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Unmet need in patients with metastatic triple-negative breast cancer initiating a first-line treatment: Data from the German OPAL registry

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Background

Despite treatment advances, the survival rates of patients (pts) with metastatic triple-negative breast cancer (mTNBC) are still low and real world data on implementation and outcome of new treatment options in clinical routine are scarce. Here, we give insights into current treatment patterns and outcome of pts with mTNBC initiating a first-line treatment (1L) in routine care in Germany using data from the OPAL registry.

Methods

In the prospective registry platform OPAL (NCT03417115), over 2000 pts with metastatic breast cancer were enrolled by 189 German sites from 01/2018 to 04/2025. Details on (sequential) treatments, patient and tumor characteristics, biomarker testing, clinical and patient-reported outcomes are collected. Follow-Up is until death, lost-to follow-up or up to 5 years after start of 1L for mTNBC. This analysis focuses on 368 pts with mTNBC initiating 1L between January 2018 and August 2023 that meet the study inclusion criteria. Database cut was on December 31st, 2024.

Results

Pts had a median age of 62 years (25% of pts $\geq$ 75 years), with 11% of pts having an ECOG performance status of $\geq$ 2. 37% of pts had de novo metastatic disease at initial diagnosis and 72% of pts had visceral metastasis at start of 1L. Of pts with PD-L1 positive tumors (n=117), 81% received a 1L with PD(L)1 inhibitors. Median progression-free survival (PFS) of pts with PD-L1 positive tumors was 7.3 months (95% confidence interval (CI) 6.5 – 9.1 months) and median overall survival (OS) was 21.5 months (16.4 – 24.8 months). Pts with PD-L1 negative tumor (n=132) most frequently received mono-chemotherapy $\pm$ bevacizumab (59%) as 1L, e.g., paclitaxel or capecitabine. Median PFS of pts with PD-L1 negative tumors was 6.3 months (5.0 – 7.6 months) and median OS was 16.7 months (14.0 – 20.7 months). For pts with unknown PD-L1 status (n=119), median PFS was 5.9 months (4.6 – 8.0 months) and median OS was 14.3 months (12.1 – 19.7 months). Overall, 54% of 1L pts had received 2L by end of study period.

Conclusions

Pts with mTNBC, regardless of PD-L1 status, have lower PFS and OS rates in 1L setting than other breast cancer subtypes, which underscores the need for evaluating new treatment options to improve mTNBC outcomes.

Legal entity responsible for the study

OPAL.

Funding

Gilead Sciences, Inc.

Disclosure

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