

MODELLING THE ANTICIPATED ORGANISATIONAL IMPACT ON HEALTH SERVICE PROVISION OF THE INTRODUCTION OF TIRBANIBULIN FOR THE TOPICAL TREATMENT OF ACTINIC KERATOSIS IN FRANCE (EPIKA STUDY).

HSD75



Pierre LEVY,¹ Brigitte DRÉNO,² Grégory CAILLET,³ Julie PAOLANTONACCI,⁴ Jean-Michel JOUBERT⁵ and Jean-Michel AMICI⁶

¹Université Paris-Dauphine; Université PSL, LEDA[LEGOS], PARIS, France; ²CHU Nantes, INSERM, CNRS, INCIT, UMR 1302/emr6001, NANTES, France; ³Affaires Médicales, Almirall SAS, ISSY-LES-MOULINEAUX, France; ⁴Real World Solutions, IQVIA, COURBEVOIE, France; ⁵Affaires Gouvernementales, Almirall SAS, ISSY-LES-MOULINEAUX, France; ⁶Service de Dermatologie, CHU Bordeaux, Hôpital Saint-André, BORDEAUX, France.

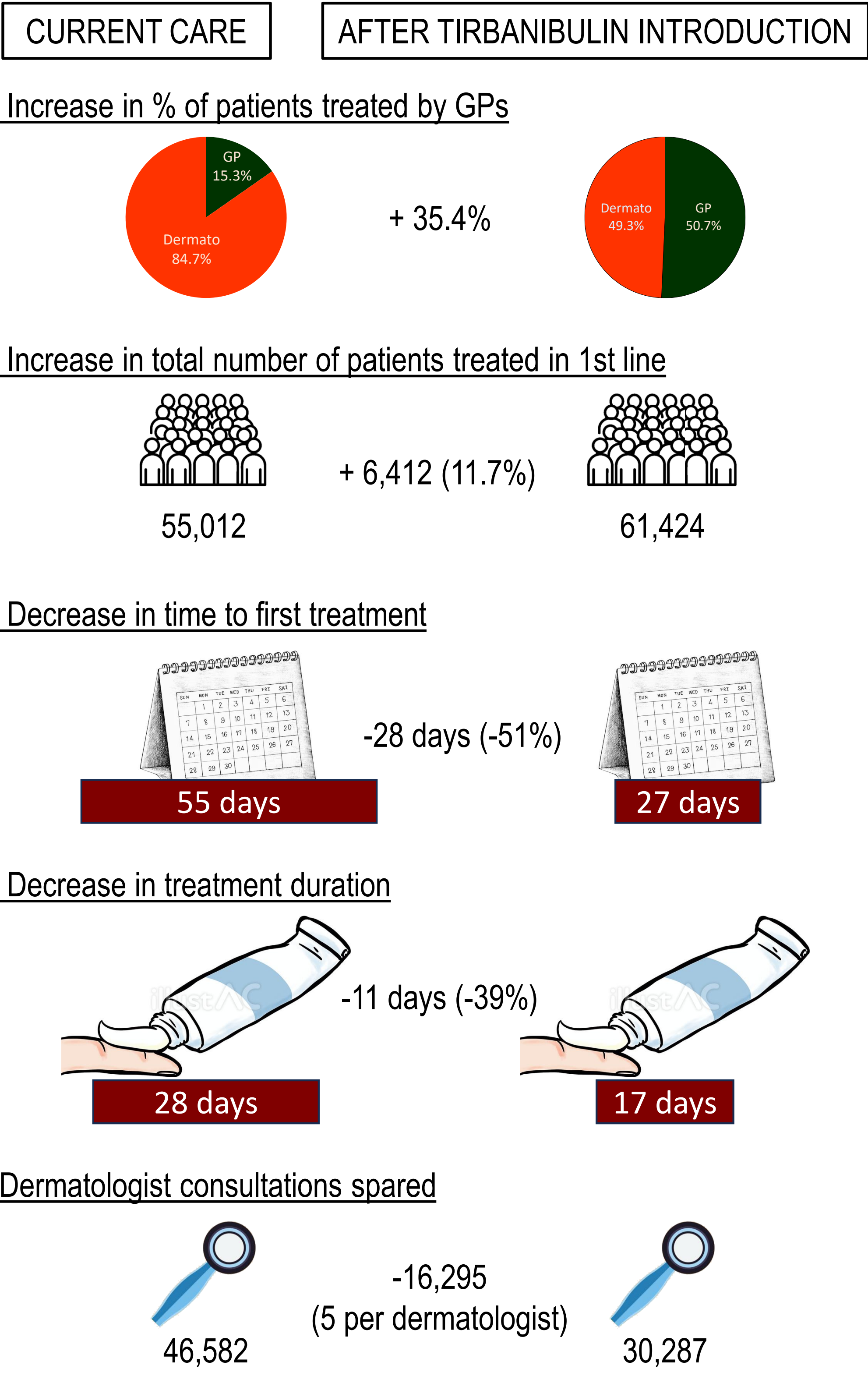
INTRODUCTIONMETHODS

- Actinic keratosis is a common skin disease caused by cumulative exposure to UV radiation, which carries a risk of transformation to cutaneous squamous cell cancer (cSCC).
 - The number of pharmacological (topical) treatments available for treating AK lesions and avoiding field cancerization is limited, and available treatments are considered difficult to use and associated with side-effects;¹ non-compliance with the treatment duration is frequent.²
 - Tirbanibulin has been demonstrated in Phase III trials to be an effective and safe treatment providing rapid resolution of lesions, with few, generally mild, adverse events reported.^{3,4,5}
 - Tirbanibulin has since been approved as a well-tolerated, more 'user-friendly' topical treatment for AK cancerisation fields up to 25 cm², with a short recommended treatment period of 5 days.
 - Assessment of the organisational impact (OI) of the introduction of new healthcare interventions is now a recognised component of health technology assessments and is now required by health authorities in certain countries, including France.^{6,7}
- This modelling study aimed to assess the potential OI of introduction of tirbanibulin for the topical treatment of AK on the French healthcare system, within the framework proposed by the French Health Authorities.⁷
 - The impact of the introduction of tirbanibulin as a topical AK treatment was assessed on the type of prescriber, the number of patients treated, the time to access treatment and compliance with the treatment duration.
 - The study incorporated data for the year 2018 on the number of patients treated for AK by France, waiting time for appointments with dermatologists or general practitioners (GPs), prescribing patterns for other simple-to-use topical treatments for acne, and historical experience with the now withdrawn ingenol mebutate.
 - The study hypotheses were validated by a committee of expert dermatologists.

MODEL INPUTS – Baseline data for AK care in 2018

Parameter	Value	Source
Number of AK patients treated	67,252	SNDS (EPIKA study) ⁸
Number of community dermatologists	3,178	French Health Statistics Office ⁹
% patients whose initial AK treatment is topical (5-FU or imiquimod)	60.2%	SNDS (EPIKA study) ⁸
% patients initiating topical treatment prescribed by a dermatologist	84.7%	SNDS (EPIKA study) ⁸
% patients initiating topical treatment prescribed by a GP	15.3%	SNDS (EPIKA study) ⁸
Waiting time to see a dermatologist in 2018	61 days	French Society for Dermatology ¹⁰
Waiting time to see a GP in 2018	6 days	French Society for Dermatology ¹⁰
Recommended treatment duration for topical treatments	28 days	Prescribing information ¹¹
% patients not respecting treatment duration for current topicals	56.0%	REAKT study ²

MODEL OUTPUTS



MODEL INPUTS – Hypotheses for AK care after introduction of tirbanibulin

Proportion of all topical prescriptions	Proportion of prescriptions filled by GPs	Recommended treatment duration	Non-compliant with treatment duration
50%	65%	5 days	1%
Source: Historical market share for ingenol mebutate	Source: Prescription patterns for moderate acne	Source: Prescribing information ¹¹	Source: Blauvelt et al. 2021. ³

CONCLUSIONS

- Introduction of a convenient and safe topical treatment for AK would be expected to transfer initial treatment from the dermatologist to the primary care sector.
- Facilitated access to first-line AK treatment should increase the overall proportion of patients treated (by 11%) and ensure earlier treatment.
- These improvements in the standard of care for AK may in turn help reduce transformation of AK to cSCC by a similar proportion.
- Reducing referrals to community dermatologists, potentially by 42%, would be expected to free up consultation time for care for more severe conditions.

REFERENCES

1. Amici JM et al. Acta Derm Venereol. 2025; 105:adv43351. doi: 10.2340/actadv.v105.43351; 2. Dréno B et al. Acta Derm Venereol. 2025; 105:adv42372, doi: 10.2340/actadv.v105.42372; 3. Blauvelt A et al. N Engl J Med. 2021; 384(6): 512-520, doi: 10.1056/NEJMoa2024040; 4. Jeong et al. J Drugs Dermatol. 2025; 24 (7): 19912s5-19912s12. doi: 10.36849/JDD.19912; 5. Gilchrist BA. Clin Pharmacol Drug Dev. 2021; 10(10): 1126-1129, doi: 10.1002/cpdd.1024; 6. Grumberg V et al. JCO Glob Oncol. 2023; 9:e2300026. doi: 10.1200/GO.23.00026.; 7. Haute Autorité de Santé: https://www.has-sante.fr/upload/docs/application/pdf/202104/organisational_impact_map_for_health_technology_assessment.pdf; 8. Lévy P et al. Value Health 2024; 27 (12): S271; 9. <https://data.drees.solidarites-sante.gouv.fr/explore/dataset/la-demographie-des-professionnels-de-sante-depuis-2012/information/>; 10. La Société Française de Dermatologie 2018; Livre Blanc: les défis de la dermatologie en France; 11. EMA. Tysabri prescribing information. https://www.ema.europa.eu/en/documents/product-information/klsyri-epar-product-information_en.pdf

This study was funded by Almirall SA.

Declaration of interest: JMA, PL and BD report honoraria from Almirall SA; GC and JMJ are employees of Almirall SA.