Results of Phase 2 Study Evaluating the Efficacy and Safety of SB206, Topical Berdazimer Sodium Gel, in Subjects with Molluscum Contagiosum

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Introduction

Topical Berdazimer Sodium Gel

- Nitric oxide (NO), an endogenous small molecule, provides localized immunity against foreign organisms by acting both as a short-lived immune modulator and a direct broad-spectrum antimicrobial agent.1
- Until recently, the development of topical NO treatments was limited by the inability to store and safely deliver NO to the site of infection or inflammation.2
- SB206 is an investigational product that consists of 2 components; a gel containing berdazimer sodium coadministered with a hydrogel.
- Berdazimer sodium is a macromolecule comprised of a polysiloxane backbone with covalently bound N-diaziniumdione NO donors.
- Coadministration with a hydrogel promotes NO release from the macromolecule at the time of application.3

Molluscum Contagiosum

- Molluscum contagiosum (MC) is a common poxvirus skin infection that primarily affects young children.2,3
- Resolution of MC lesions using current treatment options, includes physical ablation of MC lesions by curettage, cryotherapy, laser, or chemical destruction of involved skin via topically applied medications.4,5
- No FDA-approved topical treatments indicated for MC as of today.

Hypothesis

- SB206 12% applied at home, once daily, may fulfill an unmet medical need for a convenient, effective, and well-tolerated topical treatment for molluscum contagiosum.

Methods

- A Phase 2, multi-center, randomized, double-blind, vehicle-controlled, ascending dose study of SB206 in subjects with molluscum contagiosum.

Table 1: Subject disposition.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Vehicle gel (N=66)</th>
<th>SB206 gel (N=190)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (range)</td>
<td>7.6 (2–16)</td>
<td>6.9 (2–42)</td>
</tr>
<tr>
<td>Sex (%)</td>
<td>Male 39 (59.1%)</td>
<td>Female 94 (49.5%)</td>
</tr>
<tr>
<td>Female</td>
<td>27 (40.9%)</td>
<td>96 (50.5%)</td>
</tr>
<tr>
<td>Race (%)</td>
<td>White 58 (87.9%)</td>
<td>Other 8 (12.1%)</td>
</tr>
<tr>
<td>Other</td>
<td>170 (93.5%)</td>
<td>20 (10.5%)</td>
</tr>
<tr>
<td>Baseline lesion count, mean (range)</td>
<td>18.3 (3–76)</td>
<td>19.3 (3–96)</td>
</tr>
<tr>
<td>Baseline lesion count, category (%)</td>
<td>3 to 18</td>
<td>41 (62.1%)</td>
</tr>
<tr>
<td>19 to 70</td>
<td>45 (67.6%)</td>
<td>116 (61.1%)</td>
</tr>
<tr>
<td>History of atopic dermatitis (%)</td>
<td>11 (16.7%)</td>
<td>31 (16.9%)</td>
</tr>
</tbody>
</table>

Table 2: Demographics and baseline characteristics of ITT population.

Figure 4: Complete clearance of all molluscum lesions at each treatment visit for the mITT population. Complete clearance is defined as a subject having a lesion count of 0 at a visit.

Figure 5: Percent change from baseline in lesion count for the mITT population.

Conclusions

- Efficacy: Statistically significant difference in the proportion of subjects achieving complete clearance of all molluscum lesions at Week 12 between SB206 12% QD and Vehicle.
  - Both ITT and mITT populations demonstrated consistent results.
  - Statistically significant efficacy signal was observed with 12% QD as early as 2 weeks in the percent change from baseline as well as in the proportion of subjects with at least a 75% reduction in lesion count.
- Safety: SB206 appeared to be safe and well tolerated.
  - Administration site reactions were the most prevalent AEs.
  - Few discontinuations due to AEs, and none with 12% QD.
  - 12% QD will be carried forward to the Phase 3 studies.

References