Systemic Treatment of Non-Melanoma Skin Cancers in France: Real-World Analysis using French Data from the National Hospitalization Database

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INTRODUCTION & OBJECTIVES

- Cemiplimab, an anti-PD1 antibody is approved for the treatment of patients with metastatic or locally advanced Cutaneous Squamous Cell Carcinoma (CSCC) who are not candidates for curative surgery or radiation.
- Cemiplimab was available from 2018 to 2021 through French Early Access Program (EAP).
- In January 2021, cemiplimab was reimbursed but was not included on the "liste en sus" (LES [ex-DRG funding list]).
- A real-world analysis based on data from the national hospitalization database (PMSI) was performed to study the evolution of systemic treatment pathways for patients with Non-Melanoma Skin Cancers (NMSC) before, during and after cemiplimab EAP, aiming to understand the impact of a non-inclusion on LES.
- CSCC are including in the PMSI NMSC code, among with Basal Cell Carcinoma (BCC) and Merkel Cell Carcinoma (MCC).

METHODS

- This study is a retrospective longitudinal study based on data from the French national hospitalization database (PMSI) between 2016 and 2021.
- Eligible patients were adults above 18 years old, selected through ICD-10 code C44 - "other and unspecified malignant neoplasm of skin" as primary diagnosis (DP), related diagnosis (DR) or significant associated diagnosis (DAS).
- Patients had to have received a systemic therapy for their NMSC in hospital, identified through DP, DR or DAS Z511[a], or GHM 28Z07[a], 17M05[b] or 17M06[c].
- Results were presented by prevalence between 2016 and 2021 and incidence between 2018 and 2021 (including a 2 years wash-out to ensure patients did not receive any previous systemic therapy for the treatment of NMSC).
- Among included patients, the systemic therapy administered were specifically identified when funded via an EAP or the LES and evolution of their use over time was described. A geographical analysis of their use was also performed.

RESULTS (1/2)

- A total of 6749 patients were identified, mostly male (67%) with a median age of 75 years at treatment initiation.
- Total number of yearly NMSC treated patients highly increased during the study period (+120%) (Table 1).

Table 1 – Included patients by year in France – Prevalence & incidence

	Prevalent treated patients (n)	Incident treated patients (n)
2016	912	Wash-out
2017	1212	Wash-out
2018	1448	1001
2019	1795	1212
2020	2108	1358
2021	2163	1287

- Proportion of the hospital admission including a therapy administered through the EAP or funded via the LES also increased on the study period until 2020, before a slight decrease in 2021 (Table 2).

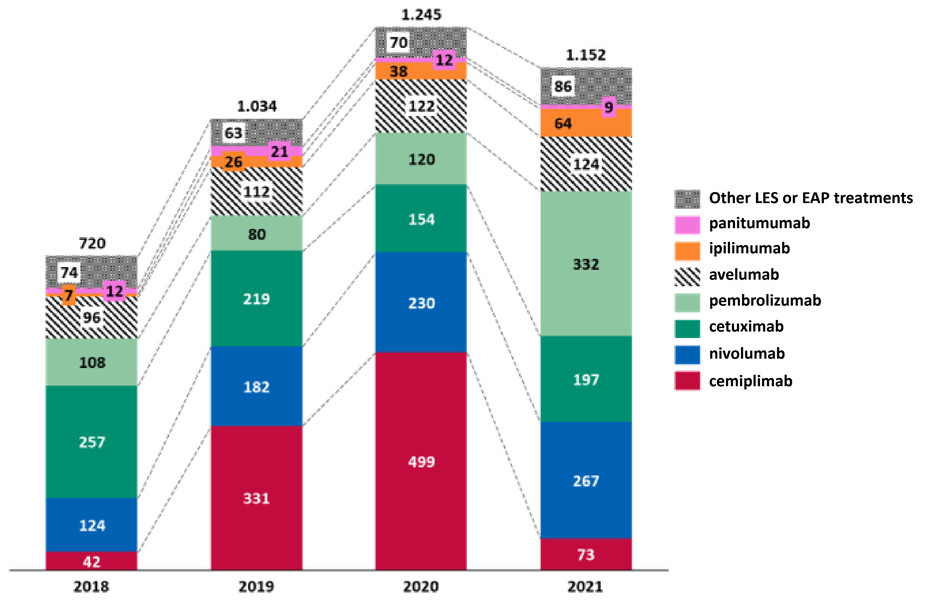
Table 2 – Part of the treatment strategy including EAP or LES drugs - France

	Total hospital admission (n)	Part of the admission including at least one EAP or LES drug (%)
2016	6876	42%
2017	8575	55%
2018	10891	60%
2019	13484	63%
2020	14283	76%
2021	15955	73%

- Among those, more-used therapies were, in descending order: cemiplimab, cetuximab, nivolumab, pembrolizumab and avelumab.
- At the end of cemiplimab EAP in its advanced-CSCC indication in January 2021, an important decrease of cemiplimab initiation among treated patients (-85%: from 499 to 73 patients) in 2021 is observed (*cf. Figure 1*)
- Concomitantly, a large increase of other anti-PD1 initiated, (e.g., +177%: from 120 to 332 patients).

RESULTS (2/2)

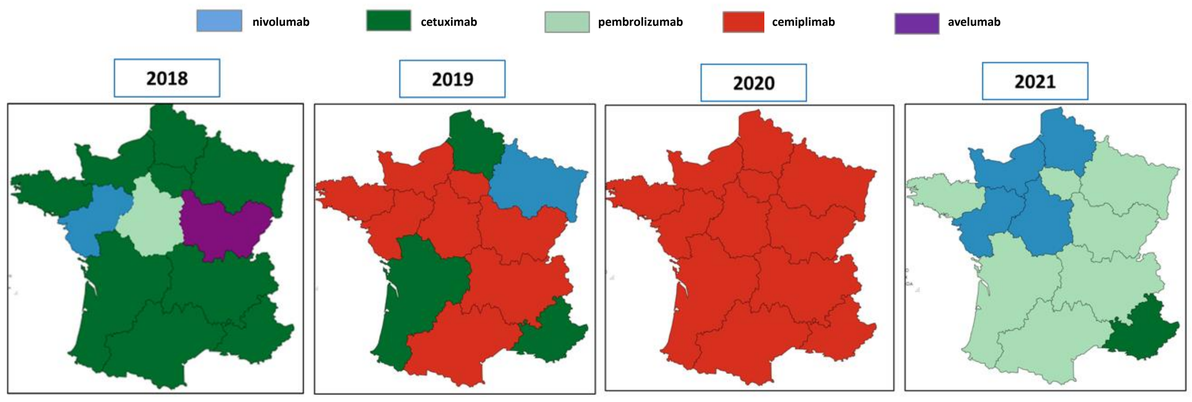
*Figure 1 – Evolution of the therapeutic strategy between 2018 and 2021 by initiated EAP/LES drugs**



*Systemic treatment administration not EAP/LES are excluded.

- A geographical analysis shows the evolution of the main therapeutic option used by department over the study period.

Figure 2 – Evolution of the therapeutic strategy by main LES/EAP drug administered by region



DISCUSSION

- The French National Hospitalization Database (PMSI) is a large and exhaustive base, that may provide precious insights on the evolution of the therapeutic pathways, given inherent bias and limitations are identified and controlled. In this study, two limitations were identified:
  - While the objective of the study is to understand the impact of the non-inclusion on the LES of cemiplimab CSCC indication, the included population corresponds to a larger population (i.e. NMSC includes CSCC, BCC and MCC). However, the results are expected to be mainly representative of the CSCC therapeutic strategy, excepted for the avelumab usage. Indeed BCC, although more prevalent, is less likely to evolve to locally advanced/metastatic stages, eligible to systemic treatment and when needed, systemic treatment are performed mainly via the retail path (hedgehog inhibitors). Regarding the MCC therapeutic strategy, it is well defined with one approved anti-PD1: avelumab.
  - As only EAP/LES drugs are specifically identified, cemiplimab usage could have remain in 2021 as part of the DRG funding (and as the part of the EAP/LES drugs among systemic therapies administered slightly decreased in 2021. However, this usage is less likely given its significative budget impact for hospitals.
  - To that extent, this study is a representative view of how the NMSC therapeutic strategy evolved during the past few years.

CONCLUSION

Non-inscription of cemiplimab on LES in France is associated with increased usage of others anti-PD1 therapies. Lack of approved treatment fully available also enhance inequities across the French territory depending on clinical practice and budget among the different centers.

REFERENCES

[a]Tumor chemotherapy session, [b]Acute Leukemia chemotherapy session, [c]Other tumor chemotherapy session

DISCLOSURES

Presenting author is a Sanofi employee and may hold shares and/or stock options in the company.

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