Poster 3514

Economic Impact of Adverse Event Management in HR+/HER2− Metastatic Breast Cancer: A Comparative Analysis of Datopotamab deruxtecan and standard of care in the Brazilian Private Healthcare System

Henrique Tortele dos Santos, BSc[1], Aline Brito Villa MBA[2], Thiago Belchior de Oliveira, PhD[3], Leandro dos Santos, BSc[1], Caio de Marchi Huerta, MSc[1], Fabiano de Almeida Costa, MD[4], Gisele Lemes Veiga Araujo, MSc[1]

[1]Daiichi Sankyo, Market Access, São Paulo, Brazil; [2]Daiichi Sankyo, Business Intelligence, São Paulo, Brazil; [3]Daiichi Sankyo, Medical Affairs, São Paulo, Brazil; [4]COE Ensino e Pesquisa, São José dos Campos, Brazil.

Objective

This study aims to evaluate and compare the economic burden of managing grade ≥3 AEs in patients with HR+/HER2− metastatic breast cancer who have progressed on endocrine therapy and received at least one line of systemic therapy.

Background

TROPION-Breast01[1] (TB01), a phase III clinical trial evaluated the safety and efficacy of datopotamab deruxtecan (Dato-DXd) in comparison to the investigator's choice of standard single-agent chemotherapy (ICC). Dato-DXd demonstrated a manageable safety profile, characterized by a significantly lower incidence of grade ≥3 adverse events (AEs) compared to ICC (21% vs. 45%).[1]

Methods

The therapeutic regimens analyzed in this study were derived from two pivotal clinical trials: TB01, which compared Dato-DXd with ICC (i.e., capecitabine, eribulin, gemcitabine, vinorelbine), and TROPICS-02[2], which assessed sacituzumab govitecan (SG) versus ICC. TB01 and TROPICS-02 had the same ICC. AEs frequencies were extracted from the aforementioned clinical trials. Clinically and economically relevant events were identified by applying a ≥10% frequency threshold for any-grade AEs in each study arm, for which, grades ≥3 AEs were included for the cost analysis. Cost estimation was performed using a micro-costing approach[3], incorporating direct medical expenses specifically associated with the management of grade ≥3 AEs. The total AE-related cost per treatment arm was calculated by multiplying the unit cost of each selected AE by its respective frequency and summing the resulting values.

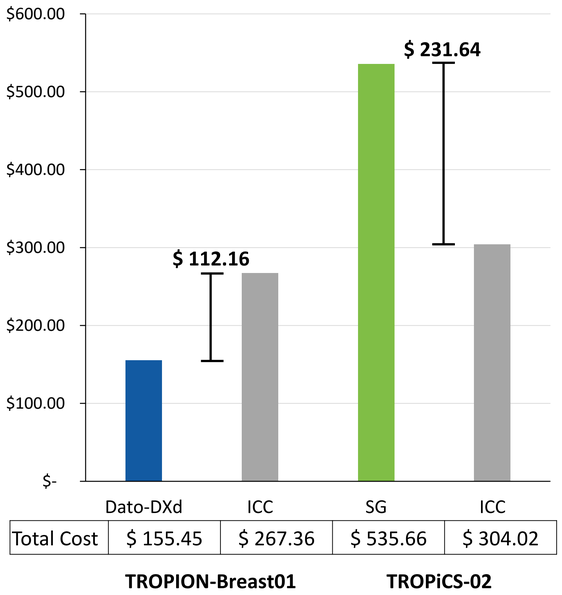
Results

The AEs included for analysis are summarized in Table 1. Treatment with Dato-DXd resulted in an estimated AE related cost of US$ 155.45, reflecting a 41.9% decrease in toxicity-related expenditures relative to its respective ICC arm comparator (US$ 267.36), while SG was associated with a total AE-related cost of US$ 535.66, compared to US$ 304.02 for its respective ICC arm comparator, indicating a 76.2% increase in costs related to adverse event management.

Table 1. AEs frequency (%)

Adverse Events	TROPION-Breast01[1]		TROPiCS-02[2]	
	Dato-DXd (n=360)	ICC (n=351)	SG (n=268)	ICC (n=249)
Neutropenia	1.1	30.8	50.7	38.2
Anaemia	1.1	2.0	6.3	3.2
Leukopenia	0.6	6.8	8.6	5.2
Lymphopenia	-	-	3.7	3.2
Thrombocytopenia	-	-	0.4	3.6
Diarrhea	-	1.1	9.3	1.2
Nausea	1.4	0.6	1.1	2.8
Vomiting	1.1	0.6	0.4	1.6
Abdominal pain	-	-	0.7	-
AST increased	0.6	0.6	-	1.2
ALT increased	-	-	-	2.4
Fadigue	1.7	2.0	5.6	2.8
Asthenia	0.8	1.1	1.9	0.8
Decreased appetite	0.8	0.6	0.4	0.4
Stomatitis	6.4	2.6	-	-
Dry eye	0.6	-	-	-
Keratitis	0.6	-	-	-
PPE	-	2.0	-	-
Neuropathy	-	-	1.1	2.4
Constipation	-	-	-	-
Alopecia	-	-	-	-

Graphic 1. AEs cost results in US$*



*Cost per patient during a 30-day period. 1US Dolar = 5.6 BRL

Conclusion

This analysis identified differences in AE-related costs across treatment modalities, emphasizing the economic relevance of toxicity management in patients with HR+/HER2− metastatic breast cancer who have progressed on endocrine therapy and received at least one line of systemic treatment. Dato-DXd demonstrated lower expenditure associated with adverse event management compared to its respective ICC arm comparator. SG was associated with higher AE-related costs relative to its respective ICC arm comparator. These findings align with previous evidence, including the Ryczek et al. (2024)[4]. This data highlights the importance of incorporating toxicity-related costs into treatment decision-making within the Brazilian Private Healthcare System.

Abbreviations

HR: hormone receptor, HER2: human epidermal growth factor receptor 2, ADC: antibody-drug conjugate; AE: adverse events; Dato-DXd: datopotamab deruxtecan; SG: sacituzumab govitecan; ICC: investigator's choice of standard single-agent chemotherapy; ALT: alanine transaminase; AST: aspartate aminotransferase; PPE: Palmar-plantar eythrodyses

References

1. Bardia A, Jhaveri K, Im SA, et al. Datopotamab deruxtecan versus chemotherapy in previously treated inoperable/metastatic hormone receptor–positive human epidermal growth factor receptor 2–negative breast cancer: Primary Results from TROPIONBreast01. J Clin Oncol 2025;43:285-296.
2. Rugo HS, Bardia A, Marmé F, et al. Overall survival with sacituzumab govitecan in hormone receptor-positive and human epidermal growth factor receptor 2-negative metastatic breast cancer (TROPiCS-02): a randomised, open-label, multicentre, phase 3 trial Lancet. 2023. Oct 21;402(10411):1423-1433.
3. Araujo GLV, Tortele H, Oliveira TB et al. Economic burden of the adverse events during treatment of metastatic breast cancer (mBC) HR+/HER2- patients in Brazilian Private HealthcareSystem. 2025-11, ISPOR Europe 2025, Glasgow, Scotland Value in Health, Volume 28, Issue S2.
4. Ryczek E, Jones C, Bradford R, et al. The Economic Burden of Managing Grade ≥3 AEs Following Treatment of Inoperable/Metastatic HR-Positive/HER2-Negative Breast Cancer in Italy, Spain and the United States. Value in Health, Volume 27, Issue 12, Supplement S93 December 2024.

Please scan this quick response (QR) code with your smartphone camera or app to obtain a copy of these materials.

Copies of this poster obtained through this QR code are for personal use only and may not be reproduced without permission from SABCS 2025 and the authors of this poster.

Disclosure and Acknowledgement

This work was supported by Daiichi Sankyo Brazil. Some authors are affiliated with the company as employees: HTS, ABV, TBO, LS, CMH, GLVA.

We thank Global team from Daiichi Sankyo for valuable guidance and insights throughout the development of this project.

Poster presented at SABCS 2025 by Gisele L V Araujo, MSc. Corresponding author email address: gisele.araujo@daiichisankyo.com or henrique.santos@daiichisankyo.com.