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Itch Reduction and Quality of Life Improvement in AD for First Human Use of Zabalfin

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Introduction & Objectives:

The main patient-related concern in atopic dermatitis (AD) is persistent, disrupting itch (pruritus). Itch relief leads to improvement in quality of life (QOL) for AD patients. An unmet need exists for an AD drug without restrictions on long-term continuous use that provides a strong improvement in pruritus and QOL, treats inflammation and bacteria to control bacteria-associated AD flares, treats infected AD, and is worry-free for extended use in children and adults. Current AD drugs have shortcomings in efficacy, pain/stinging and/or boxed warnings. Zabalafin (AB-101) is a novel, topical first-in-class multi-target therapeutic natural source drug with multiple bioactive compounds providing multiple mechanisms of action including antipruritic, anti-inflammatory, and antibacterial activity, indicating zabalafin should be effective in AD.

This first-in-human Phase 2 study was designed to assess the itch and QOL improvement and the safety and efficacy of zabalafin hydrogel against the inflammatory and bacterial components of AD.

Materials & Methods:

All participants entered uniquely with secondary infected AD as determined by the Secondary Infection Rating Scale (SIRS) and investigator clinical judgment and were assessed for infection and AD response, including itch and QOL improvement. Investigators were queried for clinical assessment of infection resolution.

Population included mild, moderate, and severe AD in ages 3 through adult. Participants received zabalafin BID 8 weeks open label. Participants returned for evaluation at multiple visits throughout the trial for assessments.

Itch relief was assessed using the Pruritus Numeric Rating Scale (NRS), where decrease of ≥ 4 points at end of treatment (EOT) is considered clinically meaningful. QOL was assessed using Patient Oriented Eczema Measure (POEM), where decrease of ≥6 points at EOT is considered clinically meaningful. AD assessment scales including EASI and IGA were used to evaluate inflammatory response.

Results:

Interim results for 10 participants are reported with 7 participants age 3-17; 3 age 18-45. All participants began with AD lesions secondarily infected. Zabalafin effectiveness in treating AD inflammation and infection was demonstrated using EASI, IGA and SIRS in all age groups. Pruritis NRS score reduction of ≥4 was achieved in 8/10 participants (80%, baseline score = 8 out of 10) at EOT. Itch reduction was demonstrated both in immediacy of onset and long term. POEM score reduction of ≥6 was achieved in 10/10 participants (100%, baseline = 18.6 out of 28) at EOT.

Conclusion:

These results for zabalafin suggest its capability to be an effective treatment of both non-infected AD and AD with secondary bacterial infection. Zabalafin demonstrated clinically meaningful results in pediatric and adult

populations for itch and QOL improvement. Zabalafin is a promising unique topical AD drug for children and adults with the potential for limitless long-term continuous use.