INTRODUCTION

- Topical treatment options for chronic plaque psoriasis lack products that are safe with long-term usage, are well tolerated, and are used as single agents over the body.
- Roflumilast cream, a phosphodiesterase-4 (PDE-4) inhibitor that is more potent than other PDE-4 inhibitors, is under investigation as a once-daily, nonsteroidal, topical treatment for plaque psoriasis.
- In a phase 2b randomized, double-blind, 12-week trial of 331 adults with chronic plaque psoriasis, roflumilast cream once daily was found to be superior to vehicle cream and was well tolerated.
- This multicenter, open-label, 52-week study was also conducted to assess long-term safety of roflumilast 0.3% cream in patients with chronic plaque psoriasis.

METHODS

- In this phase 2 long-term safety study, roflumilast cream, an investigational, nonsteroidal, nonopioid, topical treatment for plaque psoriasis, was used as single agent over the entire body.
- Rates of gastrointestinal and psychiatric AEs were low.
- 97% of AEs were rated mild or moderate.
- 94% of adverse events (AEs) were rated mild or moderate.
- 29% of patients had no evidence of irritation per physician assessment at each visit.

RESULTS

- PERCENTAGE OF PATIENTS ACHIEVING IGA SUCCESS
  - IGA success was defined as IGA of clear/almost clear at 12 weeks.
  - In all roflumilast groups, IGA success was between 33% and 37%, and exceeded that observed among patients at Week 12 of the parent study.

- ENDPOINTS
  - Week 4, 8, 12, 16, 24, 36, 48, and 52
  - Patients with any SAE
  - Patients who discontinued study drug due to AE
  - Patients who withdrew

- Table 3. Most Common AEs (>2% Overall)
  - Most common AEs were gastrointestinal and psychiatric.
  - Rates of gastrointestinal and psychiatric AEs were low.
  - 97% of AEs were unrelated or unlikely to be related to treatment as determined by the investigator.

- Table 2. Summary of AEs (Safety Population)
  - 94% of adverse events (AEs) were rated mild or moderate.
  - 29% of patients had no evidence of irritation per physician assessment at each visit.

CONCLUSIONS

- Patients with chronic plaque psoriasis need topical treatments that provide effective control of psoriasis with low incidence of side effects that can be used for long-term treatment.
- In this phase 2 long-term safety study, roflumilast cream, an investigational, once-daily, nonsteroidal topical PDE-4 inhibitor, was well-tolerated with no new safety signals.
- Rates of discontinuations due to AEs and lack of efficacy were low.
- Durable efficacy was observed and the effect was maintained through 52 weeks of treatment in this long-term safety study and up to 64 weeks including the phase 2b study.
- Similarity of effect was observed in patients with intertriginous area involvement.
- Once-daily roflumilast cream is a promising novel therapy for treating plaque psoriasis.

REFERENCES


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DISCLOSURES

- ULG, CSL, APT, BIO, MSD, DAK, LEH, UAE, LEH, HAI, KRN, DIW, and NZ are investigators and/or consultants for Arcutis Biotherapeutics, Inc.
- ULG, CSL, APT, BIO, MSD, DAK, LEH, UAE, LEH, HAI, KRN, DIW, and NZ are investigators and/or consultants for Novartis Pharmaceuticals Corporation, the manufacturer of LK-974.
- We are or were employees of Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

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