Real-World Study Characterizing Patient Characteristics, Treatments, and Unmet Need in IO-Ineligible Patients With Metastatic Triple-Negative Breast Cancer

#074

Nguyen M[1], Shah R[1], Leclair B[1], Kariburyo-Yay F[2], Matusevich A[2], Mandora P[2]

[1]Daiichi Sankyo, Basking Ridge, New Jersey, United States; [2]ConcertAI, Cambridge, Massachusetts, United States

BACKGROUND

- Metastatic triple-negative breast cancer (mTNBC) is the most aggressive breast cancer subtype, with an estimated 15% five-year survival rate[1-3]
- Immunotherapy (IO) has demonstrated substantial anticancer effects[4] and is approved for mTNBC patients with tumors over-expressing programmed cell death-ligand 1 (PD-L1)[4]; however, up to 70% of patients with previously untreated mTNBC may not be candidates for IO[5,6]
- Literature characterizing treatment patterns and clinical outcomes among these patients is limited

METHODS

Study design

Retrospective cohort study

Data source

U.S. electronic health record data from ConcertAI Patient360™ Breast dataset (01/2021–06/2025)

Study population

- Adults (≥18 years) with mTNBC who received first-line (1L) treatment in the metastatic setting
- Patients were classified as "Candidates for IO" or "Not Candidates for IO"

Not Candidates for IO

- PD-L1 negative
- If treated in the early setting:
  - Received IO in the neoadjuvant/adjuvant setting with disease-free interval (DFI) <12 months
- In the absence of the above information, did not receive IO in the metastatic setting

Candidates for IO

- PD-L1 positive
- If treated in the early setting:
  - Received IO in the neoadjuvant/adjuvant setting with DFI >12 months
- In the absence of the above information, received IO in the metastatic setting

Statistical methods

Descriptive analysis, including counts and frequencies, Kaplan-Meier for time-to-event endpoints (statistical significance: p<0.05)

RESULTS

3,164 Patients diagnosed with mBC during the study identification period (July 2021 to April 2025)

2,833 Patients initiated 1L treatment in the metastatic setting

432 Patients with mBC that was triple negative (mTNBC) and fulfilled all inclusion criteria

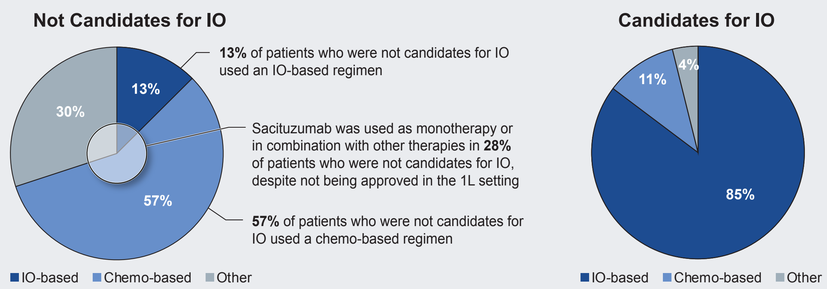
Not Candidates for IO n=303 (70.1%)

Candidates for IO n=129 (29.9%)

Baseline Characteristics

	Overall (n=432)	Not Candidates for IO (n=303)	Candidates for IO (n=129)
Age (median)	61.0 yrs	61.0 yrs	61.0 yrs
Race/ethnicity			
White	276 (63.9%)	187 (61.7%)	89 (69.0%)
Not Hispanic/Latino	298 (69.0%)	206 (68.0%)	92 (71.3%)
Provider setting			
Academic	56 (13.0%)	41 (13.5%)	15 (11.6%)
Community	325 (75.2%)	223 (73.6%)	102 (79.1%)
Integrated delivery network	51 (11.8%)	39 (12.9%)	12 (9.3%)
Metastatic presentation			
Recurrent	286 (66.2%)	217 (71.6%)	69 (53.5%)
De novo	101 (23.4%)	52 (17.2%)	49 (38.0%)
Undocumented	45 (10.4%)	34 (11.2%)	11 (8.5%)
Presence of brain metastases	45 (10.4%)	38 (12.5%)	7 (5.4%)
ECOG performance status at index date			
0-1	309 (71.5%)	214 (70.6%)	95 (73.6%)
≥2	37 (8.6%)	28 (9.2%)	9 (7.0%)
Undocumented	86 (19.9%)	61 (20.1%)	25 (19.4%)
PD-L1 testing			
Tested at any time	285 (66.0%)		
Tested prior to 1L	187 (43.3%)		

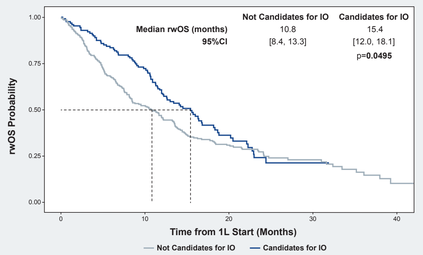
Treatments Used at 1L in Patients Who Were Not Candidates for IO and Patients Who Were Candidates for IO*



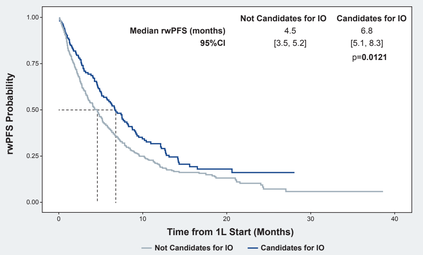
*IO-based is any IO-containing regimen; chemo-based is any chemo-containing regimen without IO; other regimens do not include IO or chemo

Clinical Outcomes

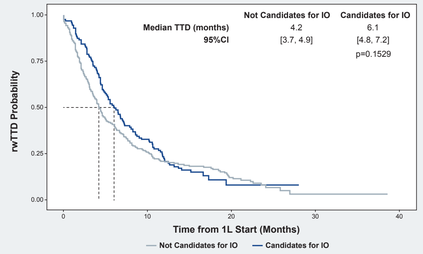
Real-World Overall Survival



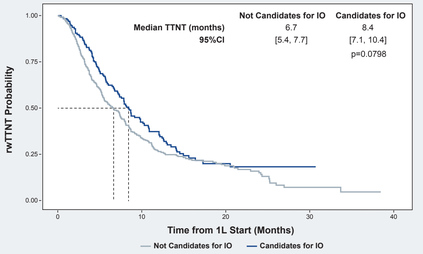
Real-World Progression-Free Survival



Real-World Time to Treatment Discontinuation



Real-World Time to Next Treatment



CI: Confidence interval

CONCLUSIONS

- In this cohort, patients who were not candidates for IO had a numerically higher rate of brain metastases
- While patients who were not candidates for IO relied on conventional chemotherapy as 1L treatment, some were treated with IO or sacituzumab govitecan despite not being recommended by clinical guidelines in the 1L setting for this population
- Real-world progression-free and overall survival were significantly worse for patients who were not candidates for IO compared to patients who were candidates for IO
- Limited treatment options and poor clinical outcomes, particularly in patients who are not candidates for IO, highlight a significant unmet need in this population

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Marvin Nguyen, Ruchit Shah, and Bridgette Leclair are employees of Daiichi Sankyo Inc. Furaha Kariburyo-Yay, Aliza Matusevich, and Prithviraj Mandora are employees of ConcertAI.