Rapid Improvement with BPX-01 Minocycline Topical Gel in the Treatment of Moderate-to-Severe Inflammatory Acne Vulgaris: a Randomized, Double-Blind, Vehicle-Controlled Study

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Introduction

Acne affects up to 50 million Americans annually.1 It can be caused by sebaceous gland hyperactivity, abnormal keratinocyte desquamation, and bacteria-related local inflammatory changes.2,3 Comedones and inflammatory papules, pustules and nodules are sites of proliferation for Propionibacterium acnes bacteria.

The study medication: topical minocycline gel

BPX-01 is the first completely solubilized minocycline gel for topical use. It is intended for the treatment of non-nodular, moderate-to-severe inflammatory acne vulgaris in patients nine years of age and older. Its preliminary safety and efficacy profile have been demonstrated in extensive preclinical testing and a phase 2a study:

- No drug-related adverse events
- No detectable plasma minocycline
- No cutaneous toxicity
- 100% patient satisfaction

Methods

This phase 2b study was intended to describe the safety and efficacy of topical minocycline in the treatment of inflammatory acne vulgaris.

- Randomized, double-blind, vehicle-controlled, close-ranging study in 225 patients with moderate-to-severe acne
- 12-week study evaluating 3 arms: BPX-01 1%, BPX-01 2%, vehicle
- Conducted at 15 U.S. sites
- Patients ages 9 to 40; IGA* of 3 or 4, 20-80% non-nodular inflammatory lesions

Primary Endpoint: Absolute mean change in number of inflammatory lesions from baseline at week 12 Secondary Endpoint: Proportion of subjects with at least a two-grade reduction in GAI to clear or almost clear (0 or 1) at week 12

Results: Rapid and Effective

A reduction of 25% in the number of inflammatory lesions is considered clinically important and is recognized by patients as an indicator of an effective treatment. Because this milestone was reached within two weeks of treatment with BPX-01, it has the potential to result in optimal treatment compliance and improved patient satisfaction. The rapid rate of improvement (43% after four weeks) outpaced that observed in a separate clinical trial with oral minocycline for acne in which improvement exceeding 40% required 12 weeks of treatment.4 with much lower systemic exposure. Additionally, BPX-01 2% resulted in 58.5% reduction in lesions with consistent trends toward improvement in IGA, PBI, and satisfaction scores. The medication was well tolerated with good safety profile and was largely undetectable in blood plasma, hence no systemic side effects are anticipated.

In conclusion, BPX-01 2% minocycline topical gel resulted in rapid improvement and better outcomes than vehicle control in the treatment of moderate-to-severe non-nodular inflammatory acne vulgaris.

This treatment may provide an effective new option with a favorable safety profile and potential for high patient compliance.