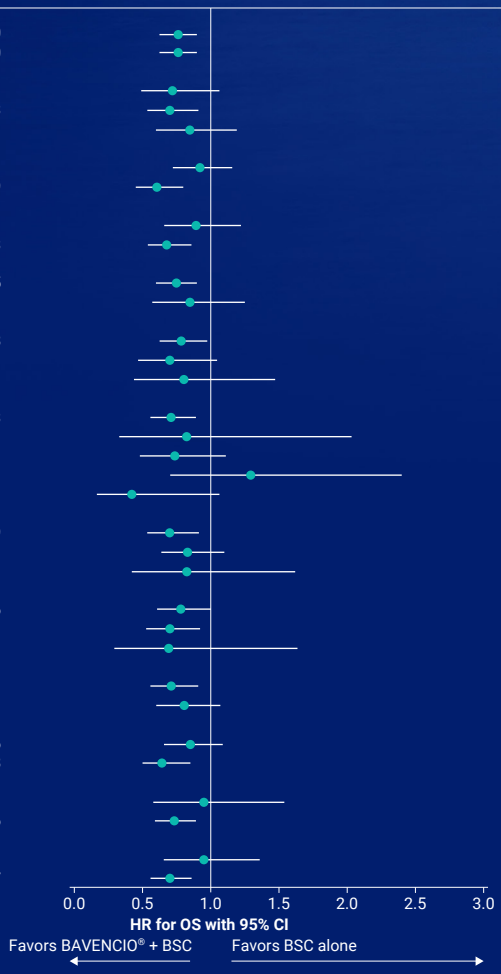
BAVENCIO® First-line maintenance treatment in mUC

OVERALL SURVIVAL AT ITS CORE

Indication:
BAVENCIO® is indicated for the first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed with first-line platinum-based induction chemotherapy.[1]

Subgroup analysis of OS in the overall population[2]

Subgroup	BAVENCIO® + BSC (No. of events/no. of patients)	BSC (No. of events/no. of patients)	HR for OS (95% CI)*
All patients (stratified)†	215/350	237/350	0.76 (0.631-0.915)
All patients (unstratified)	215/350	237/350	0.75 (0.627-0.908)
Best response to 1L chemotherapy			
CR	43/90	54/89	0.72 (0.482-1.076)
PR	108/163	117/163	0.70 (0.541-0.914)
SD	64/97	66/98	0.84 (0.596-1.188)
Metastatic disease site when initiating 1L chemotherapy			
Visceral	130/191	130/191	0.91 (0.713-1.162)
Nonvisceral	85/159	107/159	0.60 (0.451-0.798)
Age			
<65 years	85/129	71/107	0.89 (0.651-1.224)
≥65 years	130/221	166/243	0.68 (0.544-0.862)
Sex			
Male	163/266	189/275	0.74 (0.596-0.908)
Female	52/84	48/75	0.84 (0.568-1.250)
Race			
White	151/232	162/238	0.78 (0.625-0.975)
Asian	41/75	55/81	0.70 (0.464-1.044)
Other	23/43	20/31	0.80 (0.435-1.470)
Pooled geographic region			
Europe	136/214	146/203	0.71 (0.558-0.892)
North America	7/12	14/22	0.82 (0.330-2.035)
Asia	40/73	49/74	0.73 (0.479-1.108)
Australasia	23/34	18/37	1.29 (0.697-2.398)
Rest of the world	9/17	10/14	0.42 (0.163-1.061)
PD-L1 status at baseline			
Positive	102/189	108/169	0.69 (0.530-0.912)
Negative	101/139	100/131	0.83 (0.630-1.096)
Unknown	12/22	29/50	0.82 (0.418-1.614)
1L chemotherapy regimen			
Gemcitabine + cisplatin	108/183	134/206	0.78 (0.607-1.008)
Gemcitabine + carboplatin	97/147	91/122	0.70 (0.523-0.929)
Gemcitabine + carboplatin + cisplatin‡	10/20	11/20	0.69 (0.294-1.639)
ECOG performance status			
0	125/213	141/211	0.72 (0.563-0.913)
≥1	90/137	96/139	0.81 (0.606-1.078)
Creatinine clearance at baseline			
≥60 mL/min	113/181	125/196	0.84 (0.652-1.085)
<60 mL/min	101/168	109/148	0.64 (0.491-0.845)
Liver lesions at baseline			
Yes	33/43	33/44	0.95 (0.585-1.541)
No	182/307	204/306	0.73 (0.597-0.892)
Lung lesions at baseline			
Yes	59/83	57/83	0.95 (0.658-1.364)
No	156/267	180/267	0.70 (0.564-0.866)



JAVELIN Bladder 100: BAVENCIO® 1L maintenance offers locally advanced or metastatic UC patients the longest mOS from start of 1L therapy[3,4]

JAVELIN Bladder regimen (1L platinum-containing chemotherapy followed by BAVENCIO® 1L maintenance in patients without PD)[3]

4-6 cycles (x3 weeks) | No PD

1L chemotherapy: 3-5 months	TFI: 4-10 weeks	Median OS with avelumab 1L maintenance: 23.8 months[2]

Estimated median OS from start of 1L therapy: ≈27.8-31.3 months

ICI as 2L therapy after 1L platinum-containing chemotherapy[5]

Median PFS with 1L chemotherapy: 6-8 months	Median OS with 2L pembrolizumab: 10.1 months

≈16.1-18.1 months

ICI in combination with 1L platinum-containing chemotherapy[6-7]

Median OS with 1L chemotherapy + atezolizumab or pembrolizumab: 16.0-17.0 months

16.0-17.0 months

ICI as 1L monotherapy (for cisplatin-ineligible patients with a PD-L1+ tumor only)[8-9]

Median OS with 1L atezolizumab or pembrolizumab: 12.3-18.5 months

12.3-18.5 months

ICI + ICI as 1L therapy (anti-PD-L1 + anti-CTLA-4)[10]

Median OS with 1L durvalumab + tremelimumab: 15.1 months

15.1 months

* HRs and CIs were calculated using a Cox proportional hazards model. † Patients were stratified by best response to 1L chemotherapy (CR or PR vs SD) and metastatic disease site when initiating 1L CT (visceral vs non-visceral). ‡ Includes patients who switched platinum regimens while receiving 1L CT.

1L, first-line; 2L, second-line; BSC, best supportive care; CI, confidence interval; CR, complete response; CT, chemotherapy; CTLA-4, cytotoxic T lymphocyte antigen-4; ECOG, eastern cooperative oncology group; HR, hazard ratio; ICI, immune checkpoint inhibitor; OS, overall survival; PD-L1, programmed death-ligand 1; PR, partial response; SD, stable disease; TFI, treatment free interval.

1. BAVENCIO Singapore Prescribing Information (2021). **2.** Powles T, et al. Poster E7. Presented at: ASCO GU Symposium; February 17-19, 2022; San Fransisco, CA. **3.** Powles T, et al. N Engl J Med 2020;383:1218-30. **4.** Grivas P, et al. Cancer Treat Rev. 2021;97:102187. **5.** Fradet Y, et al. Ann Oncol 2019;30:970-6. **6.** Galsky MD, et al. Lancet 2020;395:1547-57. **7.** Powles T, et al. Lancet Oncol 2021;22:931-45. **8.** Balar AV, et al. Lancet 2017;389:67-76. **9.** Vuky J, et al. J Clin Oncol 2020;38:2658-66. **10.** Powles T, et al, Lancet Oncol 2020;21:1574-88.

Bavencio® (avelumab). Indication(s): Bavencio® is indicated as monotherapy for the treatment of patients with metastatic Merkel cell carcinoma (MCC). Bavencio in combination with axitinib is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC). Bavencio is indicated for the first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed with first-line platinum-based induction chemotherapy. **Dosage:** The recommended dose of Bavencio as monotherapy is 800 mg administered intravenously over 60 minutes every 2 weeks. Administration of Bavencio should continue according to the recommended schedule until disease progression or unacceptable toxicity. The recommended dose of Bavencio in combination with axitinib is 800 mg administered intravenously over 60 minutes every 2 weeks and axitinib 5 mg orally taken twice daily (12 hours apart) with or without food until disease progression or unacceptable toxicity. **Contraindications:** None. **Special populations:** Elderly - No dose adjustment is needed for elderly patients (≥ 65 years). Pediatric population - The safety and efficacy of Bavencio® in children and adolescents below 18 years of age have not been established. Renal impairment - No dose adjustment is needed for patients with mild or moderate renal impairment. There are insufficient data in patients with severe renal impairment for dosing recommendations. Hepatic impairment - No dose adjustment is needed for patients with mild hepatic impairment. There are insufficient data in patients with moderate or severe hepatic impairment for dosing recommendations. **Special warnings and precautions for use:** Infusion-related reactions, which might be severe, have been reported in patients receiving Bavencio®. Most immune-related adverse reactions with Bavencio® were reversible and managed with temporary or permanent discontinuation of Bavencio®, administration of corticosteroids and/or supportive care. Immune-related pneumonitis, hepatitis, colitis, thyroid disorders, immune-related adrenal insufficiency and Type 1 diabetes mellitus occurred in patients treated with Bavencio®. Bavencio® can cause immune-related nephritis. Other clinically important immune-related adverse reactions were reported in less than 1% of patients: pneumonitis including fatal cases, hepatitis including fatal cases, myocarditis including fatal cases, pancreatitis including fatal cases, myositis, hypopituitarism, uveitis, myasthenia gravis, myasthenic syndrome, and Guillain-Barré syndrome. For more information and management of immune-mediated adverse events and infusion-related reactions, see full prescribing information of Bavencio®. **Drug Interactions:** It is not expected that Bavencio® will have pharmacokinetic drug-drug interactions with other medicinal products.

Full prescribing info is available on request.

For healthcare professionals only.

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BAVENCIO® avelumab 20 mg/mL Concentrate for solution for infusion

SG-AVEBL-00073