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Real-world progression-free survival from first-line treatment initiation in patients with PD-L1-negative locally recurrent inoperable or metastatic triple-negative breast cancer in the US

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KEY FINDINGS

This study offers modern real-world proxies of progression-free survival (PFS) in patients with PD-L1-negative locally recurrent inoperable or metastatic triple-negative breast cancer (Ir/m TNBC)

- This patient population experienced rapid disease progression following initiation of first-line (1L) treatment, with a median time to progression of less than 5 months
- Among the 703 patients who experienced a progression, nearly half of patients (43.8%) were observed to receive a second line of therapy (LOT)

CONCLUSION

This study underscores a critical unmet need for effective 1L treatment options with tolerable safety profiles to improve outcomes in patients with PD-L1-negative Ir/mTNBC

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BACKGROUND

- Patients with PD-L1-negative (Combined Positive Score [CPS] <10) locally recurrent inoperable or metastatic triple-negative breast cancer (Ir/m TNBC) have limited treatment options with guidelines recommending chemotherapy as the preferred first-line (1L) treatment[1]
- Recent real-world evidence indicates that survival of patients with PD-L1-negative Ir/m TNBC in the United States (US) remains poor, with median survival of 1 year[2]
- US evidence on real-world progression-free survival (rwPFS) from 1L treatment initiation in PD-L1-negative Ir/m TNBC remains limited, and more data are needed to better understand clinical outcomes and support evidence-based treatment decision-making

STUDY OBJECTIVE

Describe rwPFS

among patients receiving 1L treatment for

PD-L1-negative Ir/mTNBC

METHODS

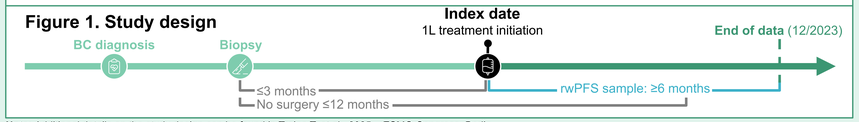
Study design

- Retrospective cohort study of adults receiving 1L treatment for PD-L1-negative Ir/m TNBC using Komodo Research Data (KRD+; 01/2016–12/2023), a large US claims database
- Real-world proxies of progression were defined with medical expert guidance (Dr. Tiffany Traina) and included death, hospice admission, initiation of a second line of systemic treatment, or initiation of radiotherapy
- rwPFS was assessed from 1L initiation to the earliest of 1) first observed proxy of progression or 2) end of follow-up among patients initiating 1L at least 6 months before the end of data availability

PD-L1-negative Ir/m TNBC identification algorithm (Figure 1)

- Lr/mBC status was defined as systemic treatment initiation within 3 months of a biopsy and no surgery observed in the 12 months following the biopsy
- TNBC and PD-L1 statuses were identified based on treatments received from 1L initiation (index date)

Figure 1. Study design



Note: Additional details on the study design can be found in Traina T. et al., 2025 – ESMO Congress, Berlin.
1L: first-line; BC: breast cancer; rwPFS: real-world progression-free survival

RESULTS

Figure 2. Sample selection

Patients with incident BC[a]	Patients with Ir/mBC	Patients with Ir/mTNBC	Patients with PD-L1–negative Ir/mTNBC[b]	Patients with sufficient data availability to assess rwPFS
N = 273,229	N = 4,403 (1.6%)	N = 1,664 (37.8%)	N = 929 (55.8%)	N = 910 (98.0%)

BC: breast cancer; Ir/m: locally recurrent inoperable or metastatic; rwPFS: real-world progression-free survival; TNBC: triple-negative breast cancer

Notes: [a]Diagnosis of BC was defined as ≥2 claims, ≥30 days apart, with a BC diagnosis code. Patients were required to have ≥12 months of continuous health plan enrollment prior to their first BC diagnosis without diagnoses of other primary or history of cancers, and without prior chemotherapy or radiotherapy based on procedure and treatment codes. [b]Patients with indicators of *BRCA1/2* mutations, including diagnosis for genetic susceptibility to malignant neoplasm of breast or receiving *BRCA1/2*-specific treatments (olaparib or talazoparib) at any time, were excluded from the sample.

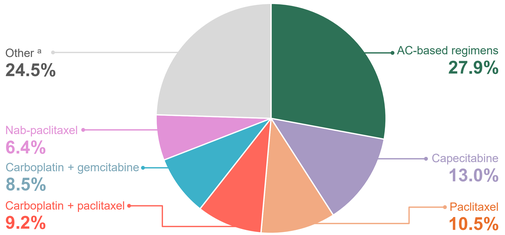
Table 1. Demographics

	Patients with Ir/mTNBC included in rwPFS analysis N = 910
Age at index (years), mean [median] (IQR)	58.8 [59.0] (51.0-66.0)
Sex[a], N (%)	
Female	897 (98.6%)
Male	11 (1.2%)
Race & ethnicity known, N (%)	**631 (69.3%)**
White	381 (60.4%)
Black or African American	165 (26.2%)
Hispanic or Latino	57 (9.0%)
Asian or Pacific Islander	18 (2.9%)
Other[b]	10 (1.6%)
Payer type on index date, N (%)	
Commercial	590 (64.8%)
Medicare	243 (26.7%)
Medicaid	77 (8.5%)
Most common comorbidities[c], N (%)	
Liver disease	245 (26.9%)
COPD	207 (22.7%)
Diabetes	200 (22.0%)
Peripheral vascular disease	125 (13.7%)
De novo mTNBC[d], N (%)	**590 (64.8%)**
Follow-up duration (months)[e], mean [median] (IQR)	15.7 [10.3] (5.7-20.3)

COPD: chronic obstructive pulmonary disease; IQR: interquartile range; Ir/mTNBC: locally recurrent inoperable or metastatic triple-negative breast cancer

Notes: [a]Two patients had unknown sex. [b]Other refers to race not listed above. [c]Assessed during the 12 months before index. [d]Defined as no prior BC surgery and a non-BC neoplasm within 9 months of the first BC diagnosis. [e]Time from the index to the earliest of 1) end of continuous health plan enrollment, 2) end of data, or 3) death.

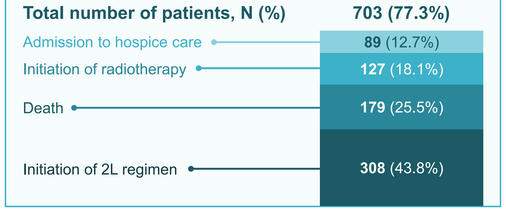
Figure 3. Frequency of observed 1L treatments



1L: first-line; AC: cyclophosphamide + doxorubicin

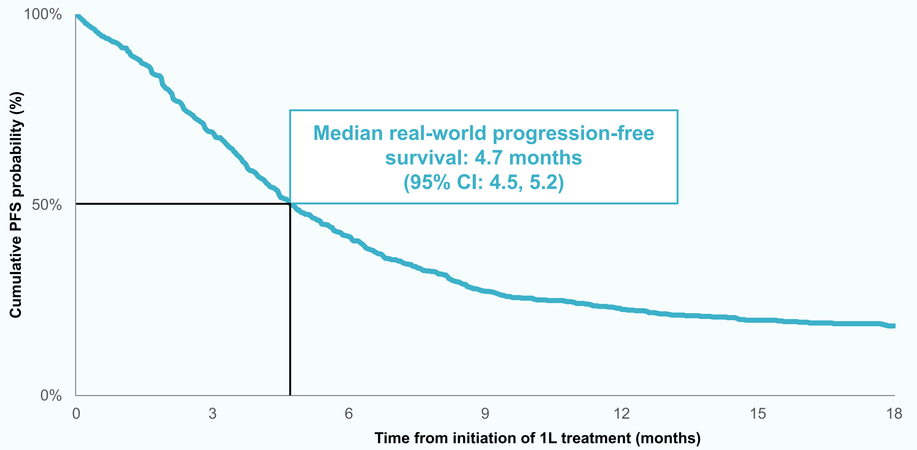
Note: [a]Regimens representing less than 5% are grouped and reported as "other". The five most frequent regimens within the "other" category are carboplatin (3.6%), methotrexate (2.6%), cyclophosphamide+docetaxel (2.4%), fluorouracil (2.4%), and eribulin (1.5%).

Figure 4. First real-world proxy of progression among patients with ≥1 proxy



REAL-WORLD PROGRESSION-FREE SURVIVAL (N = 910)

Figure 5. rwPFS from initiation of 1L treatment for PD-L1–negative Ir/mTNBC



	0 month	3 months	6 months	12 months	18 months
Patients at risk N (%)	910 (100.0%)	610 (67.0%)	333 (36.6%)	140 (15.4%)	93 (10.2%)
Cumulative number of events N (%)	0 (0.0%)	281 (30.9%)	512 (56.3%)	653 (71.8%)	678 (74.5%)
Cumulative progression-free survival (%) (95% CI)	-	69.0 (65.9, 71.9)	41.7 (38.4, 45.0)	22.6 (19.7, 25.6)	18.3 (15.5, 21.2)

1L: first-line; CI: confidence interval; Ir/mTNBC: locally recurrent inoperable or metastatic triple-negative breast cancer; rwPFS: real-world progression-free survival

References

1.Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Clinical Practice Guidelines in Oncology for Breast Cancer V.4.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed Sept 01, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.
2.Traina T. et al., 2025. Poster FPN 563P – ESMO Congress, Berlin.

Limitations

- As clinical information (e.g., biomarker) is not directly available in claims data, the identification of the study sample and the LOT, and the description of rwPFS, relied on algorithms developed with a medical expert. rwPFS analyses also included imputed death dates to supplement death dates based on a claims-based algorithm
- This study is subject to common limitations of analyses using insurance claims databases, such as missing data and inaccurate insurance claims
- This study assessed outcomes among patients eligible for systemic therapy. As such, outcomes may vary in the broader Ir/mTNBC population including those not candidates for systemic therapy

Disclosures

- *Presenter:* T. A. Traina has received consulting/advisory fees from BioNTech SE, Genentech/Roche, Pfizer, AstraZeneca, Merck, Daiichi Sankyo, Gilead Sciences, GlaxoSmithKline, Tersera, Stemline Therapeutics, Exact Sciences, Veracyte, Aktis Oncology, and Ellipses Pharma; and research funding from BioNTech SE, Pfizer, AstraZeneca, Astellas Pharma, Genentech/Roche, and Daiichi Sankyo.
- *All authors:* E. Serra, J. Bedard, M. Levesque-Leroux, P. Gagnon-Sanschagrin and A. Guérin are employees of Analysis Group ULC, a consulting company that has provided paid consulting services to BioNTech. S. Guenther, G. Joseph, V. Guan, and J. Salcedo are employed by BioNTech and own stocks
- This study was executed by Analysis Group ULC and sponsored by BioNTech SE

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