Healthcare Resource Utilization and Real-World Burden of Illness in Patients With PD-L1-Negative Metastatic Triple-Negative Breast Cancer in the First-Line Setting

Poster EE549

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Conclusions

- In this retrospective cohort study, patients in the United States with programmed death ligand 1 (PD-L1)–negative metastatic triple-negative breast cancer (mTNBC) were analyzed to evaluate treatment patterns, clinical outcomes, and healthcare resource utilization (HCRU)
- The most common first-line (1L) treatment type was chemotherapy (monotherapy), and the most common second-line (2L) and third-line (3L) treatment type was antibody-drug conjugates; the most frequently used treatment in 2L and 3L was sacituzumab govitecan
- Median real-world overall survival (rwOS; 17.1 months), real-world progression-free survival (rwPFS; 5.1 months), and real-world time to next treatment (rwTTNT; 6.5 months) indicated rapid disease progression and treatment switching
- HCRU among those with PD-L1− mTNBC was high, characterized by heavy reliance on acute medical services
- These results demonstrate a substantial unmet need in this patient population

Plain Language Summary

- People with metastatic triple-negative breast cancer (mTNBC) often need to use large amounts of healthcare resources, which can be associated with high costs
- Recently introduced drugs for mTNBC target a protein called programmed death ligand 1 (PD-L1); until the approval of a drug called sacituzumab govitecan, people with mTNBC that did not express PD-L1 (PD-L1–negative) had limited treatment options
- Researchers wanted to analyze the treatments that people whose tumors were PD-L1–negative received, how long people took treatments and lived, and how they utilized healthcare resources
- People with PD-L1–negative mTNBC were most likely to receive chemotherapy as first-line treatment, and most likely to receive drugs called antibody-drug conjugates as second- and third-line treatment
- People with PD-L1–negative mTNBC lived for roughly 17 months and lived without their disease becoming worse or dying for roughly 5 months
- People with PD-L1–negative mTNBC required a high number of hospitalizations and other medical visits
- People with PD-L1–negative mTNBC experienced poor outcomes and needed to use substantial healthcare resources, which indicates that there are potential areas of improvement in treatment

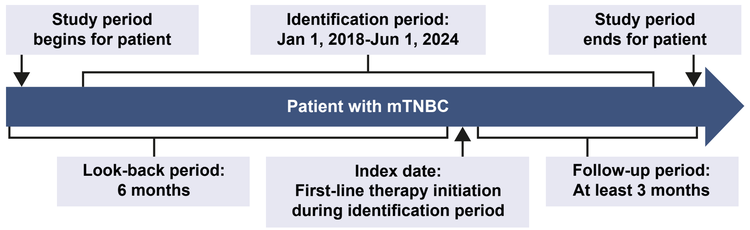
Introduction

- mTNBC has a relative 5-year survival rate of 15%[1]
- In patients with TNBC, HCRU has been observed to be higher compared with other breast cancer subtypes (more hospitalizations and emergency room visits), and TNBC is associated with high annual costs[2-4]
- PD-L1 inhibitors are approved for use in patients with PD-L1+ mTNBC and have demonstrated improved progression-free survival in combination with chemotherapy or, more recently, sacituzumab govitecan, an antibody-drug conjugate[5,6]
- However, patients with PD-L1− mTNBC have historically had more limited available treatment options, leaving a potential unmet need in this patient population; sacituzumab govitecan was also recently approved for 1L treatment of patients with PD-L1– mTNBC[7,8]
- In this analysis, patient characteristics, treatment patterns, real-world clinical outcomes, and HCRU are summarized in patients with PD-L1− mTNBC in the 1L setting

Methods

- In this retrospective cohort study, real-world clinical outcomes and HCRU were evaluated in patients in the United States using secondary de-identified data linked to claims from the Tempus Lens Platform, which includes patient-level clinical and molecular data from a mix of academic and community cancer centers
- The baseline period was time from initial breast cancer diagnosis to index date, inclusive (**Figure 1**)
- The follow-up period for clinical outcomes was > 1 day from index date (inclusive) until death, last record, or end of study period (June 5, 2025), whichever was first (**Figure 1**)
- The follow-up period for HCRU was > 3 months from index date; patients who died within 3 months post-index were followed for the time period before death to avoid survival bias (**Figure 1**)
- Continuously enrolled patients must have had ≥ 1 pharmacy or medical claim per month in the Tempus database during the look-back period and follow-up period, or have confirmed continuous enrollment for the look-back and follow-up periods
- Treatment patterns were described
- rwOS, rwPFS, and rwTTNT were estimated using Kaplan-Meier methods with risk-set adjustment to account for delayed entry into the database
- All-cause HCRU was reported per-patient-per-month (PPPM) in a subset of patients with PD-L1− mTNBC and continuous claims enrollment

Figure 1. Study Design



mTNBC, metastatic triple-negative breast cancer.

- Within the Tempus database, 973 patients met the study requirements (**Table 1**)
  - 477 patients had known PD-L1 status, and 316 had PD-L1– disease and were included in analysis of baseline and clinical characteristics, treatment patterns, and outcomes; 135 were continuously enrolled and included in analysis of HCRU

Table 1. Study Attrition

Inclusion Criteria	Patients, n	% Attrition
Metastatic breast cancer diagnosis	23,304	—
Age 18-89 years (inclusive)	22,372	96
TNBC status within 90 days of metastatic diagnosis	3023	14
Initiated 1L between Jan 1, 2018–Jun 1, 2024 (index date)	1482	49
≥ 3 months follow-up after index	1275	86
Not enrolled in investigational new drug during study period	1207	95
No other primary cancer within 5 years prior to index[a]	1106	92
No history of SG use before or as part of 1L therapy	1046	95
Did not receive 1L hormone therapy	973	93
PD-L1–negative or –positive result at index (90 days before or after initiation of 1L)[b]	477 PD-L1–, n = 316 PD-L1+, n = 161	49
Continuously enrolled patients	219	46
Continuously enrolled patients with known 1L duration	207 PD-L1–, n = 135 PD-L1+, n = 72	95

[a]Except for nonmelanoma skin cancers. [b]PD-L1 positivity was defined as 22C3 combined positive score (CPS) > 10, SP263 CPS > 1%, or SP142 immune cells > 1%; when test results were not available, PD-L1 status could be determined from other unstructured data elements such as physician notes.
1L, first-line; PD-L1, programmed death-ligand 1; SG, sacituzumab govitecan; TNBC, triple-negative breast cancer.

Results

- Median follow-up was 16.2 months in the PD-L1− population
- A majority of patients were treated at nonacademic institutions and had recurrent disease; of patients with recurrent disease, the most common treatment prior to 1L was anthracyclines (**Table 2**)

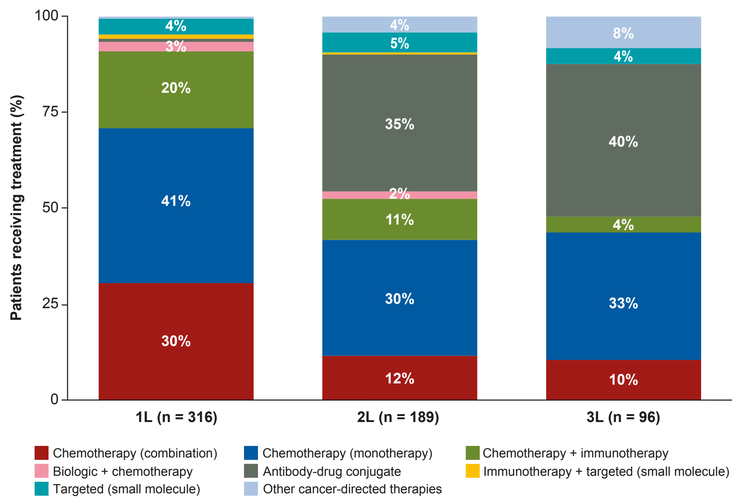
Table 2. Demographics and Baseline Characteristics

All Patients	PD-L1− Population (n = 316)
Mean age (SD), years	59.7 (13.6)
Female sex, n (%)	315 (> 99)
Institution type,[a] n (%)	
Nonacademic	206 (65)
Academic	80 (25)
Academic and nonacademic	21 (7)
Median time from metastatic diagnosis to 1L treatment, days (range)	36 (0-427)
HER2 status, n (%)	
HER2 IHC 0	129 (41)
HER2 low (IHC 1 or 2+/ISH−)	114 (36)
HER2 negative (IHC 0, 1, or 2+/ISH−), unspecified	73 (23)
Number of sites of metastases at 1L treatment,[b] n (%)	
1	137 (43)
2	75 (24)
≥ 3	97 (31)
Documented liver metastases at 1L treatment, n (%)	91 (29)
Unknown/not documented	225 (71)
Documented brain metastases at 1L treatment, n (%)	57 (18)
Unknown/not documented	259 (82)
Patients with recurrent disease,[c] n (%)	182 (58)
Treatment-free interval in patients with recurrent disease,[d] n/N (%)	
< 12 months	89/182 (49)
> 12 months	65/182 (36)
No prior systemic treatment	17/182 (9)
Received treatments prior to 1L treatment in patients with recurrent disease, n/N (%)	
Anthracyclines	118/182 (65)
Platinum	44/182 (24)
Capecitabine	35/182 (19)
Immunotherapy	16/182 (9)
Taxanes	0/182

[a]Unknown/not documented, n = 9. [b]Unknown/not documented, n = 7. [c]Patients with either documented treatment prior to metastatic diagnosis or primary diagnosis preceding metastatic diagnosis by ≥ 3 months. [d]Unknown/missing, n = 11.
1L, first-line; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; PD-L1, programmed death ligand 1.

- Of patients who received 1L therapy, 60% received 2L therapy; of those who received 2L therapy, 51% received 3L therapy (**Figure 2**)
- The most common type of treatment regimen in the 1L setting was chemotherapy (monotherapy), and antibody-drug conjugates in the 2L and 3L settings (**Figure 2**)
- The most common treatment regimen was capecitabine in the 1L setting (n = 49, 16%), sacituzumab govitecan in the 2L setting (n = 52, 28%), and sacituzumab govitecan in the 3L setting (n = 32, 33%)
- Reasons for 66 patients receiving 1L immunotherapy despite their tumors being PD-L1− included PD-L1 status not included at time of 1L initiation (35%, n = 23), used nonstandard PD-L1 cutoffs (26%, n = 17), conflicting results (23%, n = 15), change in initial diagnosis (2%, n = 1), used atezolizumab (potential off-label use in real-world practice; 2%, n = 1), and no reason given (14%, n = 9)

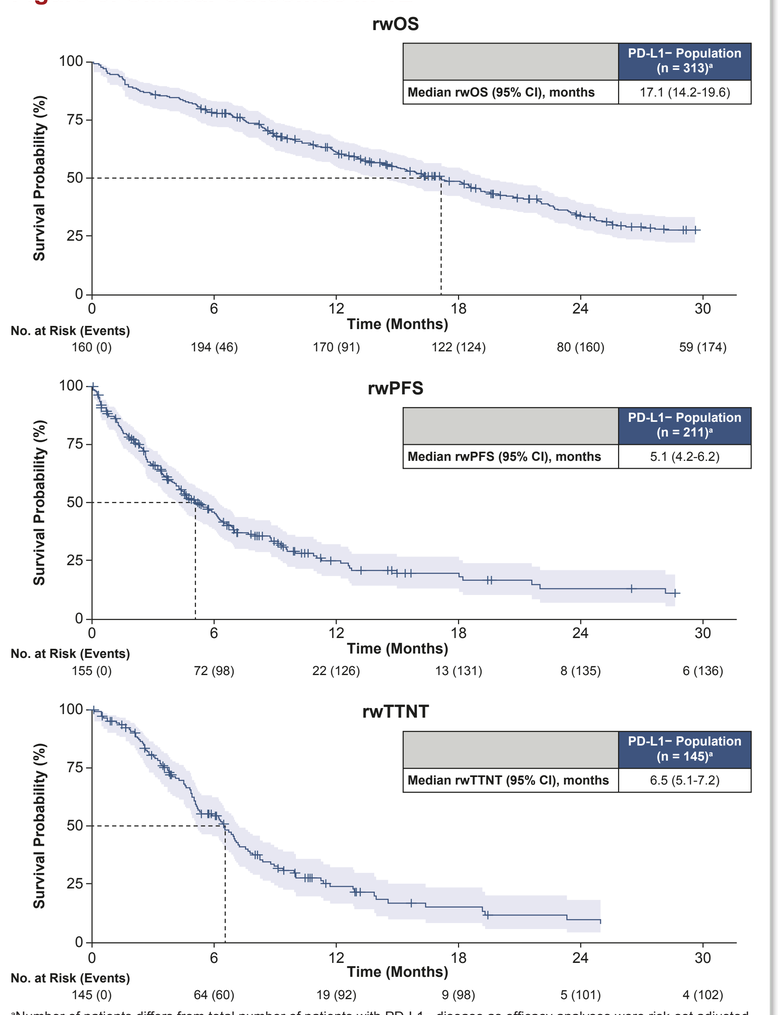
Figure 2. Treatment Patterns



1L, first-line; 2L, second-line; 3L, third-line.

- Median rwOS was 17.1 months, median rwPFS was 5.1 months, and median rwTTNT was 6.5 months (**Figure 3**)

Figure 3. Clinical Outcomes in 1L



[a]Number of patients differs from total number of patients with PD-L1− disease as efficacy analyses were risk-set adjusted to account for left-truncated data.
1L, first-line; PD-L1, programmed death ligand 1; rwOS, real-world overall survival; rwPFS, real-world progression-free survival; rwTTNT, real-world time to next treatment.

- Of 135 patients eligible for all-cause HCRU analysis, roughly half of patients had ≥ 1 hospitalization; patients were hospitalized approximately once per month, attended roughly 2 outpatient and 3 office appointments per month, and had approximately 2 emergency room visits per year (**Table 3**)

Table 3. Summary of All-Cause HCRU

	PD-L1− Population (n = 135)
Inpatient hospitalizations	
Patients with ≥ 1 event, n (%)	71 (53)
PPPM (95% CI)	0.88 (0.62-1.25)
Median length of stay, overall inpatient hospitalizations (range), days	1 (1-407)
Emergency room visits	
Patients with ≥ 1 event, n (%)	61 (45)
PPPM (95% CI)	0.21 (0.15-0.29)
Outpatient medical visits	
Patients with ≥ 1 event, n (%)	112 (83)
PPPM (95% CI)	1.98 (1.59-2.47)
Office visits	
Patients with ≥ 1 event, n (%)	115 (85)
PPPM (95% CI)	2.55 (2.07-3.14)

HCRU, healthcare resource utilization; PD-L1, programmed death ligand 1; PPPM, per patient per month.

Limitations

- Retrospective survival analyses are vulnerable to immortal time bias and left-truncation from delayed entry; risk-set adjustment was implemented as appropriate to account for these biases
- Findings are restricted to institutions participating within the Tempus network, which could limit broad generalizability; however, the sample captures a diverse real-world population treated across community practices and academic centers across all major US regions

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Disclosures: **YZ** is employed by and owns stock in Gilead Sciences, Inc.

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