

# EFFICACY AND TOLERANCE OF A KERATOLYTIC AND HYDRATING SHAMPOO IN SUBJECTS WITH MILD-TO-MODERATE SCALP PSORIASIS: RESULTS FROM A DOUBLE-BLIND, RANDOMIZED, VEHICLE-CONTROLLED STUDY CONDUCTED UNDER REAL-LIFE CONDITIONS

Philippe Massiot<sup>1</sup>, Pedro Contreiras Pinto<sup>2</sup>, Virginie Rasmont<sup>3</sup>, Bianca Maria Piraccini<sup>4</sup>, Lidia Rudnicka<sup>5</sup>, Daniel Fernandes Melo<sup>6</sup>, Sergio Vano-Galvan<sup>7</sup>, Wen-Yu Wu<sup>8</sup>, Stephanie Leclerc-Mercier<sup>3</sup>, Delphine Kerob<sup>9</sup>

<sup>1</sup>L'Oréal Research and Innovation, Clichy, France, <sup>2</sup>PhDTrials, Lisboa, <sup>3</sup>Vichy Laboratoires, Levallois-Perret, France, <sup>4</sup>Division of Dermatology, Department of Specialized, Diagnostic, and Experimental Medicine, University of Bologna, Bologna, <sup>5</sup>Department of Dermatology, Medical University of Warsaw, Poland, <sup>6</sup>Dermatology Department, University of State of Rio de Janeiro (UERJ), Rio de Janeiro, Brazil, <sup>7</sup>Ramon y Cajal University Hospital, TricoHRC, IRYCIS, University of Alcala, Madrid, Spain, <sup>8</sup>Department of Dermatology, Huashan Hospital Fudan University, Shanghai,China, <sup>9</sup>Cosmetic Active International, Levallois-Perret, France

## INTRODUCTION

Psoriasis is a chronic, inflammatory skin disease that affects 2% of the global population.<sup>1</sup> Scalp psoriasis is estimated to affect up to 80% of patients with psoriasis and can lead to a significant burden and impairment of quality of life (QoL).<sup>2-4</sup>

Due to its chronicity and the poor cosmeticity of topical treatments, compliance to local treatments is a frequent issue in psoriasis. A keratolytic and hydrating shampoo containing 2% salicylic acid, 5% urea and 1% glycerin acting specifically on psoriasis symptoms has been developed for psoriasis prone scalp.

## RESULTS

- 67 subjects were included, 65.7% females and 34.3% males, the mean age was 43.2 years and 86.6% had Phototype III.
- All subjects had sensitive scalp, 58.2% had mild and 41.8% moderate scalp psoriasis.
- After 4 weeks of product use:
  - The PSSI significantly ( $p<0.05$ ) had reduced by 39.0%, 37.2%, 63.0% and 69.0% immediately after washing at D1 and after 8, 15 and 30 days of use, respectively compared to a 22,8%, 5,5% and 19,6% decrease and 13,0% with the vehicle.
  - The symptom, emotion and functioning SCALPDEX items had significantly ( $p<0.05$ ) reduced as early as D1 sustaining until D30.
  - The IGA significantly ( $p<0.001$ ) decreased with the shampoo by 47.5% and by 6.9% with the vehicle.
  - Hair and scalp greasiness, and irritation significantly ( $p<0.05$ ) continuously improved with the shampoo until D30 while it worsened with the vehicle.
  - The evolution of symptom scores paralleled those of clinical signs.
  - The shampoo was well tolerated, subjects were highly satisfied and had an improved QoL.

**CONCLUSION**

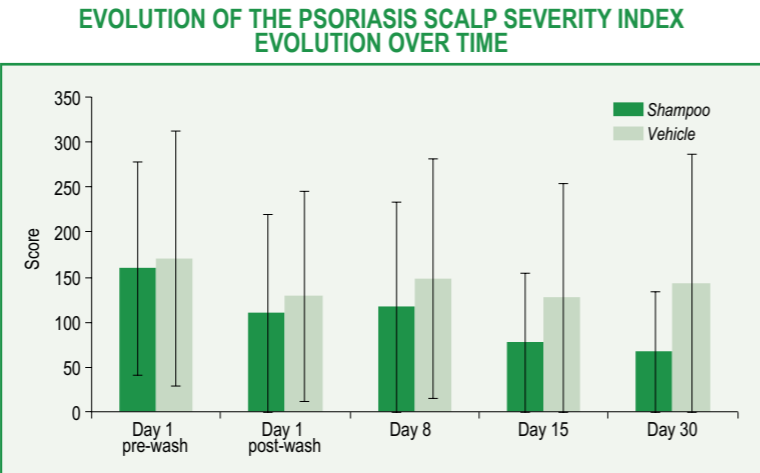
- The tested shampoo significantly improved clinical signs, symptoms and QOL of mild-to-moderate scalp psoriasis compared to vehicle, with efficacy observed as early as the first day of use, and up to 30 days.
- It was well tolerated and highly appreciated by the subjects.
- Compliance of use is expected to be good.

## OBJECTIVE

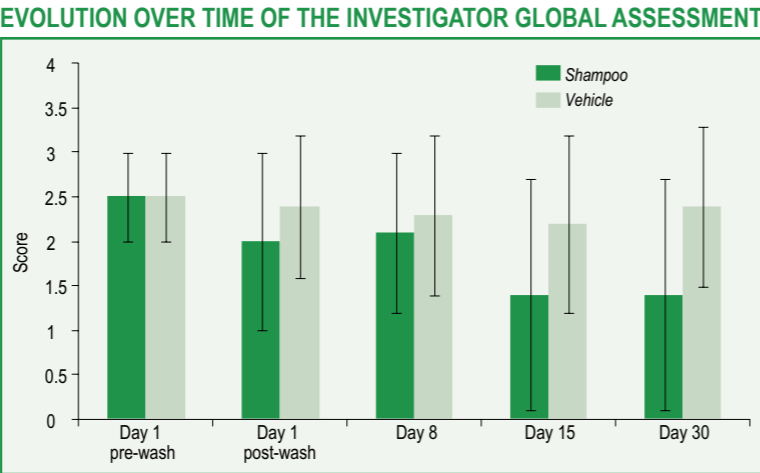
To assess, under real-life conditions in subjects with mild-to-moderate scalp psoriasis, the efficacy and local tolerance of a keratolytic and hydrating shampoo after 30 days.

## MATERIAL AND METHODS

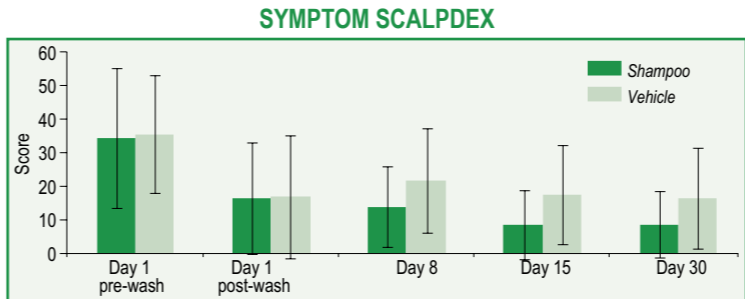
- 67 adult subjects with mild to moderate psoriasis, applied the shampoo daily for 2 minutes from D1 to D15 and 3 times/week until D29.
- Assessments included the Psoriasis Scalp Severity Index, Investigator Global Assessment (IGA), as well as hair and scalp greasiness, irritation, SCALPDEX symptoms and product acceptability.



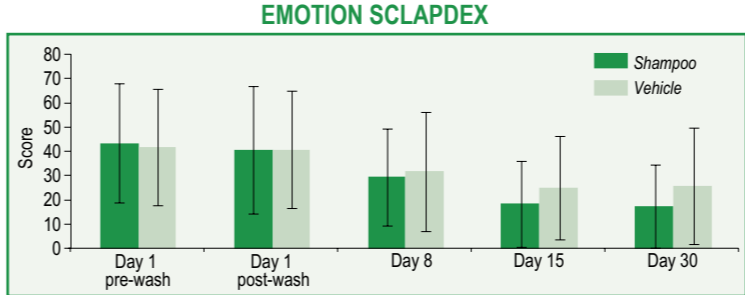
Differences of scores between the shampoo and the vehicle were statistically significant ( $p<0.05$ ) in favour of the shampoo at all post Day 1 pre-wash evaluations.



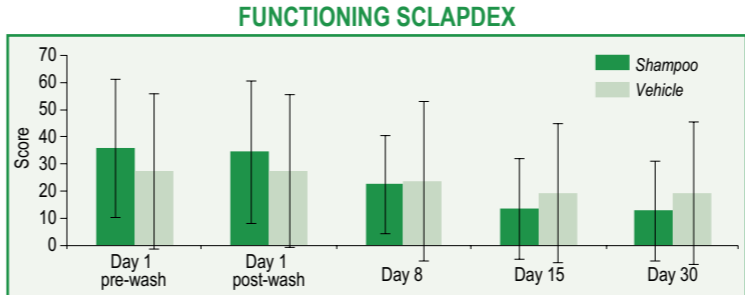
The investigators rated the shampoo significantly ( $p<0.05$ ) more beneficial than the vehicle at Day 1 post-wash, Day 15 and Day 30.



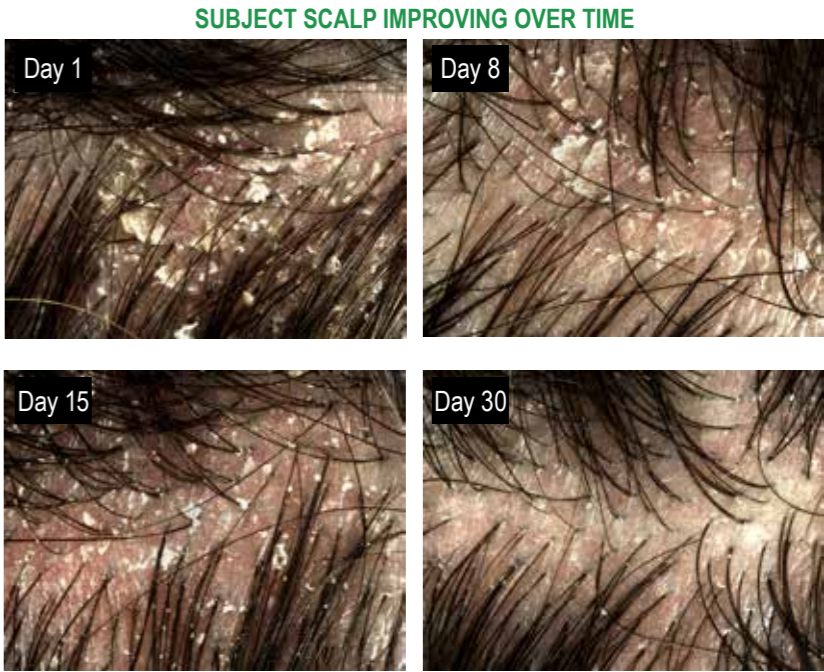
A statistically higher ( $p<0.05$ ) decrease of the symptom score in favour of the shampoo was observed at evaluation Day 15.



A statistically higher ( $p<0.05$ ) decrease of the emotion score in favour of the shampoo was observed at evaluation Day 15 and Day 30.



A statistically higher ( $p<0.05$ ) decrease of the functioning score in favour of the shampoo was observed at evaluation Day 15 and Day 30.



**REFERENCES**

- Lebwohl MG, Bachelez H, Barker J, Girolomoni G, Kavanaugh A, Langley RG, et al. Patient perspectives in the management of psoriasis: results from the population-based Multinational Assessment of Psoriasis and Psoriatic Arthritis Survey. J Am Acad Dermatol. 2014;70(5):871-81.e1-30.
- Guenther L. Current management of scalp psoriasis. Skin Therapy Lett.2015;20(3):5-7.
- Zampieron A, Buja A, Fusco M, Linder D, Bortune M, Piaserico S, et al. Quality of life in patients with scalp psoriasis. G Ital Dermatol Venereol.2015;150(3):309-16.
- van de Kerkhof PC, de Hoop D, de Korte J, Kuipers MV. Scalp psoriasis, clinical presentations and therapeutic management. Dermatology. 1998;197(4):326-34.

**Funding**  
The study was funded by Vichy Laboratoires.

**Acknowledgments**  
The authors acknowledge the participation of the subjects, the writing support of Karl Patrick Göritz, SMWS France and the art work of Dominique Poisson, France.