

INM-755 Cannabinol Cream Demonstrates Anti-itch Activity in Patients with Epidermolysis Bullosa

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BACKGROUND

Epidermolysis bullosa, or EB, is a group of rare genetic skin diseases characterized by fragile skin that can lead to extensive blistering and wounding.

Two recent surveys among patients with EB in North America reported that itch was their most bothersome symptom followed by pain. The severity of itch varied by type of EB and was highest in those with recessive dystrophic EB, the most severe subtype.^{a,b}

OBJECTIVES

- To evaluate the safety of INM-755 in patients with EB.
- To obtain preliminary evidence of efficacy of INM-755 cream on wound (W) and non-wound (NW) affected skin areas in patients with EB.

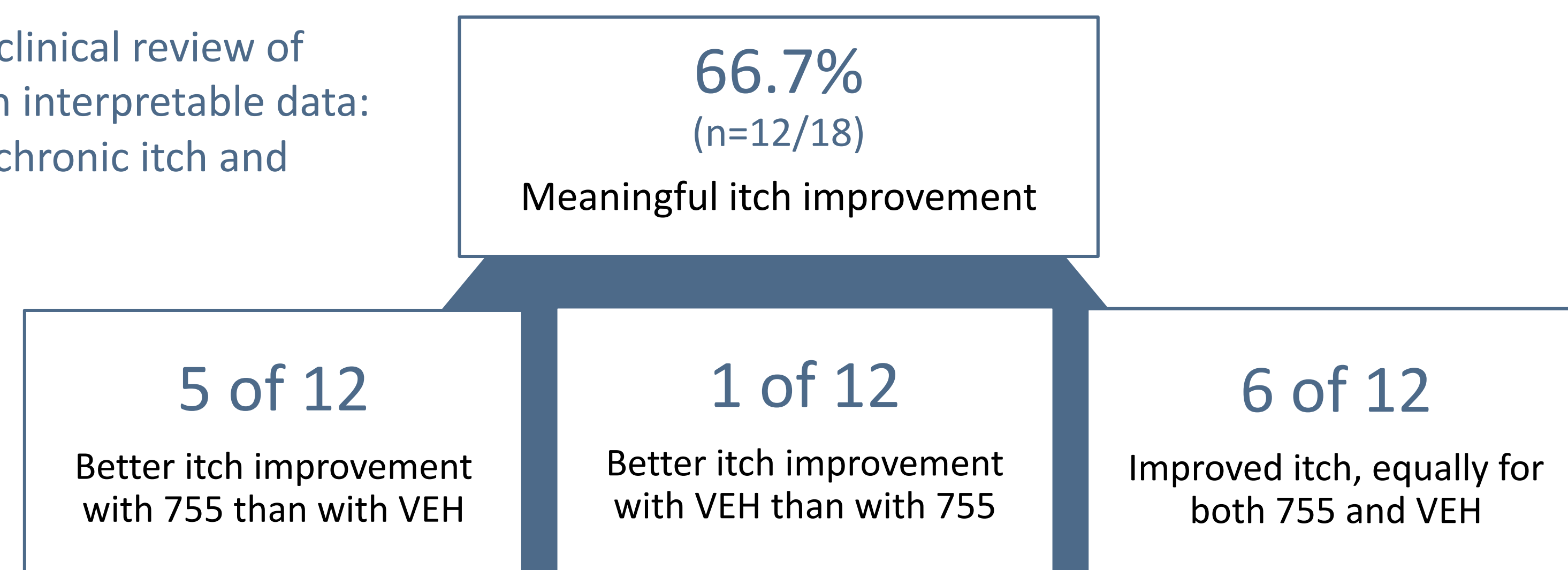
CLINICAL TRIAL DESIGN

A within-patient (WP), double-blind design in which matched index areas were randomized to INM-755 (cannabinol) cream or Vehicle cream (VEH) as a control for 28 days of treatment. A WP double-blind study design supports a valid comparison of treatments in each individual patient.

Enrolled 19 patients: 11 females; 12-72 years, median 31. All genetic subtypes of EB were enrolled: 4 EB Simplex, 2 Junctional EB, 2 Dominant Dystrophic EB, 9 Recessive Dystrophic EB and 2 Kindler EB. 18 patients had NW index areas, 2 had W index areas, 1 had both.

RESULTS

An exploratory clinical review of 18 patients with interpretable data: 17 non-wound chronic itch and 1 wound itch.

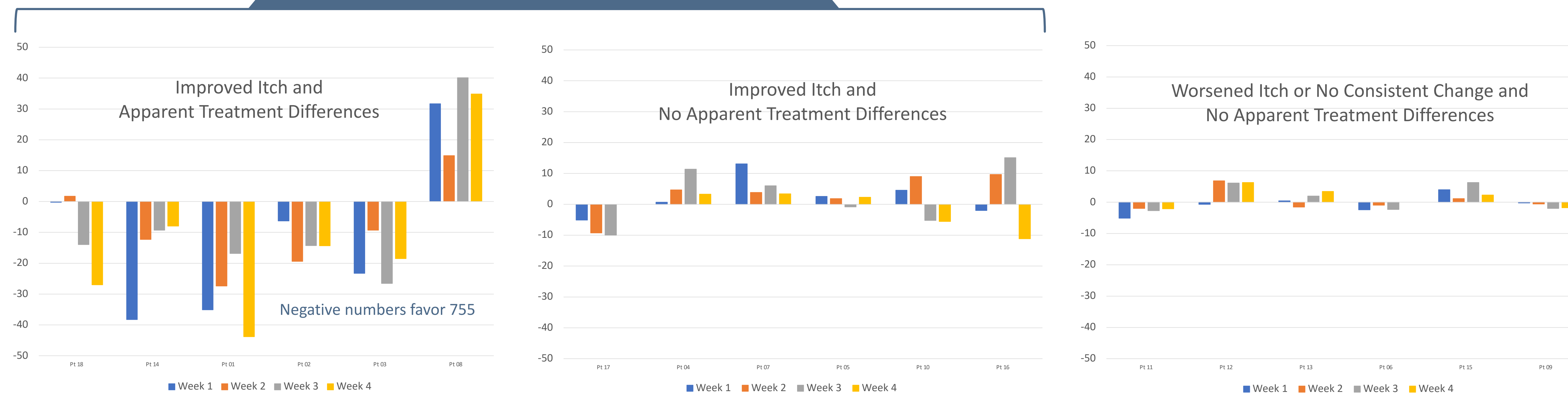


5 patients (27.8%) had better itch improvement with 755 than with VEH

At maximal improvement, the mean change from baseline was **-52 mm** for 755 and **-21 mm** for VEH for these 5 patients

Safety Results

- Few local adverse events in 3 treated areas (755) vs 2 (VEH). Eczema, erythema, pruritus considered possibly related to 755 and VEH
- At Baseline: ~2/3 NW index areas with erythema, scaling and ~1/3 with edema, stinging/burning sensation. **Immediate calming effect of the study creams on pre-existing severe signs or symptoms**
- 755 was very well tolerated on sensitive EB skin



Within-Patient Treatment Difference in Itch Visual Analogue Scale (VAS mm) Change From Baseline (755 – VEH)

- Itch scored daily by patient using 0-100 mm VAS
- Inclusion criterion: Itch ≥ 40 mm on VAS
- The minimal clinically important difference for patients with moderate itch at baseline was reported in the literature to be 13.4 mm on 100 mm VAS.^c

No statistically significant differences between 755 and control cream due, in part, to the anti-itch effect of the underlying control cream.

CONCLUSIONS

- INM-755 (cannabinol) cream was safe on sensitive EB skin.
- INM-755 (cannabinol) cream demonstrated reasonable anti-itch activity in 28% of the study cohort.
- Further development of INM-755 (cannabinol) cream as an anti-itch therapy is warranted.

References

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