

# Paradigm Therapeutics

## Category:

Best Startup

## Company Name:

Paradigm Therapeutics

## Turnover and/or Funding:

Paradigm Therapeutics, Inc., a biopharmaceutical company, received two financial investments by Eshelman Ventures, LLC in 2025 of a total of \$25.1 Million. SD-101 (Zorblisa™) is being developed as a topical whole-body treatment for all subtypes of Epidermolysis Bullosa (EB) patients. The investments will be used to accelerate activities associated with the anticipated global filings and commercial launch of the SD-101 program globally, including manufacturing and regulatory activities.

## Sub-Category:

Biotechnology

## Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):

Paradigm Therapeutics is a Charleston, South Carolina based biotechnology company developing an innovative therapy, designated as SD-101 (Zorblisa™), as a topical chronic whole skin surface topical treatment for the cutaneous manifestations observed in patients across all subtypes of Epidermolysis bullosa (EB). In EB, the skin is extremely fragile which leads to shearing of the skin resulting in a high risk of infection. EB is a disease that manifests at birth where infection leading to sepsis and death is a tremendous risk especially during the first year of life. Children with EB have a decreased life expectancy in severe cases. Treating earlier in patients with an immature immune system should be beneficial to patients and further reduce the risk of infection and possible death due to sepsis. EB affects both genders and all racial and ethnic groups equally throughout the world. Paradigm has received two investments by Eshelman Ventures, LLC bringing the total investment in 2025 for Paradigm Therapeutics to \$25.1 Million.

Epidermolysis bullosa is a rare, devastating, genetic disorder manifesting typically at birth comprising several genetic subtypes that manifest as blistering or erosion of the

skin in response to little or no apparent trauma. EB impacts the entire surface of the skin, and it is a chronic disease where the skin remains defective in terms of the anchoring fibers involved in maintaining stability of the various skin layers. As a chronic condition, it is important to have a chronic treatment that can be used as early in life as possible and continuing throughout the patient's life to treat the whole skin surface and impact not only the closure of wounds, but also the reduction of lesions which include blistering of the skin surface. In EB, one of the major morbidities is the tendency to develop chronic wounds, which predisposes patients to multiple complications including life-threatening infections, sepsis, failure to thrive and squamous cell carcinoma.

SD-101 (Zorblisa™) was the first biotech therapy to receive Breakthrough Therapy designation from the FDA. This is the only therapy being developed to treat the entire skin surface of patients across all subtypes of EB. SD-101 has been evaluated in completed Phase 2 and Phase 3 clinical studies in patients (ranging in age from 1 month to adult). In addition, long term safety of the product has been established in EB patients, with average daily usage in excess of 2 years. SD-101 has demonstrated in clinical trials the benefits of treating the entire skin surface resulting in reduction in whole body wound burden and lesions, accelerating wound closure, improvement in itching, and reduction in skin infections.

EB is a global disease with genetic mutations manifesting across all racial and ethnic groups, and both genders with similar prevalence. Current estimates suggest the following prevalence in the different regions of the world:

- US: Estimate 20,000-50,000 patients
- Europe: Estimate 50,000-80,000 patients

Globally the prevalence is estimated to be about 500,000 for patients with EB.

## **History of the development of the solution/product (Intellectual Property, preclinical and clinical data, development collaborations):**

SD-101 (Zorblisa™) has been in development since 2013, originally under the direction of the founder, Dr. Robert Ryan and now under the continued direction of Dr. Robert Ryan under the company Paradigm Therapeutics. It is the only therapy being developed to treat patients across all subtypes of EB, in addition to the only treatment that treats the entire skin surface of patients. SD-101 has been evaluated in completed Phase 1, Phase 2 and Phase 3 clinical studies in patients (ranging in age from 1 month to adult). In addition, long term safety of the product has been established in EB patients, with average daily usage in excess of 2 years.

SD-101 is a chronic EB therapy being developed to treat the entire skin surface of EB

patients from birth and older, across the 3 major EB subtypes (Simplex, Junctional and Recessive Dystrophic) and has demonstrated in clinical trials the added benefits of treating the entire skin surface resulting in reduction in whole body wound burden and lesions, accelerating wound closure, improvement in itching, and reduction in skin infections. SD-101-6.0 has demonstrated both safety and efficacy in patients 1 month and older and treating earlier in patients with an immature immune system than these other therapies should be beneficial to patients and further reduce the risk of infection and possible death due to sepsis.

The following clinically significant benefits of topical whole-body administration of SD-101 to patients from neonates to adults with Simplex, Recessive Dystrophic or Junction EB are summarized below:

- Increased target wound closure
- Accelerated time to target wound closure within 2 weeks
- Reduction in whole body wound body surface area and reduction in whole skin surface lesional skin
- Reduction in whole body skin infections
- Improvement in itching across the entire skin surface
- Whole body skin surface topical treatment
- Long term chronic usage safety established with SD-101 treatment in patients from birth to adults, with no evidence of systemic absorption

### **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:**

EB is one of the most devastating genetic diseases that manifests typically at birth. There are several characteristics of EB that are common across all subtypes:

- Wounds that would typically be acute and healing in a short timeframe in healthy people become chronic in EB patients by a common theme of disruption of the wound healing cascade.
- With the exception of localized EBS (Weber-Cockayne), the defects in the anchoring fibrils are comparable across the entire skin surface in all EB subtypes resulting in blistering and wound formation across the entire skin surface.
- Clinical manifestations visible typically at birth and occur throughout life, i.e. a chronic disease.

SD-101 (Zorblisa™) was developed to treat and impact the entire skin surface in EB patients across all subtypes. There are currently no products approved or in development that treat the entire skin surface of patients with EB, where acute and chronic open wounds are one of the major morbidities which predisposes patients to multiple complications including life-threatening infections, sepsis, failure to thrive and later development of squamous cell carcinoma.

Several topical therapies have been developed to treat EB, including some recent approvals. However, their primary focus has been treating a single wound typically in only one subtype which doesn't benefit the patient across the entire skin surface.

There have been several studies conducted and published interviewing EB patients and caregivers regarding treatments needed for aspects of the disease that are meaningful to both the patient and caregivers. These surveys and interviews have focused on patients at different stages of disease and levels of disease severity. The following study results have demonstrated that there are needed therapeutic options for treating various manifestations of the disease across the entire skin surface. These studies highlight important treatments needs by patients for various manifestations of EB, which are addressed and supported by the multi-faceted impact of treatment with SD-101 across the entire skin surface of patients across the 3 major Eb subtypes, across patient ages ranging from neonates to adults, and across patients with various levels of severity of the disease.

Respondents were asked to identify the most important factors for a future approved prescription treatment option, and the top 5 responses among patients and caregivers were the same:

- o Reducing the risk of skin cancer (77.8 and 86.0%, responses patients and caregivers)
- o Reducing the number and severity of wounds (73.0 and 87.1%, responses patients and caregivers),
- o Reducing pain (73.0 and 78.5%, responses patients and caregivers),
- o Accelerating wound healing/closure (71.4 and 80.6%, responses patients and caregivers), and
- o Reducing risk of infection (69.8 and 76.3%, responses patients and caregivers).

Addressed with demonstrated benefit with SD-101 (Zorblisa™) treatment:

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- o Reducing risk of infection (69.8 and 76.3%, responses patients and caregivers).

**Please provide appropriate references (PubMed, Abstract, Website):**

[www.paradigmtherapeutics.com](http://www.paradigmtherapeutics.com)

**References File Document upload:**

**NonConfidential Presentation Paradigm Rare Disease Therapy June 2025.pdf**

**Zorblisa\_HighRes paradigm therapeutics.jpg**