#130870

Characteristics of patients with advanced endometrial cancer who received pembrolizumab as part of an Early Access Program (EAP) in accordance with KN-775 labelling

Cagnan L[1], Hakmé A[1], Bénard N[1], Bensimon L[1], Alexandre J[2]

1. MSD France, Puteaux, France – 2. Université de Paris Cité, AP-HP, Cochin – Port Royal, service de cancérologie, Paris, France

Background

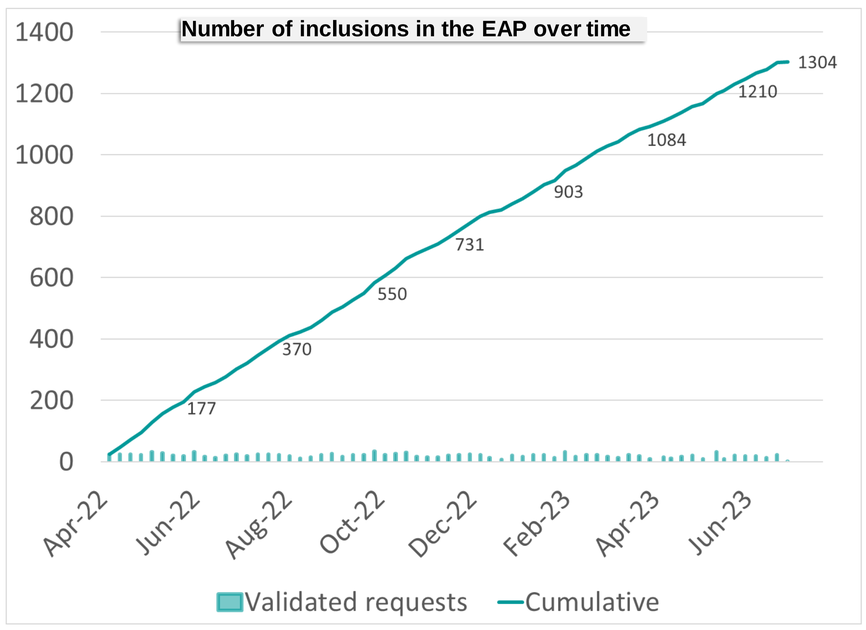
- Pembrolizumab in combination with lenvatinib obtained a European marketing authorization on November 15th, 2021 for the treatment of adult patients with advanced or recurrent endometrial cancer whose disease is progressing during or after prior platinum-based therapy at any stage and who are not eligible for curative surgery or radiotherapy.
- An Early Access Program (EAP) post-marketing authorization was granted on March 17th, 2022 by French HTA body Haute Autorité de Santé (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.

Method

- A prospective non-interventional data collection on characteristics of patients and prescribers, prescription conditions, condition of use of the drug and date of discontinuation was conducted from April 12, 2022 to July 04, 2023. Hospitals that prescribed pembrolizumab as part of the EAP had to collect data while requesting access to pembrolizumab and at discontinuation of pembrolizumab treatment. Eligible patients responded to the authorized

Results

Population and follow-up characteristics



1304 validated request forms

1278 patients treated

- In total, over 15 months, 1304 patients were included in the EAP with an average of 89 requests per month.
- The mean duration of the follow-up (from treatment access to data extraction) was **198 days** (min. 29 – max. 356).

Patients' general characteristics

1304

Age
25 – 93 years old
69.9 mean age *(s.d.8.5)*

Weight
69.6 kg
(s.d.16.9)

BMI
56.8% Overweight and obesity *(≥25kg/m²)*
38.7% Normal weight *([18.5-25]kg/m²)*
4.5% Underweight *(<18.5kg/m²)*

- Due to the nature of the disease, all patients were **females.**
- Mean age was **69.9 years**
- A majority of the patients were **overweight or obese.**

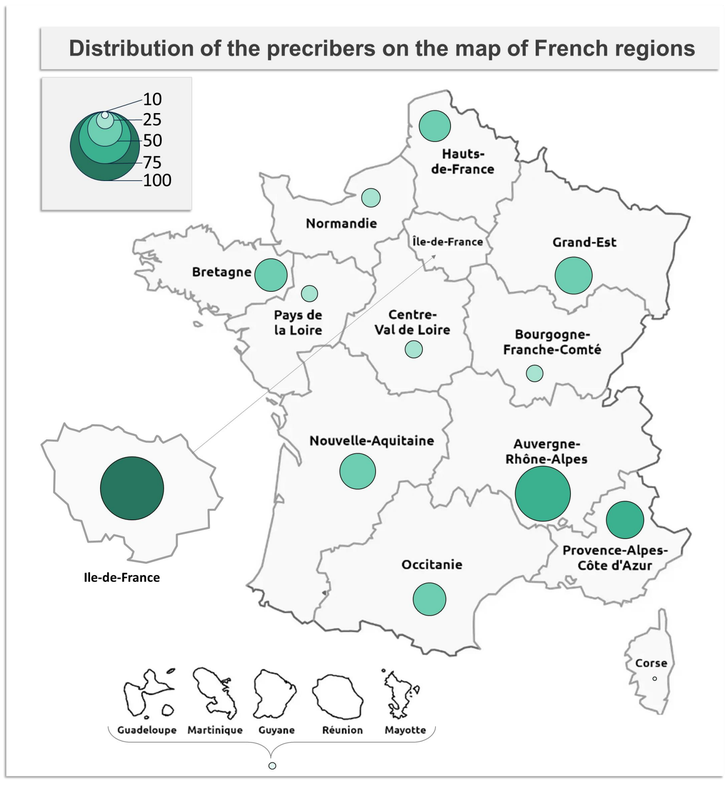
Disease history

- Most of the patients (94,2%) had **stage IV advanced endometrial cancer** (FIGO) with **metastases** in lymph node (58,1%), peritoneum (50,5%) and/or lung (41,8%).
- The 1304 patients included in the EAP represented a total of **1190 metastases**

Stage IV
Endometrial cancer
94.2%

Metastases
58.1% Lymph node
50.5% Peritoneum
41.8% Lung

Prescribers



Places of practice
35.0% Private Hospital or Institution
32.1% General Public Hospital
17.6% Cancer Control Centre
15.2% University Hospital

Location
15.6% Ile-de-France
13.7% Auvergne-Rhône-Alpes
9.2% PACA / Grand-Est

- Most of the prescribers were **oncologists (93,5%)** and worked either in **private or public hospital.**
- Most of them came from **Ile-de France**, **Auvergne-Rhône-Alpes**, PACA and Grand-Est.

Specialty
93.5% Oncologists
4,8% Onco-Radiotherapists
1% General practitioners
<1% Gynecologists, Internal medicine

Conditions of use of the drug at treatment request

- At treatment access request, **97.7%** of patients were prescribed **200mg/3weeks of pembrolizumab.**
- Associated starting doses of Lenvatinib was 20 mg/day for 75.5% of the EAP population

Treatment combination

75.5%	Pembrolizumab Lenvatinib	**200mg / 3 weeks** **20mg / day**
22.1%	Pembrolizumab Lenvatinib	**200mg / 3 weeks** **Other dose**
1.9%	Pembrolizumab Lenvatinib	**400mg / 6 weeks** **20mg / day**
0.6%	Other combinations and dosages	

- Over 15 months, a total of **279 patients (22%, N=1278) discontinued** pembrolizumab during the EAP.
- Disease progression was the main reason for discontinuation (69.2%), followed by death (18.6%).

Reason for discontinuation
69.2% Disease progression
18.6% Death

Conclusion

A total of **1278 patients** over 15 months were administered **pembrolizumab** in accordance with the SmPC and prescribed mainly at **200mg/3weeks**. **Population characteristics were comparable to the overall population**, and particularly to the French sub-group, **in the KEYNOTE-775 pivotal trial**. The increasing trend of inclusion of patient all over the EAP period demonstrates the **important therapeutic need,** not covered until the approval of this **EAP** in France.

The **EAP ended on July 4, 2023** with the **publication of the pricing & reimbursement of pembrolizumab** in the French Official Gazette.

ISPOR; Europe 2023; 12-15 November 2023. Copenhagen, Denmark