**METHODS**

**Trial Design: ADORING 1 and 2**

- **ADORING 1** and **ADORING 2** are two identically designed, Phase 3, multicenter (US and Canada), double-blind, vehicle-controlled randomized trials (Figure 2).
- Following a 30-day screening period, patients aged ≥ 2 years old with a vIGA-AD score of ≥3 (moderate to severe) and a percentage body surface area (vBSA) affected of ≥10% will be randomized to 1:1:1 to tapinarof cream 1% or vehicle for 8 weeks.

**Figure 2. Trial Design: ADORING 1 and ADORING 2**

- **Patients with moderate to severe atopic dermatitis (N=900)**
  - **≥2 years**
  - **vIGA-AD score ≥3**
  - **vBSA ≥10%**

- **Primary efficacy endpoint**: the proportion of patients with a vIGA-AD score of 0 (clear) or 1 (almost clear) and an improvement in EASI (EASI90) of ≥50% at Week 8.

**Efficacy Endpoints**

- **Primary efficacy endpoint**: the proportion of patients with a vIGA-AD score of 0 (clear) or 1 (almost clear) and an improvement in EASI (EASI90) of ≥50% at Week 8.

**Safety and Tolerability Endpoints**

- **Frequency of treatment-emergent adverse events and serious events**
- **Laboratory values, vital signs, and electrocardiograms**
- **Patient- and investigator-assessed local tolerability**

**CONCLUSIONS**

The ADORING Phase 3 clinical trial program will assess the efficacy, safety, tolerability, durability, and potential remittive effect of tapinarof cream 1% QD for the treatment of moderate to severe AD in patients down to 2 years of age.

**REFERENCES**

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Lawrence F. Eisenberg, MD, PhD; Jonathan I. Silverberg, MD, PhD, MPH; Robert Bissonnette, MD; Anna M. Tallman, PharmD; Philip M. Brown, MD, JD; David S. Rubenstein, MD, PhD; Stephen C. Piscitelli, PharmD; John E. Jett, PhD

1. School of Medicine, University of California, San Diego, CA, USA; 2. Rady Children’s Hospital, San Diego, CA, USA; 3. School of Medicine and Health Sciences, The George Washington University, DC, USA; 4. Innoderm Research Inc., Montreal, QC, Canada; 5. Dermavant Sciences Inc., Morrisville, NC, USA.