ACNE, ROSACEA, AND RELATED DISORDERS (INCLUDING HIDRADENITIS SUPPURATIVA)

ADAPALENE 0.3% / BENZOYL PEROXIDE 2.5% GEL PLUS ORAL DOXYCYCLINE IS AN EFFECTIVE AND SAFE OPTION FOR ORAL ISOTRETINION CANDIDATES WITH SEVERE INFLAMMATORY ACNE (NON NODULOCYSTIC/NON-CONGLOBATE)

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Introduction: A need exists for safe, tolerable, and efficacious treatments for severe acne vulgaris. Recommended first-line treatments for severe acne include combined topical+oral antibiotic therapy or oral isotretinoin (OI).

Objective: Investigate the efficacy/safety of daily 0.3% adapalene and 2.5% benzoyl peroxide (0.3% A/BPO) gel with oral doxycycline 200-mg (DOX, 2 50-mg delayed-release tablets BID) in severe (non nodulocystic, non-conglobate) inflammatory acne.

Methods: This was a phase 4, 12-week, single-arm, open label, multi-center investigational study. Subjects (male and female, age 12+, with severe inflammatory acne [IGA 4], n = 186) who were considered OI candidates by the investigator were enrolled; OI candidacy was re-evaluated at each study visit. Endpoints included inflammatory lesion (IL) reduction (week 12), IGA success (weeks 4, 8, and 12), percent reduction in lesions (weeks 4, 8, and 12), and subject questionnaires (week 12). Safety assessments included Adverse Events (AEs) and tolerability.

Results: Mean IL counts were significantly reduced (Mean [SD]; baseline, 44.8 [21.73]; week 12, 14.8 [16.11]; mean percent reduction, 66.2% [30.47]; P < .0001). By week 12,

37.1% of subjects achieved IGA Success (n = 69, P < .0001). Most subjects self-reported at least moderate improvement in acne (90.2%), and were “Satisfied” or “Very Satisfied” with the study treatment overall (83.2%). Nearly half (41.9%) of the subjects were no longer considered OI candidates at week 4. At 12 weeks, just 19.9% were still considered OI candidates. Twenty-seven (15.4%) AEs were considered to have a reasonable possibility of being treatment related (gastrointestinal AEs were most common; n = 7, 4.0%). Only 4 subjects discontinued due to an AE, (“skin burning sensation”; 1 mild, 2 moderate, 1 severe; all were considered “possibly related”).

Conclusion: 0.3% A/BPO+DOX is an effective and safe option for severe inflammatory acne, before starting OI treatment, or as an alternative when OI cannot be used.