

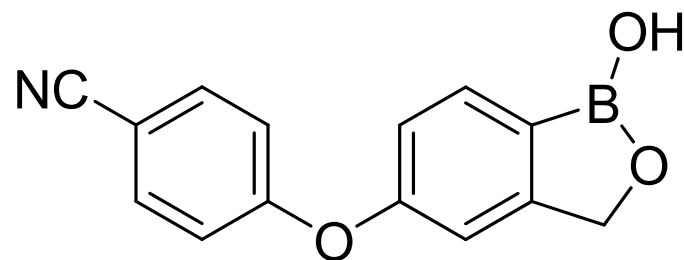
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AN2728 Demonstrates Significant Efficacy in
Three Phase Ib Psoriasis Microplaque Trials

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Background



- AN2728 (5-(4-cyanophenoxy)-1,3-dihydro-1-hydroxy-2,1-benzoxaborole) is a novel broad spectrum anti-inflammatory compound that inhibits the release of TNF- α , IL-12, IL-23, and other cytokines.

Study Objective

- To evaluate the anti-psoriatic activity of AN2728 in multiple topical formulations and concentrations using a psoriasis plaque test (microplaque assay)

Psoriasis Plaque Test (Microplaque Assay)



Up to six test articles are applied to a psoriatic plaque under occlusion

Baseline



Day 12



Study Design

Design:

- Treatment allocation: Randomized
- Blinding: Single (observer)
- Comparators: Vehicle, Betamethasone valerate, Tacrolimus

Intervention:

- AN2728 in multiple dosage forms and concentrations
- QD dosing under occlusion; 10 times over 12 days

Outcomes: assessed daily

- Thickness of inflammatory infiltrate by ultrasound
- Dynamic clinical scoring (-1, worsened to 3, completely healed)

Population:

- 12 adult (≥ 18 yrs) males with chronic plaque-type psoriasis

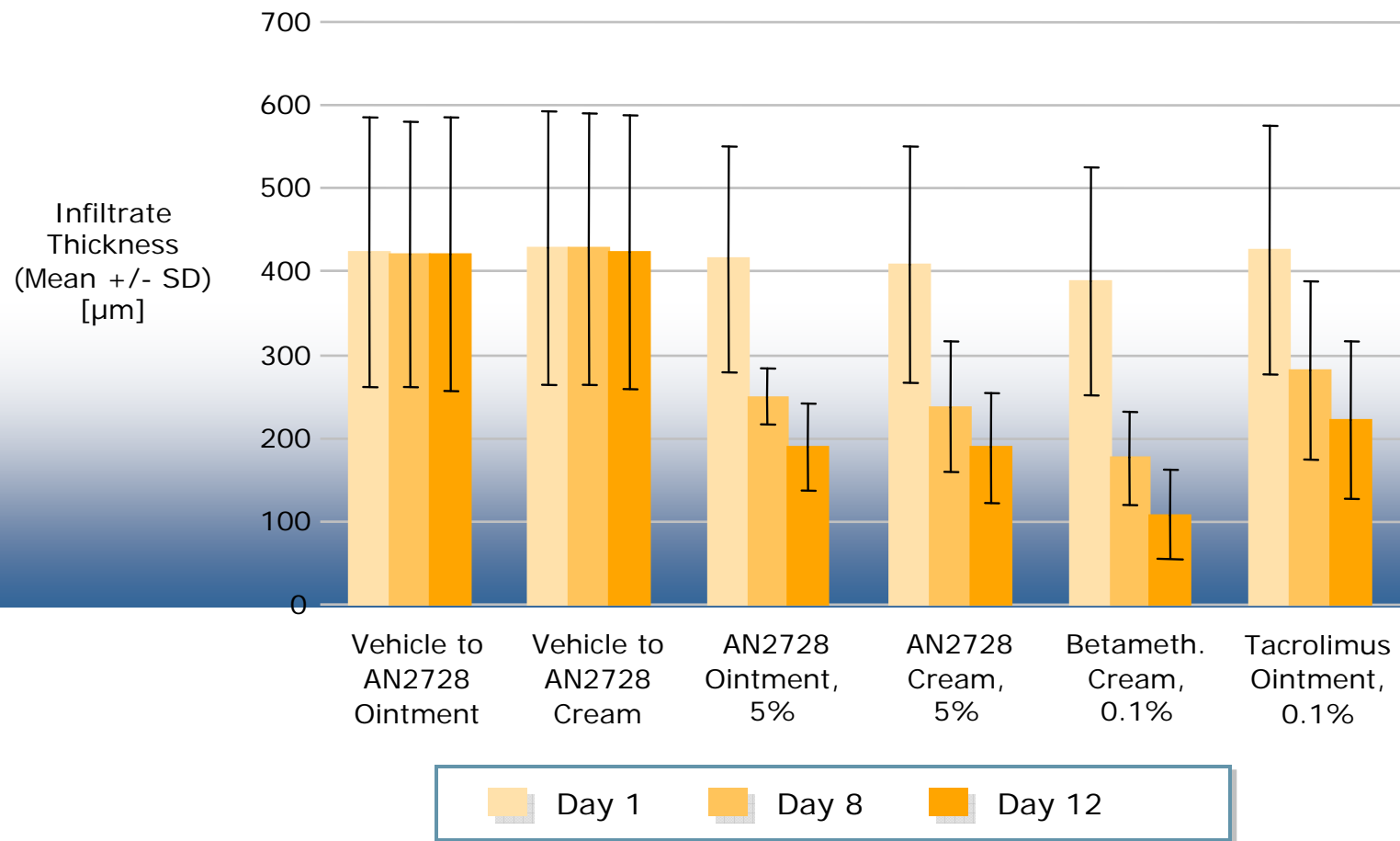
Microplaque I: Cream 5% and Ointment 5%

- Test articles

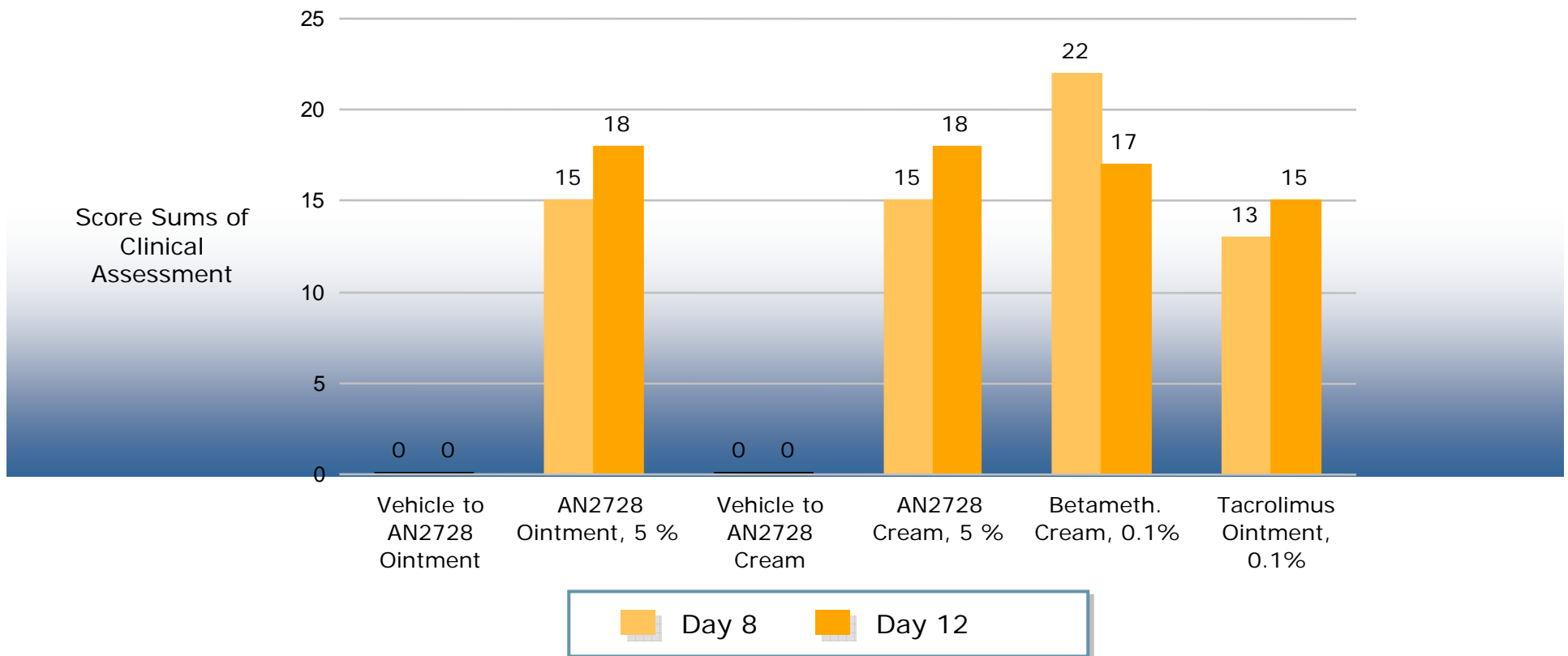
- AN2728 Cream, 5%
- Cream vehicle
- AN2728 Ointment, 5%
- Ointment vehicle
- Betamethasone valerate cream, 0.1%
- Tacrolimus ointment, 0.1%

5% Ointment and 5% Cream Demonstrated Significant Improvement Over Vehicle ($p=.02$)

Plaque Thickness [μm]



Clinical Assessment Demonstrated a Comparable Response with All Active Arms



Score: -1 = Worsened
 0 = Unchanged (No Effect)
 1 = Slight Improvement
 2 = Clear Improvement but Not Completely Healed
 3 = Completely Healed

For 12 Subjects per Group the Maximum Score Is 36

Microplaque II: Dose-Ranging Ointment

- Test articles

- AN2728 Ointment, 5%

- AN2728 Ointment, 2%

- AN2728 Ointment, 0.5%

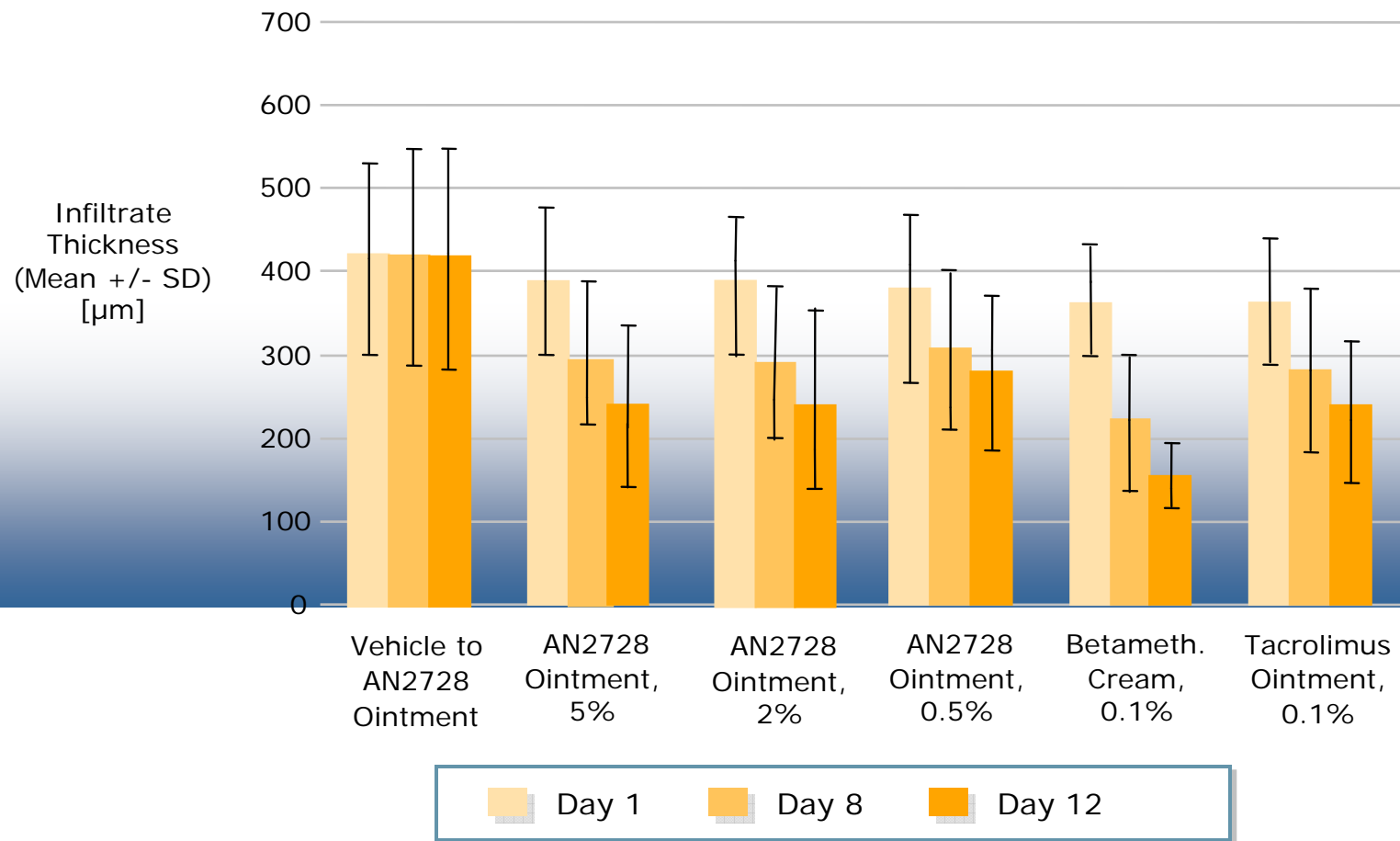
- Ointment vehicle

- Betamethasone valerate cream, 0.1%

- Tacrolimus ointment, 0.1%

All Three Ointment Dose Levels Demonstrated Significant Improvement Over Vehicle ($p < 0.002$)

Plaque Thickness [μm]



Microplaque III: Dose-Ranging Cream

- Test articles

- AN2728 Cream, 2%

- AN2728 Cream, 1%

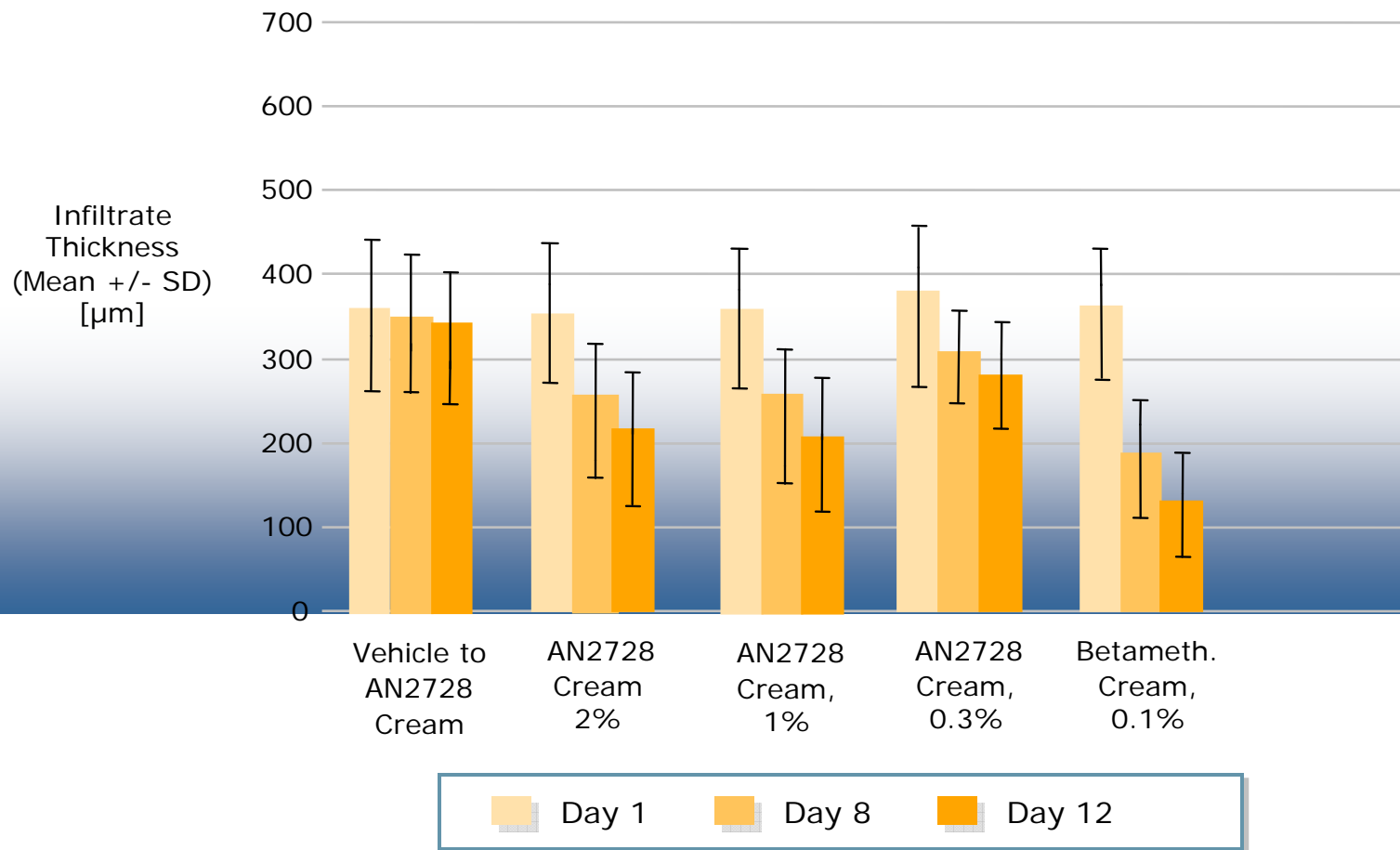
- AN2728 Cream, 0.3%

- Cream vehicle

- Betamethasone valerate cream, 0.1%

2% and 1% AN2728 Cream Demonstrated Significant Improvement Over Vehicle ($p=0.0002$)

Plaque Thickness [μm]



Conclusion

- AN2728 in both ointment and cream dosage forms demonstrates significant anti-psoriatic activity in the microplaque assay