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[C2H2409] Summary of cost-effectiveness evaluation of Sacituzumab Govitecan (TRODELVY®)

1. Indications

HR-negative/HER2-negative inoperable or recurrent breast cancer

2. Price of the drug

Sacituzumab Govitecan (TRODELVY ®) has been reimbursed from November 2025 at JPY 187,195 (as of May 2026). The price was calculated based on a similar efficacy comparison method (I) and this product was designated as an H2 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product is indicated for the treatment of patients with HR-negative/HER2-negative inoperable or recurrent breast cancer who received prior chemotherapy. The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below.

Population	HR-negative/HER2-negative inoperable or recurrent breast cancer who received prior chemotherapy
Comparator	Eribulin

4. Evaluation of additional benefits

The manufacturer conducted a systematic review (SR) to assess the additional benefits of sacituzumab govitecan and identified the ASCENT trial, which was a randomized controlled trial (RCT) comparing sacituzumab govitecan with treatments of physician's choice (TPC) including eribulin. The ASCENT trial

demonstrated improvements in overall survival and progression-free survival in the sacituzumab govitecan group compared with the TPC group. Furthermore, subgroup analyses by chemotherapy included in the TPC regimen also demonstrated consistent efficacy of sacituzumab govitecan. Based on these findings, the manufacturer concluded that sacituzumab govitecan has additional benefits over eribulin. The ATAG independently conducted the SR. The ATAG identified the ASCENT trial, as did the manufacturer, and determined that the manufacturer's interpretation of the trial results and assessment of the additional benefits were valid; consequently, the ATAG concluded that sacituzumab govitecan demonstrated the additional benefits compared with eribulin.

5. Results of the cost-effectiveness analysis

The manufacturer developed a partitioned survival model that considered three health states—progression-free survival, progressed disease, and death—to evaluate the cost-effectiveness of sacituzumab govitecan in the target population and conducted a cost-effectiveness analysis using eribulin as the comparator and quality-adjusted life years (QALYs) as the outcome. In this analysis, parameters were estimated based on data from the intention-to-treat (ITT) population in the ASCENT trial.

The ATAG conducted a reanalysis because several challenges were identified in the analysis by the manufacturer. Regarding the quality-of-life (QOL) values used in the analysis, the manufacturer mapped patient-reported outcomes to QOL values. Based on the results of a multivariable analysis, the manufacturer adopted different QOL values for the same health state depending on the treatment. The ATAG determined that it was appropriate to conduct the analysis using the same QOL values for identical health states across treatments. Because previous research on QOL values applicable to the target population was limited, the ATAG used the mapping results from the ASCENT trial provided by the manufacturer and performed a reanalysis using the average QOL values across both treatment groups for each health state. The ECCEE subsequently endorsed these results.

[Population	Comparator	ICER (JPY/QALY)
Hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer who received prior chemotherapy	Eribulin	34,735,200