RWD165

Real-World Treatment Patterns of Locally Advanced and Metastatic Urothelial Cancer (la/mUC) in France: A Secondary Database Analysis

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Objective

- To evaluate the proportion of patients initiating first-line treatment among newly diagnosed patients with locally advanced or metastatic urothelial carcinoma (la/mUC) and to describe treatment patterns

Conclusions

- Before the approval of enfortumab vedotin + pembrolizumab (EV+P) as first-line treatment, the use of novel treatments in this setting was limited[1,2]
  - Most patients who received first-line treatment received only first-line chemotherapy (92%), with only 20% receiving avelumab maintenance
  - Few patients received EV monotherapy in later lines (~15% in second-line; 27% in third-line)
- A significant proportion (34.7%) of patients with la/mUC remain untreated, highlighting an unmet need in first-line treatment initiation
- While use of EV has increased in second-line treatment or later in alignment with treatment guidelines,[3] its approval in combination with pembrolizumab sets a new first-line standard of care, independent of prior chemotherapy response, potentially reshaping treatment approaches
  - Future analyses using data from 2024 and beyond will provide more insight into the changes in treatment patterns

References

1. Joly F, et al. *Future Oncol.* 2025;21(6):665–679. 2. Joly F, et al. Presented at: ESMO Annual Meeting; 13–17 September 2024; Barcelona, Spain and online. Poster 2001P. 3. Powles T, et al. *Ann Oncol*. 2024;35(6):485–490.

Conflicts of Interest

AT and **KK** are employees of IQVIA, contracted by Astellas Pharma Inc. to conduct the study. **TS-M**, **MT**, **KL**, **MV**, **M-CT**, **AE**, and **KM** are employees of Astellas. **MR** received consulting fees from Astellas, AstraZeneca, Bayer, Bristol Myers Squibb, Ipsen, and Johnson & Johnson. **SC** received payment or honoraria from Merck and Merck Sharp & Dohme; and participated in an advisory board for Bristol Myers Squibb. **FJ** received payment or honoraria from Astellas, Merck Sharp & Dohme, and Pfizer; and received support for attending meetings and/or travel from Merck Sharp & Dohme.

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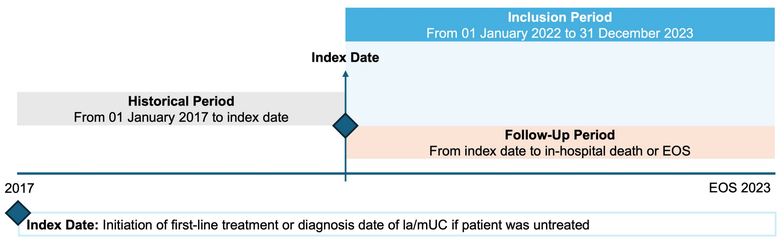
Background

- The treatment landscape of la/mUC has evolved over the last few years in France with the approval of new treatment options, including programmed death-ligand 1 (PD-L1) inhibitors (eg, avelumab maintenance), EV monotherapy from second line, and the approval and inclusion of EV+P in the 2024 guidelines as preferred first-line treatment for la/mUC[3]
- In light of these recent developments, there is a need to understand the current clinical practice of patients with la/mUC in France
- Previous studies have aimed to characterise real-world treatment patterns in patients with la/mUC in France:
  - EVOLVE 1 (2017–2020) and EVOLVE 2 (2020–2022) found that over one-third of patients with la/mUC did not receive any first-line systemic treatment[1,2]
  - In EVOLVE 2, the most common first-line treatment was chemotherapy; use of avelumab maintenance based on response to first-line treatment, second-line checkpoint inhibitors, and second-line EV were not frequently used[2]
- This third EVOLVE study (2022–2023) complements earlier findings and assesses recent changes in first and subsequent treatment lines, including EV monotherapy, prior to EV+P approval

Methods

- This was an observational, retrospective cohort study using data extracted from the Programme de Médicalisation des Systèmes d'Information (PMSI), the French hospital discharge database
- Adults newly diagnosed with la/mUC between 01 January 2022 and 31 December 2023 without any evidence of treatment for a cancer other than urothelial carcinoma after the la/mUC diagnosis were included
- Treatment patterns were mapped for patients initiating first-line treatment before 01 July 2023, allowing for a minimum follow-up of 6 months
  - All patients who received treatment were considered treated regardless of when treatment was received
- The primary endpoint was to evaluate the proportion of patients initiating first-line treatment among newly diagnosed patients with la/mUC
- The key secondary endpoint was to describe treatment patterns from the start date of first-line treatment to in-hospital death or end of study, whichever came first

Figure 1: Study Schematic



EOS, end of study; la/mUC, locally advanced or metastatic urothelial carcinoma.

Results

Patient Overview and Characteristics

- In total, 17,795 patients with la/mUC were included over a period of 2 years, of whom 6,187 (34.8%) were untreated and 11,608 (65.2%) received treatment
- Among the 11,372 patients (63.9%) who initiated first-line treatment within 3 months of diagnosis, the median age was 72.0 years and 78.8% of patients were male (**Table 1**)
  - Baseline and clinical characteristics in patients with a minimum follow-up of 6 months were consistent with the overall population
- Untreated patients were older (median, 79.0 years) and had higher comorbidity burden versus treated patients (**Table 1**)
- Prior cancers were more frequent in untreated patients, including lung and prostate cancers

Table 1: Baseline and Clinical Characteristics of Treated and Untreated Patients

	Overall (treated)[a] (N=11,372)	Overall (untreated)[b] (N=6,187)
Age, years		
Median (Q1–Q3)	72.0 (65.0–78.0)	79.0 (71.0–85.0)
Sex, n (%)[c]		
Male	8,954 (78.7)	4,813 (77.8)
Female	2,413 (21.2)	1,372 (22.2)
Missing	5 (<0.1)	2 (<0.1)
Prior treatments, n (%)[d]		
Radical cystectomy	1,960 (17.2)	764 (12.3)
Partial cystectomy	152 (1.3)	50 (0.8)
Total nephroureterectomy	755 (6.6)	185 (3.0)
Tumour resection	9,026 (79.4)	3,683 (59.5)
Radiotherapy	566 (5.0)	224 (3.6)
Intravesical instillation	1,264 (11.1)	377 (6.1)
Neoadjuvant or adjuvant chemotherapy (including nivolumab)	1,036 (9.1)	229 (3.7)
Comorbidities, n (%)[e]		
Myocardial infarction	1,179 (10.4)	886 (14.3)
Congestive heart failure	696 (6.1)	860 (13.9)
Peripheral vascular disease	1,643 (14.4)	1,149 (18.6)
Cerebrovascular disease	753 (6.6)	634 (10.2)
Chronic pulmonary disease	1,465 (12.9)	1,082 (17.5)
Diabetes[f]		
Uncomplicated	1,032 (9.1)	504 (8.1)
End-organ damage	1,101 (9.7)	944 (15.3)
Moderate or severe renal disease	1,404 (12.3)	1,345 (21.7)
Adjusted CCI score		
Median (Q1–Q3)	9.0 (8.0–11.0)	11.0 (9.0–13.0)
History of other cancer prior to UC, n (%)		
Other cancer (including lung and prostate cancers)	1,535 (13.5)	1,336 (21.6)
Lung cancer	123 (1.1)	184 (3.0)
Prostate cancer	306 (2.7)	365 (5.9)

[a]Patients diagnosed with la/mUC between 01 January 2022 and 31 December 2023 who initiated a first-line treatment within 3 months of diagnosis.
[b]Patients with la/mUC without evidence of treatment between 01 January 2022 and 31 December 2023.
[c]Percentages may not total 100% due to rounding.
[d]Patients may have received multiple prior treatments; percentages do not sum to 100%.
[e]Patients may have multiple comorbidities; percentages do not sum to 100%.
[f]The definition of diabetes with end-organ damage was completed by identification of diabetes plus ≥1 of the following conditions: myocardial infarction, moderate or severe renal disease, or cerebrovascular disease.
CCI, Charlson Comorbidity Index; la/mUC, locally advanced or metastatic urothelial carcinoma; UC, urothelial carcinoma.

First-Line Treatment Patterns

- Among the 7,907 patients who started first-line treatment before 01 July 2023, 7,241 (91.6%) received chemotherapy and 654 (8.3%) received programmed cell death protein 1 (PD-1)/PD-L1 inhibitor monotherapy (**Table 2**)
- Avelumab maintenance after chemotherapy was received by 1,589 (20.1%) patients who initiated first-line treatment

Table 2: First-Line Treatment Patterns and Durations in Patients With la/mUC by Year of Treatment Initiation (2022–2023)

	Overall (N=7,907)	Year of start date of treatment line	
		2022 (n=5,080)	2023[a] (n=2,827)
Type of first-line treatment, n (%)[b]			
Chemotherapy[c]	7,241 (91.6)	4,684 (92.2)	2,557 (90.4)
Chemotherapy followed by avelumab in maintenance	1,589 (20.1)	1,048 (20.6)	541 (19.1)
PD-1/PD-L1 inhibitor	654 (8.3)	386 (7.6)/ 395 (7.8)	260 (9.2)/ 269 (9.5)
Pembrolizumab	502 (6.3)	314 (6.2)	188 (6.7)
Atezolizumab	≤10 (≤0.1)	≤10 (≤0.2)	≤10 (≤0.4)
Nivolumab	100 (1.3)	47 (0.9)	53 (1.9)
Avelumab (not maintenance)	57 (0.7)	33 (0.6)	24 (0.8)
EV	12 (0.2)	≤10 (≤0.2)	≤10 (≤0.4)
EV+P	–	–	–
Duration of first-line treatment, days			
Median (Q1–Q3)	64.0 (29.0–152.0)	64.0 (31.0–155.0)	60.0 (29.0–148.0)

[a]Patients who initiated a first-line treatment before 01 July 2023 (a minimum of 6 months of follow-up).
[b]Patients may have received >1 type of first-line treatment; percentages are not mutually exclusive and may not sum to 100%.
[c]First-line chemotherapy includes chemotherapy and chemotherapy followed by avelumab maintenance.
EV, enfortumab vedotin; la/mUC, locally advanced or metastatic urothelial carcinoma; P, pembrolizumab; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1.

Treatment Patterns in Subsequent Lines

- Among the 7,907 patients treated in acute care units, second-line treatment was initiated in 2,596 (32.8%) patients (included over a period of 18 months), most commonly as monotherapy with PD-1/PD-L1 inhibitors (45.3%; 1,175/2,596), chemotherapy (38.9%; 1,011/2,596), and EV (~15.0%; **Table 3**)
- The median interval between first- and second-line treatment was 42 days (Q1–Q3, 21.0–90.0)
- The median duration of second-line treatment was 43 days (Q1–Q3, 15–99)
- Third-line treatment was initiated in 762 (9.6%) patients (included over a period of 18 months), primarily chemotherapy (51.2%; 390/762), EV (27.2%; 207/762), and PD-1/PD-L1 inhibitors (20.3–21.5; 155–164/762; **Table 3**)
- The median interval between second- and third-line treatment was 35 days (Q1–Q3, 21–76)
- The median duration of third-line treatment was 29 days (Q1–Q3, 8.0–85.0)

Table 3: Second- and Third-Line Treatment Patterns and Durations in Patients With la/mUC by Year of Treatment Initiation (2022–2023)

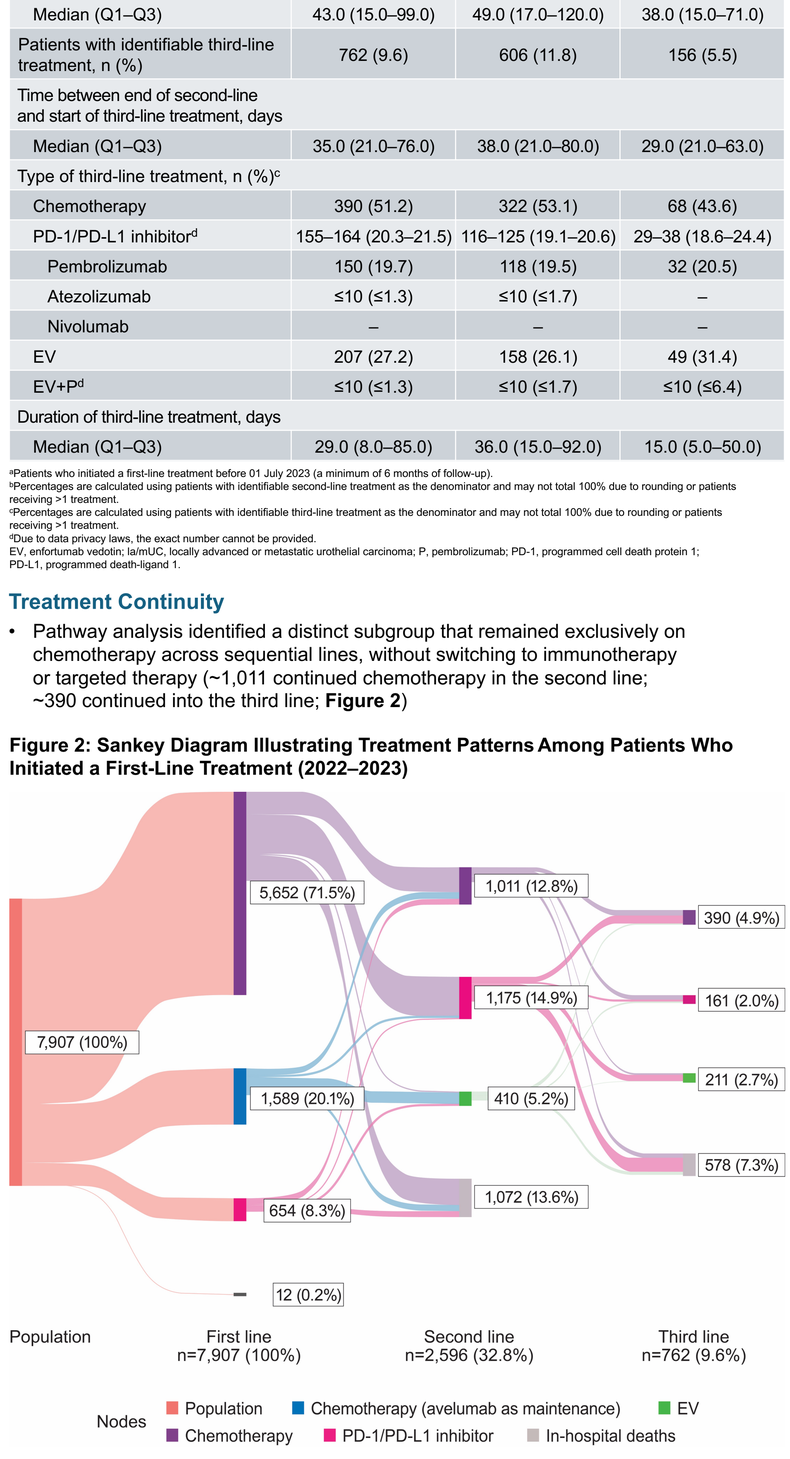
	Overall (N=7,907)	Year of start date of treatment line	
		2022 (n=5,080)	2023[a] (n=2,827)
Patients with identifiable second-line treatment, n (%)	2,596 (32.8)	1,834 (36.1)	762 (27.0)
Time between end of first-line and start of second-line treatment, days			
Median (Q1–Q3)	42.0 (21.0–90.0)	42.0 (21.0–96.0)	39.0 (21.0–77.0)
Type of second-line treatment, n (%)[b]			
Chemotherapy	1,011 (38.9)	726 (39.6)	285 (37.4)
PD-1/PD-L1 inhibitor	1,175 (45.3)	801 (43.7)	374 (49.1)
Pembrolizumab	1,141 (44.0)	776 (42.3)	365 (47.9)
Atezolizumab	≤10 (≤0.4)	≤10 (≤0.5)	–
Nivolumab	33 (1.3)	23 (1.3)	≤10 (≤1.3)
EV[c,d]	400–409 (15.4–15.8)	297–306 (16.2–16.7)	93–102 (12.2–13.4)
EV+P[d]	≤10 (≤0.4)	≤10 (≤0.5)	≤10 (≤1.3)
Duration of second-line treatment, days			
Median (Q1–Q3)	43.0 (15.0–99.0)	49.0 (17.0–120.0)	38.0 (15.0–71.0)
Patients with identifiable third-line treatment, n (%)	762 (9.6)	606 (11.8)	156 (5.5)
Time between end of second-line and start of third-line treatment, days			
Median (Q1–Q3)	35.0 (21.0–76.0)	38.0 (21.0–80.0)	29.0 (21.0–63.0)
Type of third-line treatment, n (%)[c]			
Chemotherapy	390 (51.2)	322 (53.1)	68 (43.6)
PD-1/PD-L1 inhibitor[d]	155–164 (20.3–21.5)	116–125 (19.1–20.6)	29–38 (18.6–24.4)
Pembrolizumab	150 (19.7)	118 (19.5)	32 (20.5)
Atezolizumab	≤10 (≤1.3)	≤10 (≤1.7)	–
Nivolumab	–	–	–
EV	207 (27.2)	158 (26.1)	49 (31.4)
EV+P[d]	≤10 (≤1.3)	≤10 (≤1.7)	≤10 (≤6.4)
Duration of third-line treatment, days			
Median (Q1–Q3)	29.0 (8.0–85.0)	36.0 (15.0–92.0)	15.0 (5.0–50.0)

[a]Patients who initiated a first-line treatment before 01 July 2023 (a minimum of 6 months of follow-up).
[b]Percentages are calculated using patients with identifiable second-line treatment as the denominator and may not total 100% due to rounding or patients receiving >1 treatment.
[c]Percentages are calculated using patients with identifiable third-line treatment as the denominator and may not total 100% due to rounding or patients receiving >1 treatment.
[d]Due to data privacy laws, the exact number cannot be provided.
EV, enfortumab vedotin; la/mUC, locally advanced or metastatic urothelial carcinoma; P, pembrolizumab; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1.

Treatment Continuity

- Pathway analysis identified a distinct subgroup that remained exclusively on chemotherapy across sequential lines, without switching to immunotherapy or targeted therapy (~1,011 continued chemotherapy in the second line; ~390 continued into the third line; **Figure 2**)

Figure 2: Sankey Diagram Illustrating Treatment Patterns Among Patients Who Initiated a First-Line Treatment (2022–2023)



Note: values are presented in this manner to comply with French GDPR requirements, ensuring that any group with <11 patients remains anonymised. Percentages are calculated using patients who started first-line treatment before 01 July 2023 as the denominator.
EV, enfortumab vedotin; GDPR, General Data Protection Regulation; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1.

Limitations

- There is no specific code for la/mUC in the PMSI database, so a combination of codes for urothelial carcinoma, along with additional codes indicative of progression to la/mUC, was necessary
- As tumour progression is not captured in the PMSI database, treatment lines cannot be reliably identified; therefore treatment sequences are used instead
  - This also prevents the identification of patients who may have been eligible to receive avelumab based on their response to chemotherapy and the estimation of avelumab uptake in the eligible population
- Follow-up for second- and third-line treatments is limited, which could impact treatment patterns observed in this study