TRIFAROTENE 50 µg/g CREAM FOR TREATMENT OF ACNE VULGARIS – A SUMMARY OF TWO RANDOMIZED TRIALS AND A LONG-TERM SAFETY STUDY

INTRODUCTION

Introduction to Trifarotene 50 µg/g cream:
- Retinoid receptor that selectively targets retinoid acid receptor gamma
- Low systemic exposure after topical administration

Two identical multi-center, double-blind, randomized 12-week studies of subjects with moderate facial and truncal acne comparing vehicle with once daily trifarotene 50 µg/g cream: N = 2,420

- Study 1: conducted at 109 sites, majority United States
- Study 2: conducted at 91 sites, majority Europe

Primary efficacy endpoints (MI) measured at Baseline and Weeks 1, 2, 4, 8, 12:
- Success rate: percentage of subjects with Investigator Global Assessment (IGA) of clear (0) or almost clear (1) and at least a 2-grade improvement
- Absolute change in facial inflammatory/non-inflammatory lesion count

Secondary efficacy endpoints (trank) measured at Baseline and Weeks 1, 2, 4, 8, 12:
- Success rate: percentage of subjects with Physician Global Assessment (PGA) of clear (0) or almost clear (1) and at least a 2-grade improvement
- Absolute change in truncal inflammatory/non-inflammatory lesion count

Safety endpoints:
- incidence of adverse events and local tolerability

METHODS

Study 1 and 2:
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RESULTS

Study 1 and 2: Efficacy:
- Results of all efficacy assessments of Week 12: Significant (P <.010) in favor of trifarotene 50 µg/g cream versus vehicle

Study 1: Primary efficacy endpoints:
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- Absolute change in facial inflammatory/non-inflammatory lesion count

Study 2: Primary efficacy endpoints:
- MI assessed at Baseline and Weeks 1, 2, 4, 8, 12
- Success rate: percentage of subjects with Physician Global Assessment (PGA) of clear (0) or almost clear (1) and at least a 2-grade improvement
- Absolute change in truncal inflammatory/non-inflammatory lesion count

Safety:
- Skin irritation related to trifarotene 50 µg/g cream was translated, and consistent with known patterns of topical retinoid dermatitis
- Most common related AEs included irritation, pruritus, and sunburn (incidences ≤ 1%)
- Seven AEs related to trifarotene 50 µg/g cream reported in nine subjects versus none in the vehicle group, with no serious AEs reported
- Seven related AEs led to subject discontinuation in 1.9% of the trifarotene 50 µg/g cream group in Study 1 and in 1.2% of the trifarotene 50 µg/g cream group in Study 2
- Tolerability signs related to trifarotene 50 µg/g cream assessed as mostly mild to moderate by investigator

REFERENCES

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