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.
- 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-diazeniumdiolate NO donors.
- Coadministration with a hydrogel promotes NO release from the macromolecule at the time of application.[1]

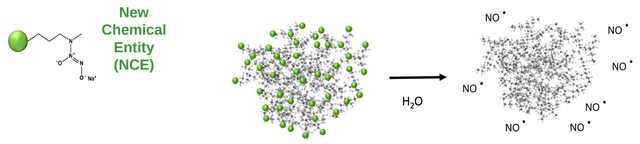

Figure 1: Berdazimer sodium.

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.

Two Components:
(1) Berdazimer Sodium Alcohol Gel
(2) pH Buffered Hydrogel

Hydroalcoholic gel with enhanced nitric oxide release, targeting viral skin infections

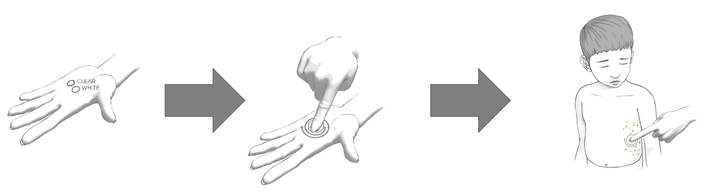

Figure 2: NI-MC201 Instructions For Use.

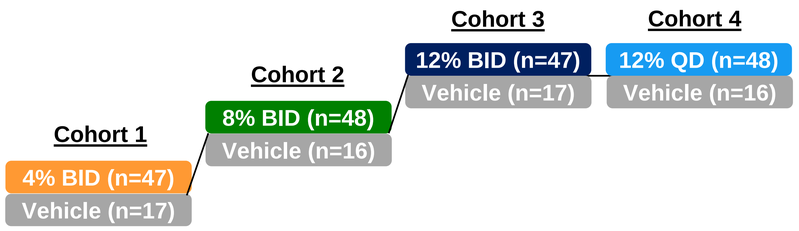

Figure 3: NI-MC201 Phase 2 clinical trial study design for SB206 in the treatment of molluscum (n=256).

- **Primary Endpoint**: Proportion of subjects achieving complete clearance of all molluscum contagiosum at week 12 (modified ITT population: consists of all subjects who are randomized and complete the study treatment).
- **Secondary Endpoints:**
  - Proportion of subjects achieving complete clearance of all MC lesions at each visit.
  - Proportion of subjects achieving ≥75% reduction from baseline in number of MC lesions.
  - Mean % change from baseline in number of MC lesions at every visit.

Phase 2 Clinical Results

	Vehicle	SB206 4% BID	SB206 8% BID	SB206 12% BID	SB206 12% QD	Overall
ITT Population[a]	66	47	48	47	48	256
Safety Population[b]	66	46	48	47	47	254
mITT Population[c]	60	38	39	37	43	217
Prematurely Discontinued Treatment	6 (9.1%)	8 (17.4%)	9 (18.8%)	10 (21.3%)	4 (8.5%)	37 (14.6%)
Adverse Event	0	3 (6.5%)	2 (4.2%)	2 (4.3%)	0	7 (2.8%)
Withdrawal by Subject	3 (4.5%)	0	1 (2.1%)	1 (2.1%)	1 (2.1%)	6 (2.4%)
Lost to Follow-up	3 (4.5%)	5 (10.9%)	5 (10.4%)	6 (12.8%)	3 (6.4%)	22 (8.7%)
Other	0	0	1 (2.1%)	1 (2.1%)	0	2 (0.8%)
Completed Study[d]	61 (92.4%)	38 (82.6%)	40 (83.3%)	39 (83.0%)	43 (91.5%)	221 (87.0%)

a. The ITT Population consists of all subjects who are randomized.
b. The Safety Population consists of all subjects who are administered study drug.
c. The mITT Population consists of all subjects who are randomized and complete the study treatment.
d. Percentage calculated based on the number of subjects in the Safety Population.

Table 1: Subject disposition.

Characteristic:	Vehicle gel (N=66)	SB206 gel (N=190)
Age, year mean (range)	7.0 (2–16)	6.9 (2–62)
Sex (%)		
Male	39 (59.1%)	94 (49.5%)
Female	27 (40.9%)	96 (50.5%)
Race (%)		
White	58 (87.9%)	170 (89.5%)
Other	8 (12.1%)	20 (10.5%)
Baseline lesion count, mean (range)	18.3 (3–70)	19.3 (3–90)
Baseline lesion count, category (%)		
3 to 18	41 (62.1%)	116 (61.1%)
19 to 70	25 (37.9%)	73 (38.4%)
History of atopic dermatitis (%)	11 (16.7%)	31 (16.3%)

Table 2: Demographics and baseline characteristics of ITT population.

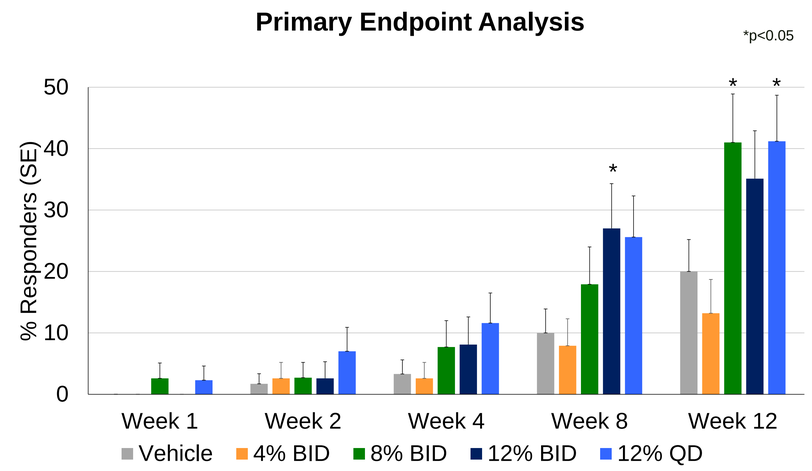

Figure 4: Complete clearance of all molluscum lesions at each treatment visit for the mITT population. Complete clearance is defined as a subject having a lesion count of 0 at a visit.

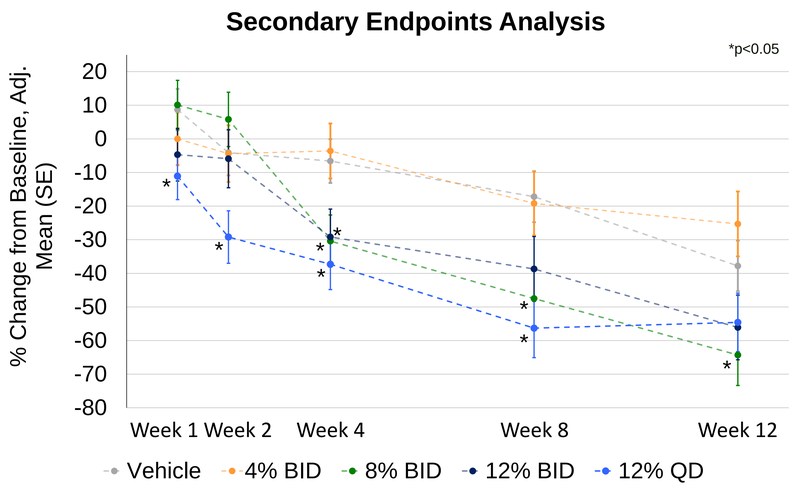

Figure 5: Percent change from baseline in lesion count for the mITT population.

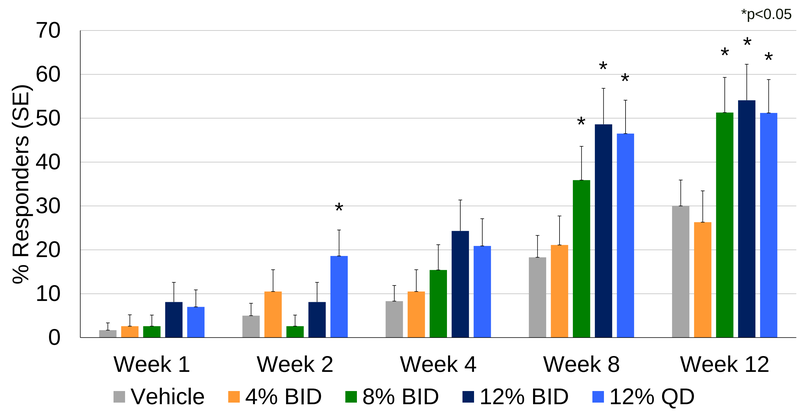

Figure 6: Proportion of subjects with at least a 75% reduction in lesion count from baseline for the mITT population.

Event	Vehicle (n=66)	SB206 4% BID (n=46)	SB206 8% BID (n=48)	SB206 12% BID (n=47)	SB206 12% QD (n=47)
Discontinued treatment due to AEs	0	3 (6.5)	2 (4.2)	2 (4.3)	0
Application-site reactions (includes erythema, exfoliation, pain, and/or pruritis)	0	2 (4.3)	2 (4.2)	2 (4.3)	0
Worsening molluscum	0	1 (2.2)	0	0	0
General disorders and administration site conditions	2 (3.0)	5 (10.9)	14 (29.2)	7 (14.9)	10 (21.3)
Application-site erythema	0	3 (6.5)	6 (12.5)	6 (12.8)	5 (10.6)
Application-site exfoliation	0	0	1 (2.1)	3 (6.4)	4 (8.5)
Application-site pain	0	2 (4.3)	3 (6.3)	3 (6.4)	4 (8.5)
Application-site pruritis	0	1 (2.2)	1 (2.1)	4 (8.5)	2 (4.3)
Pyrexia	2 (3.0)	1 (2.2)	5 (10.4)	1 (2.1)	1 (2.1)
Infections and infestations	10 (15.2)	6 (13.0)	9 (18.8)	4 (8.5)	7 (14.9)
Skin and subcutaneous tissue disorders	3 (4.5)	3 (6.5)	5 (10.4)	3 (6.4)	3 (6.4)
Gastrointestinal disorders	1 (1.5)	0	5 (10.4)	3 (6.4)	3 (6.4)
Injury, poisoning, and procedural complications	1 (1.5)	1 (2.2)	5 (10.4)	1 (2.1)	0
Respiratory, thoracic, and mediastinal disorders	5 (7.6)	0	5 (10.4)	1 (2.1)	3 (6.4)
Psychiatric disorders	0	3 (6.5)	1 (2.1)	1 (2.1)	0

Table 3: Treatment-emergent adverse events reported in >5% of subjects in any treatment group (Safety 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

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