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Characteristics of patients with locally recurrent unresectable or metastatic triple-negative breast cancer who received pembrolizumab as part of a French Early Access Program in accordance with KN-355 labelling

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Background and Method

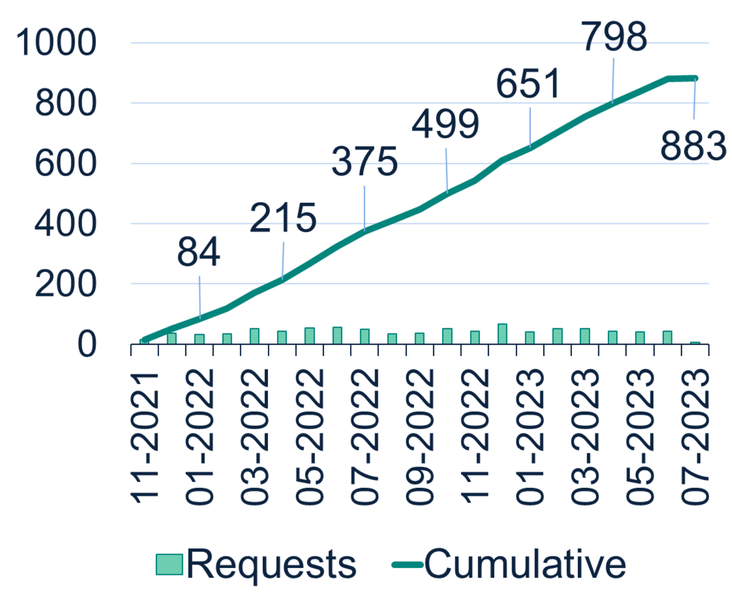
- Pembrolizumab in combination with chemotherapy obtained an European marketing authorization on October 19, 2021 for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC), whose tumours express PD-L1 at the cut-off of CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease.
- An Early Access Program (EAP) was granted on November 3, 2021 by French HTA body (HAS) based on the seriousness of the disease, the urge to treat, the lack of other appropriate treatment and the presumed innovative nature of pembrolizumab in this indication.
- For this EAP, a prospective data collection was conducted from November 5, 2021 to July 4, 2023 (date of final database lock: August 1, 2023) with 2 interim and 1 final analyses performed.
- Data from the total period of the EAP is presented (only 2nd interim data was available when the abstract was submitted).

Recruitment

- In total, 883 patients from 220 French centers were included in the EAP over 20 months (Figure 1- A).
- Patients recruitment was fairly constant during the EAP, with a mean of 42 requests per month (Figure 1-B).
- Most patients came from region of Ile-de-France (16%) and Auvergne-Rhône-Alpes (13%) and were recruited by medical oncologists (94%; Table 1 and Figure 1-C).

Figure 1. A. Evolution of the number of valid requests per month;
B.. Distribution of included patients in France (n=883)

A



B

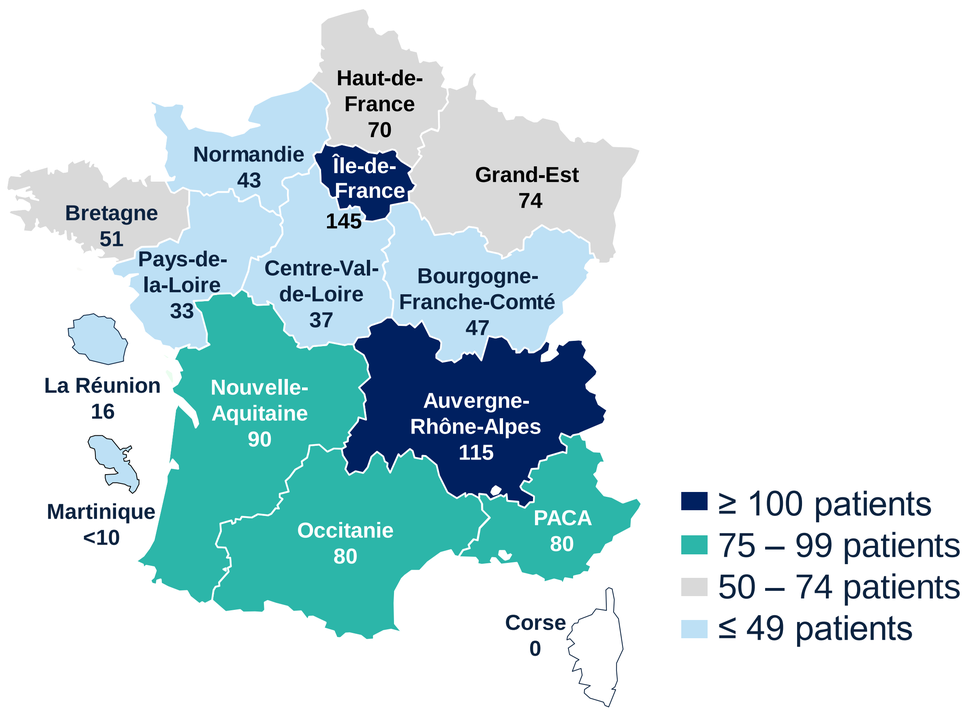


Table 1. Description of the prescribers participating in the EAP (N=501)

	Total period (Nov 5, 2021 – Jul 4, 2023; n=501)
Medical oncologist	472 (94.2%)
Radiation oncologist	27 (5.4%)
Other specialty	2 (0.4%)

Results

- Almost all patients were women (99%) with a mean age of 59 years (min-max : 27 – 94 years) and a BMI of 26 ±. 6 kg/m²
- Most women were post-menopausal (77%), few patients had the gBRCA 1-2 mutation (6%), and most patients were metastatic (90%) with lymph nodes metastases (58%).
- In addition, 23% of patients had a family history of breast cancer, 10% were current smokers, 13% former smokers, 15% had cardiovascular diseases, 8% diabetes and 2% consumed alcohol daily.
- At treatment access request and in the total population, 99% of patients were prescribed pembrolizumab as 200 mg every 3 weeks, and the associated chemotherapy was mostly paclitaxel (50%) or gemcitabine + carboplatin (39%).
- By the end of the EAP, 335 permanent discontinuation of pembrolizumab were reported.

Table 2. Clinical and treatment characteristics for included patients (n=883)

	Total period (Nov 5, 2021 – Jul 4, 2023; n=883)
Socio-demographics characteristics at treatment request	
Women (n [%])	878 (99.4%)
Age (years; mean (SD) [min – max])	59.2 (14.1) [27.0 – 94.0]
BMI (kg/m²)	25.9 (5.7)
Menopausal status for women at treatment access request (n [%])	
Post-menopausal	677 (77.1%)
Presence of gBRCA 1-2 gene mutation at treatment access request (n [%])	
Tested	407 (46.1%)
Positive	50 (5.7%)
Cancer stage at treatment access request (n [%])	
Metastatic, recurrent	418 (47.3%)
Metastatic, de novo	380 (43.0%)
Locally recurrent inoperable	85 (9.6%)
Localization of metastases at treatment access request (n [%])	
Lymph nodes	514 (58.2%)
Lung	315 (35.7%)
Bone	303 (34.3%)
Others	432 (48.9%)
Comorbidities (n [%])	
Family history of breast cancer	205 (23.2%)
Current smoker	84 (9.5%)
Former smoker	110 (12.5%)
Cardiovascular disease	129 (14.6%)
Diabetes	66 (7.5%)
Daily alcohol consumption	13 (1.5%)
Pembrolizumab regimen prescribed at treatment access request (n [%])	
200 mg every 3 weeks	873 (98.9%)
400 mg every 6 weeks	10 (1.1%)
Associated chemotherapy regimen prescribed at treatment access request (n [%])	
Paclitaxel 90 mg/m² on day 1, 8, and 15, every 28 days	428 (49.6%)
Gemcitabine 1000 mg/m² and carboplatin AUC 2 on day 1 and 8, every 21 days	337 (39.0%)
Other regimen	98 (11.4%)

Conclusion

- In the EAP, pembrolizumab was prescribed in accordance with the protocol of KEYNOTE-355[1] in combination with paclitaxel or carboplatin + gemcitabine and initiated mostly at 200 mg.
- Furthermore, patient characteristics were comparable to the overall population and to the French subgroup in the KEYNOTE-355 trial[1].
- The EAP ended on July 4, 2023 with the publication of the pricing & reimbursement of pembrolizumab in the Official Gazette.

1. Cortes J, Cescon DW, Rugo HS, Nowecki Z, Im SA, Yusof MM, et al. Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer (KEYNOTE-355): a randomised, placebo-controlled, double-blind, phase 3 clinical trial. Lancet Lond Engl. 5 déc 2020;396(10265):1817-28.

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