Maximal Use Study of Tapinarof Cream 1% in Subjects with Extensive Plaque Psoriasis

John E. Jett,1 Michael McLaughlin,2 Mark S. Lee,2 Lawrence Carlos Parish,3 Glenn Taito,4 Timothy Wilson,5 Matthew C. Somervile,6 Wayne DellaMaestra,7 Stephen C. Pischelli1

1Dermavant Sciences, Inc., Durham, NC, USA; 2Progressive Clinical Research, San Antonio, TX, USA; 3Pfizer Global, Inc., Philadelphia, PA, USA

SYNOPSIS

In this 29-day, open-label, multicenter study, one patient (4.8%) withdrew consent, and one patient (4.8%) was lost to follow-up.

OBJECTIVES

The primary objectives were to evaluate the safety and tolerability, and PK of topical tapinarof cream 1% in adult patients with extensive plaque psoriasis.

The secondary objectives were to evaluate clinical responses in subjects with extensive plaque psoriasis.

RESULTS

No patient had measurable concentrations of tapinarof sulfate at any time point (% of total range up to ~4600 pg/mL).

There were no clinically meaningful changes in clinical laboratory values, vital signs, QTc interval, or other ECG parameter values.

There were no treatment interruptions and no patient discontinued study drug due to treatment-emergent adverse events (TEAEs).

Tapinarof was well tolerated at application sites, including in seven patients (33.3%) who applied tapinarof to sensitive areas, such as genitals, face, neck, and skin folds.

More patient change in PGA score from baseline to Day 29 was <−50% (P=0.0031).

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All nominal time points were not statistically different from each other with extensive plaque psoriasis up to 46% BSA.

Efficacy results:

Tapinarof cream 1% demonstrated significant efficacy after only 4 weeks of treatment in subjects with moderate to severe plaque psoriasis.

Nominal time points were not statistically different from each other with extensive plaque psoriasis up to 46% BSA.

CONCLUSIONS

Tapinarof cream 1% has favorable safety profile and is well tolerated, including in sensitive areas, without any clinically meaningful effect on QT interval or other ECG parameters per FDA requirements for all investigational drugs.

Application of tapinarof cream 1% to face, neck, and skin folds is limited because extensive plaque psoriasis up to 46% BSA.

Tapinarof is under development for the treatment of plaque psoriasis.

REFERENCES


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