Early Real-World Description of Baseline Demographics and Clinical Characteristics of Patients with Plaque Psoriasis on Tapinarof Cream 1%

Janine Fournier,[1] Aseel Bin Sawad,[1] Erin Zwick,[2] Mariola Vazquez,[1] Doral Fredericks,[1] Anna M. Tallman,[1] Krithika Rajagopalan[2]

[1]Dermavant Sciences, Inc., Morrisville, NC, USA; [2]Anlitiks Inc., Windermere, FL, USA

INTRODUCTION

- Tapinarof (VTAMA®, Dermavant Science, Inc.) is a first-in-class, non-steroidal, topical aryl hydrocarbon receptor (AhR) agonist approved by the Food and Drug Administration (FDA) for the treatment of plaque psoriasis in adults,[1] and under investigation for the treatment of psoriasis in children down to 2 years of age and for atopic dermatitis in adults and children down to 2 years of age
- Tapinarof cream 1% once daily (QD) demonstrated statistically significant efficacy versus vehicle and was well tolerated in adults with mild to severe plaque psoriasis in two identical, 12-week, pivotal phase 3 trials, PSOARING 1 (NCT03956355) and PSOARING 2 (NCT03983980)[2]
  - Efficacy continued to improve beyond the 12-week trials in PSOARING 3 (NCT04053387), the long-term extension trial, with a high rate of complete disease clearance (Physician Global Assessment [PGA]=0; 40.9%), approximately 4-month remittive effect off therapy, and durability of response on therapy for up to 52 weeks[3]
- Since the FDA approval of tapinarof, data on the characteristics of patients receiving this treatment in routine clinical practice can be analyzed to better understand the use of this first-in-class AhR agonist in the real world

OBJECTIVE

- To analyze the demographics, clinical and treatment-use characteristics of patients with plaque psoriasis receiving tapinarof cream in routine clinical practice in the US

MATERIALS AND METHODS

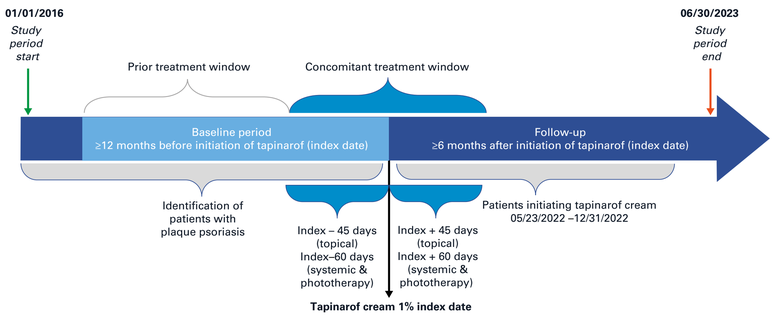
Study Design

- A retrospective database analysis of adults diagnosed with plaque psoriasis between January 1, 2016 and June 30, 2023 was conducted using Anlitiks' All-Payor Claims (AAPC) database (**Figure 1**)
  - The AAPC database contains open-source, near real-time, fully adjudicated pharmacy and medical claims consisting of tokenized, de-identified, encrypted patient-level data representing 80% of the insured US population

Study Population

- All patients with a confirmed diagnosis of plaque psoriasis (≥2 claims for ICD-10-CM L40.0) who met the inclusion or exclusion criteria
- Inclusion criteria:
  - Initiated tapinarof cream (index date) on or between May 23, 2022 and December 31, 2022 based on the first filled claim (paid) for tapinarof cream
  - ≥18 years old at initiation of treatment with tapinarof cream
  - ≥12-month baseline period prior to initiation of tapinarof cream and ≥6 months of follow up after initiation of tapinarof cream[4]
- Exclusion criteria:
  - Pregnancy during pre- or post initiation of tapinarof cream

Figure 1. Study Design



Key Definitions

- **Index date**: First paid claim date for tapinarof cream
- **Monotherapy with tapinarof cream**: Tapinarof cream only with no other concomitant paid claim(s) of topical therapy, phototherapy, or systemic agents for plaque psoriasis
- **Concomitant therapy with tapinarof cream**[5–7] Tapinarof cream along with concurrently paid claims for (i) topical therapy on index date or ±45 days, (ii) systemic or phototherapy on index date or ±60 days (**Figure 1**)
- **Prior therapy to tapinarof cream**: Therapy used during the pre-index period before concomitant therapy onset date

Variables of Interest

- Demographics: Age, sex, and insurance type
- Clinical characteristics: Comorbidities
- Prior and concomitant treatment

Statistical Analysis

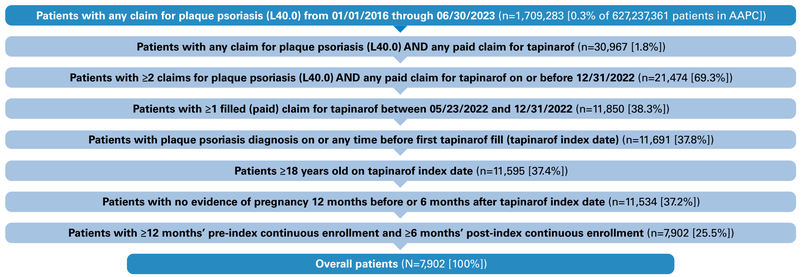
- Mean and standard deviation (SD) were calculated for all continuous variables
- Frequency and percentage were reported for all categorical variables

RESULTS

Baseline Patient Demographics

- Of 1,709,283 patients with plaque psoriasis, 7,902 initiated tapinarof cream as shown in **Figure 2**, and patient baseline demographics are depicted in **Table 1**

Figure 2. Study Population



AAPC, Anlitiks' All-Payor Claims.

Table 1. Demographics of Patients with Plaque Psoriasis on Tapinarof Cream (n=7,902)

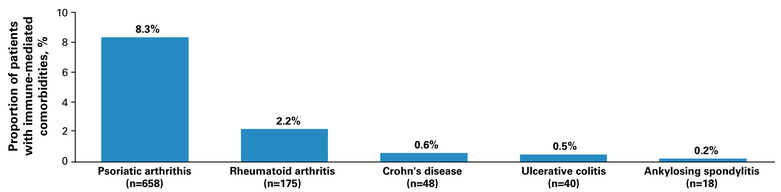
	Tapinarof cream
Age, years, mean (SD)	51.1 (13.8)
Sex, n (%)	
Female	4,183 (52.9)
Male	3,689 (46.7)
Unknown/missing	30 (0.4)
Insurance type*, n (%)	
Commercial	5,273 (66.7)
Medicare	704 (8.9)
Medicaid	520 (6.6)
Other/VA/health exchange	1,375 (17.4)
Unknown/missing	30 (0.4)

*Insurance was determined based on the payer listed on the paid claim closest to or on tapinarof paid claim.
SD, standard deviation; VA, veterans affairs.

Comorbidities

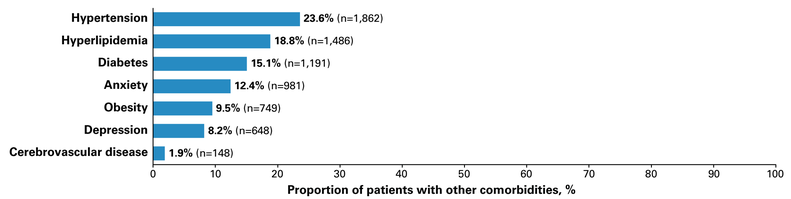
- The most prevalent immune-mediated comorbidity was psoriatic arthritis (8.3% [n=658]) (**Figure 3**)
- Cardiometabolic comorbidities were the most prevalent; the top three being hypertension (23.6% [n=1,862]), hyperlipidemia (18.8% [n=1,486]), and diabetes (15.1% [n=1,191]) (**Figure 4**)

Figure 3. Proportion of Patients with Immune-Mediated Comorbidities*



*The percentages are not mutually exclusive, and patients may have ≥1 immune-mediated comorbidity.

Figure 4. Proportion of Patients with Other Comorbidities*



*The percentages are not mutually exclusive, and patients may have ≥1 comorbidity.

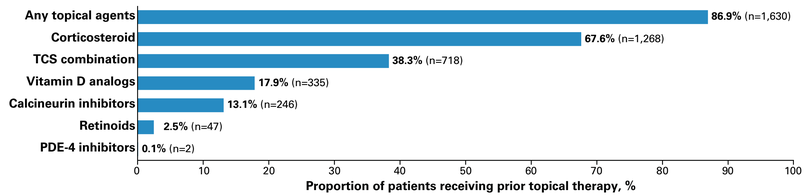
Use of Tapinarof Cream

- 65.2% (n=5,156/7,902) of patients received tapinarof monotherapy
- Of those patients receiving concomitant therapies while on tapinarof:
  - 83.6% (n=2,297/2,746) were receiving other topical agents
  - 19.4% (n=534/2,746) were receiving systemic agents
  - 4.8% (n=132/2,746) were receiving phototherapy

Treatment Prior to Initiation of Tapinarof Cream

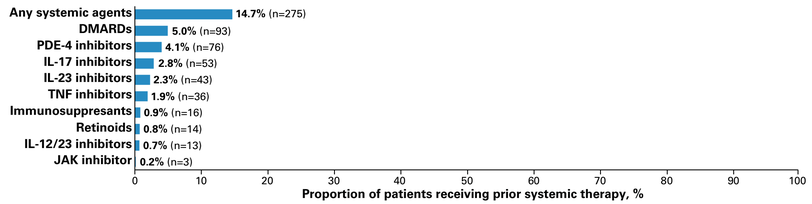
- 76.3% (n=6,027/7,902) of patients did not use any therapy prior to initiating tapinarof cream
- Of those patients receiving prior therapies before initiation of tapinarof cream:
  - 86.9% (n=1,630/1,875) had received topical agents (**Figure 5**)
  - 14.7% (n=275/1,875) had received systemic agents (**Figure 6**)
  - 4.8% (n=90/1,875) had received phototherapy

Figure 5. Proportion of Patients Receiving Prior Topical Agents*



*The percentages are not mutually exclusive, and patients may have ≥1 paid claim.
PDE-4, phosphodiesterase-4; TCS, topical corticosteroids.

Figure 6. Proportion of Patients Receiving Prior Systemic Agents*



*The percentages are not mutually exclusive, and patients may have ≥1 paid claim.
DMARD, disease-modifying anti-rheumatic drug; IL, interleukin; JAK, Janus kinase; PDE-4, phosphodiesterase-4; TNF, tumor necrosis factor.

Limitations

- As with any claims database studies, coding errors and missed data may occur
- Disease definitions are based on ICD-10-CM codes and these codes do not reflect disease severity
- Records on claims were submitted for the purpose of reimbursement. However, these paid claims do provide real-world insights

CONCLUSIONS

- This study provides an early analysis of patients with plaque psoriasis initiating tapinarof cream 1% QD in the "real world", i.e., in routine clinical practice, outside the setting of clinical trials
- The results show that patients initiating tapinarof cream have comorbidity profiles consistent with the general population with plaque psoriasis in the US
- Approximately 24% of patients had received prior therapies before initiating tapinarof cream
- While 65% of patients in this real world analysis used tapinarof cream as monotherapy, healthcare providers also found utility for combining tapinarof cream 1% with other treatment modalities including other topical agents, systemic agents and/or phototherapy

REFERENCES

1. Dermavant Sciences. VTAMA (tapinarof) cream, 1%: US prescribing information. 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215272s000lbl.pdf. Accessed September 2023. 2. Lebwohl MG, et al. *N Engl J Med.* 2021;385:2219–2229. 3. Strober B, et al. *J Am Acad Dermatol.* 2022;87:800–806. 4. Wu JJ, et al. *J Comp Eff Res.* 2020;9:767–779. 5. Feldman SR, et al. *J Comp Eff Res.* 2019;8:45–54. 6. Armstrong AW, et al. *Dermatol Ther.* 2017;7:97–109. 7. Chastek B, et al. *J Dermatol Treat.* 2013;24:25–33.

ACKNOWLEDGMENTS

This study is funded by Dermavant Sciences, Inc. J.F., A.B.S., M.V., D.F., and A.M.T. are employees of Dermavant Sciences, Inc. with stock options. E.Z. and K.R. are employees of Anlitiks Inc. Editorial and medical writing support under the guidance of the authors was provided by Anlitiks, US, and ApotheCom, UK, and was funded by Dermavant Sciences, Inc., in accordance with Good Publication Practice (GPP) guidelines (*Ann Intern Med.* 2022;175:1298–1304).

Contact Janine Fournier at janine.fournier@dermavant.com with questions or comments.