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

COMBINED DOXYCYCLINE 40 MG MODIFIED RELEASE CAPSULES PLUS IVERMECTIN 1% CREAM THERAPY FOR SEVERE PAPULOPUSTULAR ROSACEA

J Del Rosso [1] - S Johnson [2] - M Jackson [3] - R Chavdra [4] - A Harvey [5]

Jdr Dermatology Research/thomas Dermatology, -, Las Vegas, United States [1] - Johnson Dermatology Clinic, -, Fort Smith, United States [2] - University Of Louisville, -, Louisville, United States [3] - Galderma, Medical Evidence, Tour-de-peilz, Switzerland [4] - Galderma, Medical Affairs, Fort Worth, United States [5]

Introduction: Rosacea is a chronic inflammatory skin disease, often best managed with combination therapy; however, relatively few rigorous controlled studies of combination therapies have been conducted. Doxycycline 40mg modified release (DMR) and ivermectin 1% cream (IVM) are well-established rosacea treatments with proven efficacy, tolerability and safety, and different and complementary targets in the inflammatory cascade of rosacea.

Objective: Evaluate DMR+IVM vs IVM+placebo in severe papulopustular rosacea (PPR; Investigator Global Assessment [IGA]-4) treatment efficacy, quality of life improvement, percentage of subjects reaching “Clear” (IGA-0; 100% reduction of inflammatory lesions plus no erythema), and relief of other rosacea-associated symptoms.

Materials and Methods: 12-week, multicenter, randomized (DMR+IVM or IVM + placebo), investigator-blinded, parallel-group comparative study. Subjects were aged ≥18 years with severe PPR (IGA-4) including ≥20 to 70 inflammatory lesions on the face. All subjects used Cetaphil Redness Relieving facial wash and Cetaphil Redness Relieving Moisturizer, SPF 30. Primary efficacy assessment: percent change in inflammatory lesion count (baseline to week 12); other assessments included Clinician’s Erythema Assessment (CEA), change in stinging/burning and flushing, adverse events, and cutaneous tolerability.

Results: A total of 273 IGA-4 rosacea subjects participated; 60% with CEA-4, 50% had moderate to severe stinging/burning, and 40% had ocular symptoms. Compared with IVM alone, DMR+IVM exhibited:
• Significantly superior efficacy: Inflammatory lesion reduction (-80.29 vs -72.56, p=0.032) and IGA score improvement (p=0.032).
• Faster onset of action, significant as early as week 4.
• Significantly increased number of subjects achieving IGA-0 (11.9% vs. 5.1%, p=0.043%)

and 100% lesion reduction (17.8% vs 7.2%, p=0.006) at week 12.
Both treatment arms substantially reduced CEA, burning/stinging, flushing frequency, Dermatology Life Quality Index, and ocular symptoms. DMR+IVM was well tolerated, with no increases in GI related symptoms or treatment related discontinuations relative to IVM+placebo.

Conclusion: DMR+IVM was a safe and more efficacious PPR treatment option compared to monotherapy.