Efficacy, Tolerability and Safety of SB204 Gel in Adolescents (9 to 17 Years of Age) With Acne Vulgaris

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Introduction

• SB204, a nitric oxide-releasing topical drug candidate, is in development for the treatment of acne vulgaris.
• SB204 was previously evaluated in multiple-center, randomized, double-blind, vehicle-controlled, parallel-group, phase 2 trials in acne (AC301 and AC302).
• Acne vulgaris is a common skin disease in adolescents.
• A post hoc analysis was conducted on a subset of 905 adolescents ranging from ages 9 to 17 years old.
• SB204 has potential immunomodulating and broad-spectrum antimicrobial activity.

Immunomodulatory Activity of Nitric Oxide in Acne

Nitric oxide inhibits the NLRP3 inflammasome, decreasing the downstream release of IL-1β and IL-17, as well as, klf4 IP3.

Study Overview

Demographics

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<tr>
<th>Gender</th>
<th>n</th>
<th>Male</th>
<th>Female</th>
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<tbody>
<tr>
<td>Age, years</td>
<td></td>
<td>0-9</td>
<td>10-12</td>
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<tr>
<td>Baseline, mean (SD)</td>
<td></td>
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<td>Sex</td>
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Tolerability Results

The percent change from baseline in the number of total lesions was statistically significant reduction (p<0.05) in inflammatory, non-inflammatory and total lesion reductions for SB204 compared to vehicle. The percent change from baseline in the number of non-inflammatory lesions was -33.4% for SB204 and -24.2% for vehicle (p=0.0013). The percent change from baseline in the number of inflammatory lesions was -34.1% for SB204 and -36.4% for vehicle (p=0.0117). The percent change from baseline in the number of total lesions was -37.4% for SB204 and 0.6% for vehicle (p<0.001). Statistical significance was achieved for IGA assessment of 2-grade change from baseline.

Conclusions

• In a subset of only adolescent subjects (9 to 17 years of age) treated with topical SB204 4% once-daily, there was a statistically significant reduction (p=0.003) in inflammatory, non-inflammatory and total lesion reductions with SB204 4% compared to vehicle.
  • The percent change from baseline in the number of non-inflammatory lesions was -33.4% for SB204 and -24.2% for vehicle (p=0.0013).
  • The percent change from baseline in the number of inflammatory lesions was -34.1% for SB204 and -36.4% for vehicle (p=0.0117).
  • The percent change from baseline in the number of total lesions was -37.4% for SB204 and -9.1% for vehicle (p<0.001).
  • Statistical significance was achieved for IGA assessment of 2-grade change from baseline.

• All doses of SB204 administered in the studies were well tolerated and the adverse event profile was similar in active and vehicle treated subjects.

*values are based on analysis of covariance, using LOCF as imputation (ITT population)

**Administrative Assessment Scoring

1. Grade: Up to many inflammatory and non-inflammatory lesions, but no more than a few nodulocystic lesions.
2. Severity: Mild. Up to many non-inflammatory lesions and fewer than usual inflammatory lesions, but no more than 2 or 3 nodulocystic lesions.
3. Moderate: Up to many inflammatory and non-inflammatory lesions, but no more than a few nodulocystic lesions.
4. Severe: Up to many inflammatory and non-inflammatory lesions, but more than a few nodulocystic lesions.