Phase 2B Trial of Roflumilast Cream (ARQ-151) for the Treatment of Chronic Plaque Psoriasis

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**KEY FACTS**

- Psoriasis is a chronic, inflammatory skin disorder that affects more than 8 million people in the U.S.
- 90% of cases are plaque psoriasis, which results in raised, itchy, red patches on the skin. It can also affect the nails and scalp.

**STUDY RESULTS**

- Roflumilast 0.3% cream was associated with statistically significant improvement at Week 12 compared to vehicle.
- Psoriasis Area and Severity Index (PASI) of at least 75% at 12 weeks: 16% of patients treated with roflumilast 0.3% achieved separation from vehicle in IGA of clear or almost clear plus 2-grade improvement from baseline (IGA success). At Week 12:
  - 93% of patients treated with roflumilast 0.3% achieved clear or almost clear, compared to 27% of patients treated with roflumilast 0.15% and 16% of patients treated with vehicle.
  - 88% of patients treated with roflumilast 0.3% had an Intertriginous-IGA score of 0 (clear) at Week 12.

**SAFETY**

- Rates of application site reactions were similar between roflumilast 0.3% and vehicle groups.

**STUDY DESIGN**

- 331 ADULTS ≥18 YEARS OF AGE
- > 6 MONTHS WITH CHRONIC PSORIASIS

**CURRENT TREATMENT OPTIONS**

- **Topical Treatments**
  - Can be inconvenient and may require frequent visits to a dermatologist.
  - Side effects include skin irritation and burning.
- **Oral Medications**
  - Side effects include weight gain, liver function abnormalities, and increased blood pressure.
- **Phototherapy**
  - Side effects include skin irritation, risk of skin cancer, and increased risk of skin infections.
- **Biologics**
  - Side effects include serious infections, increased risk of malignancy, and increased risk of heart attack, stroke, and certain types of cancer.

- **Other Considerations**
  - Patients with limited mobility or cognitive impairment may have difficulty using or responding to topical treatments.
  - Patients with psoriasis affecting the face, scalp, or intertriginous areas (such as the armpits and under breasts) may find it challenging to use topical creams.
  - Patients with psoriasis affecting the palms or soles may find it difficult to deliver drugs to these areas.

- **Key Takeaway**
  - Roflumilast cream (ARQ-151) is a highly effective, non-steroidal topical therapy for chronic plaque psoriasis.
  - Roflumilast 0.3% cream demonstrated a superior clinical response to vehicle cream on key psoriasis efficacy endpoints.

For full results and information, visit www.arcutis.com