Budget impact analysis of avelumab + best supportive care (BSC) as first-line maintenance treatment in patients with locally advanced or metastatic urothelial carcinoma (la/mUC) in Ireland

L. Russell,[1] K. Christoforou,[2] M. McAlister,[1] S. T. Alexopoulos,[2] A. Bullement[3]

[1]Pfizer Healthcare Ireland, Dublin, Ireland; [2]Merck Serono Ltd., Feltham, UK, an affiliate of Merck KGaA; [3]Delta Hat, Nottingham, UK

SCOPE

- **The objective of this study was to estimate the budget impact of avelumab + BSC in the overall la/mUC treatment paradigm in Ireland and to demonstrate potential cost offsets**
- **The National Centre for Pharmacoeconomics (NCPE) budget impact model (BIM) template was used to derive the estimated gross budget impact (GBI) and net budget impact (NBI) (scenarios with and without avelumab + BSC as a first-line [1L] maintenance treatment for la/mUC)[1]**

CONCLUSIONS

- **The total cumulative 5-year GBI was estimated to be €32.57 million, including value-added tax (VAT)[2]**
- **Reflecting scenarios with and without the introduction of avelumab 1L maintenance in the treatment paradigm, the 5-year NBI including VAT was estimated to be €17.93 million.[2] This estimate demonstrates the potential cost offsets achieved with avelumab 1L maintenance through the displacement of second-line immunotherapy**
- **Avelumab 1L maintenance treatment for la/mUC, has the potential to address unmet clinical needs and improve survival outcomes while maintaining health-related quality of life in patients with la/mUC with a modest budget impact[2,3]**

Correspondence: **Leah Russell, leah.russell@pfizer.com**

BACKGROUND

- Bladder cancer is one of the most commonly diagnosed cancers worldwide; urothelial carcinoma is the most common type, accounting for >90% of cases[4,5]
- In Ireland, an annual average of 223 deaths from bladder cancer occurred in 2015-2017, accounting for 2% of all deaths from cancer.[6] Survival is especially poor in patients with advanced/metastatic bladder cancer[7]
- The current 1L standard of care in Ireland for patients with la/mUC is platinum-based chemotherapy; although a high proportion of patients respond to 1L platinum-based chemotherapy, durable and complete long-term response is uncommon[8-10]
- Prior to the Health Service Executive (HSE) reimbursement of avelumab for la/mUC in Ireland, beginning 1st September 2022, the population under assessment that achieved complete response, partial response, or stable disease following platinum-based chemotherapy was regularly monitored until disease progression. Response was seldom durable, and median progression-free survival (PFS) could be short[2-4]
- Avelumab, indicated as a monotherapy for 1L maintenance treatment of adult patients with la/mUC who are progression free following platinum chemotherapy, demonstrated statistically significant improvement in overall survival in patients with la/mUC.[3] Avelumab + BSC is included in international treatment guidelines as the new standard of care for patients with la/mUC[11-13]
- The NCPE is commissioned by the Corporate Pharmaceutical Unit of the HSE to assess evidence of the comparative effectiveness and cost effectiveness of medicines for use by patients in Ireland
- Here we present a budget impact analysis of avelumab + BSC as 1L maintenance treatment for patients with la/mUC in Ireland, which was included as part of the pharmacoeconomic assessment submitted to the HSE and NCPE

METHODS

- A BIM was developed in line with the NCPE BIM template[1]
- This Excel-based model was used to derive the GBI and NBI results (scenarios with and without avelumab as 1L maintenance treatment)
- A 5-year time horizon was applied, adopting the perspective of the HSE in Ireland. The estimated eligible patient population under assessment reflected Irish-specific epidemiology data, when available, for the population in scope
- When Irish-specific epidemiology data were not available, published international literature was used, providing data inputs to address such gaps
- To calculate the direct cost of medicines to the HSE, the NCPE guidelines were followed (**Table 1**)[14]
- Dosing information for different lines of treatment was informed by national treatment protocols and product licences[15]
- Avelumab medicine acquisition costs were estimated using time-on-treatment data derived from the accompanying avelumab + BSC cost-effectiveness analysis[8]
- For the NBI analysis and associated results, the current and future treatment paradigms for patients with la/mUC were identified and validated by clinical experts[8]

Table 1. Avelumab medicine acquisition costs

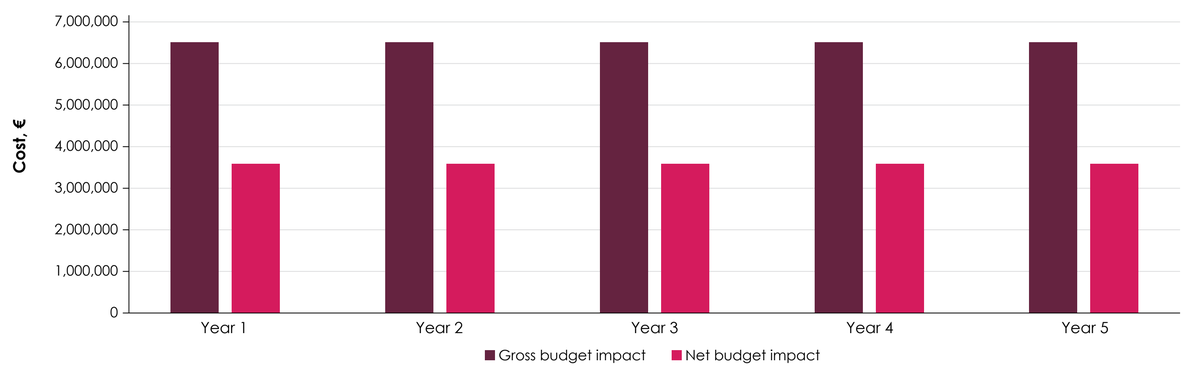
	Cost factor for 200 mg vial	Cost	Calculations
A	Ex-factory price/price to wholesale	€896.63*	
B	Wholesale mark-up	Not applicable	
C	Hospital price	€896.63	€896.63 + €0 (A + B)
D	Mandatory rebate: –5.5%†	–€49.31	€896.63 × 5.5% (A × 5.5%)
E	VAT on medicine cost: 23%	€206.22	€896.63 × 23% (C × 23%)
F	Total medicine cost to the HSE per pack, including VAT	€1,053.54	€896.63 – €49.31 + €206.22 (C – D + E)
G	Total medicine cost to the HSE per pack, excluding VAT	€847.32	€896.63 – €49.31 (C – D)

HSE, Health Service Executive; **VAT**, value-added tax.
*As per published Technical Summary Report December 22, 2021.[1]
†At the time of writing.

RESULTS

- Approximately 95 patients per year were estimated to be eligible for treatment with avelumab + BSC in Ireland, yielding a 5-year cumulative total of 475 patients[2]
- The cumulative 5-year GBI was estimated to be €32.57 million including VAT, translating to an estimated average annual cost of €6.51 million[2] (**Figure 1**)
- From an NBI perspective, reflecting scenarios with and without the introduction of avelumab 1L maintenance in the treatment paradigm, the estimated 5-year net budget impact including VAT is €17.93 million[2]
- The estimated average yearly incremental net investment is €3.59 million, which reflects the impact of displacing second-line immunotherapy over 5 years and would facilitate access to avelumab for patients with la/mUC in Ireland (**Figure 1**)

Figure 1. Yearly estimated average budget impact for avelumab as 1L maintenance for la/mUC



1L, first line; **la/mUC**, locally advanced or metastatic urothelial carcinoma.

Limitations

- As with any BIM, the results are only as valid as the inputs and assumptions made within the model
- The limitations of this BIM are omission of adverse event costs and the use of market-share assumptions that relied on clinician assumptions and internal forecasting data
- This analysis does not account for any confidential discounts, and medicine acquisition costing analysis was conducted at an ex-factory/price-to-wholesale level

REFERENCES 1. Lamrock F, et al. National Centre for Pharmacoeconomics budget impact model template version 1.3. February 2021. **2.** NCPE. Cost-effectiveness of avelumab (Bavencio®) for first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are progression free following platinum-based chemotherapy. Accessed October 6, 2022. https://www.ncpe.ie/wp-content/uploads/2021/03/Avelumab-21001-Technical-Summary.pdf. **3.** Powles T, et al. *N Engl J Med.* 2020;383(13):1218-30. **4.** O'Meara S, et al. *Ir J Med Sci.* 2021;190(2):531-8. **5.** Wong MCS, et al. *Sci Rep.* 2018;8(1):1129. **6.** NCRI. Cancer fact sheet: bladder. Accessed October 6, 2022. https://www.ncri.ie/sites/ncri/files/factsheets/Factsheet%20bladder.pdf. **7.** NCRI. Survival statistics: bladder cancer invasive (C67). Accessed October 6, 2022. https://www.ncri.ie/data/survival-statistics. **8.** von der Maase H, et al. *J Clin Oncol.* 2000;18(17):3068-77. **9.** De Santis M, et al. *J Clin Oncol.* 2012;30(2):191-9. **10.** Merck–Pfizer. Data on file. 2021. **DISCLOSURES LR** is an employee of Pfizer Healthcare Ireland. **KC** is an employee of Merck Serono Ltd., Feltham, UK, an affiliate of Merck KGaA. **MM** is an employee of Pfizer Healthcare Ireland. **STA** is an employee of Merck Serono Ltd., Feltham, UK, an affiliate of Merck KGaA. **AB** received consulting fees from Pfizer Healthcare Ireland and Merck Serono (Ireland) Ltd., Dublin, Ireland, an affiliate of Merck KGaA. **ACKNOWLEDGMENTS** This research was sponsored by Pfizer Healthcare Ireland and Merck Serono (Ireland) Ltd., Dublin, Ireland, an affiliate of Merck KGaA (CrossRef Funder ID: 10.13039/100009945), as part of an alliance between Pfizer and Merck. Editorial support was provided by Clinical Thinking and funded by Pfizer and Merck.

Poster No. EE432. Presented at ISPOR Europe 2022, 6-9 November 2022; Vienna, Austria.