduce the overall area of skin affected by lesions. We are committed to completing the development program and advancing SD-101 toward potential regulatory approval, with the goal of expanding treatment options for patients and families affected by this debilitating disease. We are also working with potential partners to support the therapyâ??s future global development and availability.â?•

â??Eshelman Ventures is honored to invest in Paradigm Therapeutics and support the advancement of SD-101 as a potential new treatment for epidermolysis bullosa,â?• said Dr. Fred Eshelman of Eshelman Ventures, LLC. â??The significant daily challenges faced by individuals living with EB and their families underscore the urgent need for additional treatment options. We are proud to support Paradigmâ??s efforts to advance this program and work toward improving the lives of patients affected by this devastating condition.â?•

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About SD-101 (Zorblesiaâ?¢) Clinical Development

SD-101 (Zorblesiaâ?¢) is an investigational topical cream designed for daily application across the skin surface. The formulation can be stored at room temperature and does not require specialized clinical handling, potentially supporting practical use in patients and caregivers.

SD-101 has been evaluated in completed Phase II and Phase III clinical studies involving a total of 217 pediatric and adult patients with EB simplex, recessive dystrophic EB, or junctional EB, including very young infants. In these studies, SD-101 was applied daily over the entire body for three months. The clinical development program has evaluated wound closure, changes in the extent of skin involvement, and safety.

Based on the results of these studies, Paradigm is conducting the SD-007 trial to further evaluate the efficacy and safety of SD-101. Patients completing SD-007 may be eligible to continue treatment in SD-008.

SD-101 has received Rare Pediatric Disease, and Orphan Drug designations. These designations support the development of treatments for serious or rare conditions but do not constitute marketing approval. Upon regulatory approval, Paradigm will be eligible to receive a Priority Review Voucher (PRV).

Paradigm has selected Kapadi, a clinical research organization (CRO), to support management of the global Phase 3 study.

About Epidermolysis Bullosa (EB)

Epidermolysis bullosa is a group of rare genetic disorders characterized by exceptionally fragile skin that blisters and tears in response to minor friction or trauma. Symptoms often begin at birth or in early childhood and can persist throughout a patientâ??s lifetime.

Depending on the subtype and severity, EB can cause extensive skin blistering, open wounds, pain, itching, infections, scarring, and other serious complications. The disease can significantly affect mobility, daily activities, and quality of life for patients and their families. Severe forms can be life-threatening.

Although treatment options have advanced, substantial unmet medical needs remain, particularly for therapies designed to address widespread wounds and lesions across the skin surface and to serve patients across multiple EB subtypes.

About Paradigm Therapeutics, Inc.

Paradigm Therapeutics, Inc. is a privately held, clinical-stage biopharmaceutical company focused on developing innovative therapies for rare diseases with significant unmet medical needs. The companyâ??s lead program, SD-101 (Zorblesiaâ?¢), is an investigational topical therapy being developed to address the skin manifestations of epidermolysis bullosa. Following the completion of Phase II and Phase III clinical studies, Paradigm is advancing a clinical development program to further evaluate SD-101â??s efficacy and safety.

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About Kapadi

Kapadi is a global CRO focused on oncology and cell and gene therapy clinical development. With a presence across North America, Europe, Asia, and Australia, Kapadi helps biopharma sponsors accelerate complex clinical programs through scientific expertise, regulatory excellence, and technology-enabled operations.

About Eshelman Ventures, LLC

Eshelman Ventures, LLC is an investment fund founded by Dr. Fred Eshelman that focuses on innovative healthcare, life sciences, and biopharmaceutical companies with the potential to transform patient care and address severe unmet medical needs.

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. Paradigm disclaims any intent or obligation to update these forward-looking statements.

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