Efficacy and Safety of SB204 Gel in the Treatment of Acne Vulgaris

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The results from a Phase 2, multi-center, randomized, double-blinded, vehicle-controlled study comparing the efficacy, safety, and tolerability of two concentrations of the topical nitric oxide-releasing gel, SB204, to Vehicle Gel in subjects with acne vulgaris are reported. The SB204 drug product contains, NVN1000, a new molecular entity which has immunomodulatory and antimicrobial activity and inhibits lipogenesis. Subjects who met the study entry criteria were enrolled and randomized to receive twice daily topical applications of SB204 1%, SB204 4%, or Vehicle Gel for 12 weeks. Endpoints included the absolute change in non-inflammatory lesion counts (1’ endpoint), inflammatory lesion counts and Investigator Global Assessment (IGA) (2’ endpoints) at end of treatment. 153 subjects were randomized and 129 completed the study. In the intent to treat (ITT) analysis, the mean absolute change from baseline for non-inflammatory lesions at the end of treatment was -0.30 for Vehicle Gel, -12.1* for SB204 1%, and -11.0* for SB204 4% (* denotes $p\leq0.05$ compared to Vehicle Gel). The mean absolute change from baseline in inflammatory lesions at the end of treatment was -9.30 for Vehicle Gel, -13.7 for SB204 1% and -15.5* for SB204 4%. In the IIT population, the median reduction for inflammatory lesions was 62% at week 12. Statistically significant reductions in both inflammatory and non-inflammatory lesions were observed as early as week 4 ($p\leq0.05$). There was a noticeable decrease in disease severity following treatment with SB204; no significant differences were measured among treatment groups for the dichotomized IGA requiring a two-grade change and subjects achieving “clear” or “almost clear”. Both the SB204 1% and 4% doses were safe and generally well tolerated with no serious adverse events reported. The adverse event and laboratory profile were similar in SB204 and Vehicle Gel treated subjects. Exploratory measurements of sebum produced on the forehead were also collected in a subset of subjects (n=70). At week 12, subjects treated with SB204 had 80% less sebum on the surface of their skin than those treated with Vehicle Gel. This study demonstrates the therapeutic potential of topical nitric oxide in dermatology and characterizes the safety and efficacy of SB204 for the treatment of acne vulgaris.