

First-Line CDK4/6 Inhibitor Plus Aromatase Inhibitor Treatment Patterns and Outcomes in Metastatic Breast Cancer: Real-World Data From Two US Claims Databases

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Objectives

- This retrospective, observational cohort study evaluated real-world data from two US Health Claims databases (KOMODO and OPTUM) to explore the baseline characteristics, treatment patterns, and outcomes of patients with mBC treated with first-line CDK4/6i + AI

Conclusions

- Data from two independent databases showed high levels of baseline comorbidities in patients with mBC treated with first-line CDK4/6i + AI
- There was a high rate (~40%) of first-line CDK4/6i + AI discontinuation within a year of starting treatment
- These data support the need for novel therapies in the first-line treatment of mBC

Plain language summary

Why did we perform this research?

- More than two-thirds of all breast cancers grow in response to hormones like estrogen or progesterone but do not have receptors for a protein called HER2; this type of breast cancer is called hormone receptor (HR)-positive, HER2-negative
- The typical first treatment for patients with HR-positive, HER2-negative breast cancer that has spread from its original site (metastatic breast cancer) is a CDK4/6 inhibitor with an aromatase inhibitor
- However, there is not much data about co-existing illnesses, treatment choice, and length of time on treatment for patients receiving first-line CDK4/6 inhibitor + aromatase inhibitor in real-world clinical practice

How did we perform this research?

- This study used data from two large US healthcare claims databases: OPTUM and KOMODO
 - Patients were included if they had been diagnosed with metastatic breast cancer between April 2017 and either March 2024 (OPTUM) or September 2024 (KOMODO)
 - All patients had received first-line CDK4/6 inhibitor + aromatase inhibitor for metastatic breast cancer
 - All patients had at least 3 months of follow-up
- Co-existing illnesses, length of time on treatment, and time before next treatment were described for patients receiving first-line CDK4/6 inhibitor + aromatase inhibitor

What were the findings of this research?

- Patients with metastatic breast cancer treated with first-line CDK4/6 inhibitor + aromatase inhibitor had high levels of co-existing illness at diagnosis
- Around 40% of patients stopped receiving CDK4/6 inhibitor and/or aromatase inhibitor within a year of starting treatment
- These data support the need for new first-line therapies to treat metastatic breast cancer

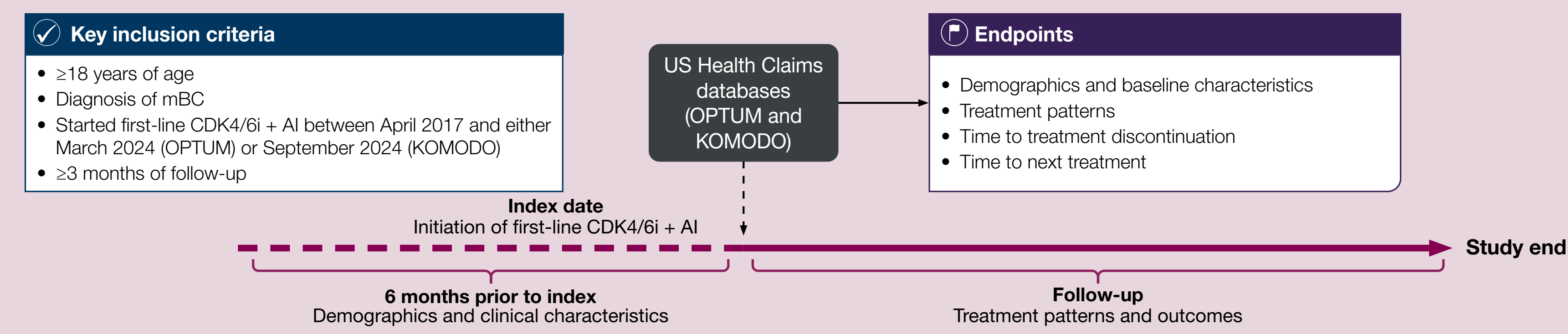
Introduction

- HR-positive/HER2-negative breast cancer accounts for more than two-thirds of all cases¹
 - CDK4/6i in combination with an AI is the standard first-line treatment for patients with HR-positive, HER2-negative mBC^{2,3}
- However, real-world evidence describing baseline comorbidities, treatment patterns, and treatment duration among patients receiving first-line CDK4/6i + AI remains limited
- This study used large US claims databases to characterize baseline comorbidities, treatment patterns, and treatment duration among patients receiving first-line CDK4/6i + AI in routine clinical practice

Methods

- This retrospective, observational cohort study used data from two US healthcare claims databases: KOMODO and OPTUM (**Figure 1**)
 - Patients diagnosed with mBC between April 2017 and March 2024 (OPTUM) or September 2024 (KOMODO) were included
 - Eligible patients received first-line CDK4/6i + AI for mBC, and had at least 3 months of follow-up
- Descriptive statistics were used to summarize demographics, baseline characteristics (including comorbidities), and treatment patterns
- Time to treatment discontinuation (TTD) was defined as the discontinuation of either component of the CDK4/6i + AI regimen
- TTD and time to next treatment (TTNT) were estimated using Kaplan–Meier methods

Figure 1: Study design



Results

Baseline characteristics

- The KOMODO cohort comprised 6464 patients with a median age of 61 years; the OPTUM cohort comprised 2133 patients with a median age of 69 years (**Table 1**)
 - In KOMODO, 65.1% of patients were insured with a commercial plan; in OPTUM, 65.2% of patients were insured with Medicare
- Baseline comorbidities appeared more common in the OPTUM cohort than in the KOMODO cohort, including hypertension, cardiovascular disorders, diabetes, and chronic pulmonary disease (**Table 2**)

Table 1. Baseline characteristics		
Characteristics, n (%)	KOMODO (N=6464)	OPTUM (N=2133)
Age, years, median (range)	61 (21–89)	69 (27–90)
Payor type		
Commercial	4200 (65.1)	741 (34.7)
Medicare	1789 (27.7)	1391 (65.2)
Medicaid	458 (7.1)	–
Commercial and Medicare	–	1 (0.1)
Missing/unknown	17 (0.3)	0
Year of mBC diagnosis		
2017	609 (9.4)	217 (10.2)
2018	918 (14.2)	280 (13.1)
2019	981 (15.2)	366 (17.2)
2020	853 (13.2)	281 (13.2)
2021	896 (13.9)	273 (12.8)
2022	1061 (16.4)	356 (16.7)
2023	999 (15.5)	360 (16.9)
2024	147 (2.3)	–
Follow-up duration, months, median (range)	21 (3–90)	20 (3–84)
Charlson comorbidity index, mean (SD)	1.8 (2.57)	2.1 (2.67)

Table 2. Baseline comorbidities*

Comorbidities, n (%)	KOMODO (N=6464)	OPTUM (N=2133)
Hypertension	2856 (44.2)	1224 (57.4)
Chronic pulmonary disease	981 (15.2)	428 (20.1)
Cardiac arrhythmia	849 (13.1)	361 (16.9)
Diabetes	1097 (17.0)	558 (26.2)
Fluid and electrolyte disorders	561 (8.7)	265 (12.4)
Peripheral vascular disorders	449 (6.9)	283 (13.3)
Depression	1087 (16.8)	412 (19.3)
Hypothyroidism	1110 (17.2)	496 (23.3)
Renal failure	417 (6.5)	287 (13.5)
Valvular disease	440 (6.8)	214 (10.0)
Obesity	1301 (20.1)	471 (22.1)
Liver disease	794 (12.3)	281 (13.2)

*≥10% in at least one cohort.

Abbreviations

AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; CI, confidence interval; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; SD, standard deviation; mBC, metastatic breast cancer; TTD, time to treatment discontinuation; TTNT, time to next treatment.

References

- National Cancer Institute. Cancer Stat Facts: Female Breast Cancer Subtypes 2022. Accessed March 30, 2026. <https://seer.cancer.gov/statfacts/html/breast-subtypes.html>
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- Burstein HJ, et al. *J Clin Oncol* 2021;39(35):3959–77.

Treatment patterns

- Treatment patterns were broadly similar between the KOMODO and OPTUM cohorts
 - Between 2017 and 2024, use of palbociclib decreased, while use of ribociclib and abemaciclib increased (**Figure 2**)
 - Over the same period, use of letrozole decreased, whereas use of anastrozole increased (**Figure 3**)

Figure 2. Treatment patterns from 2017 to 2024 (CDK4/6i)

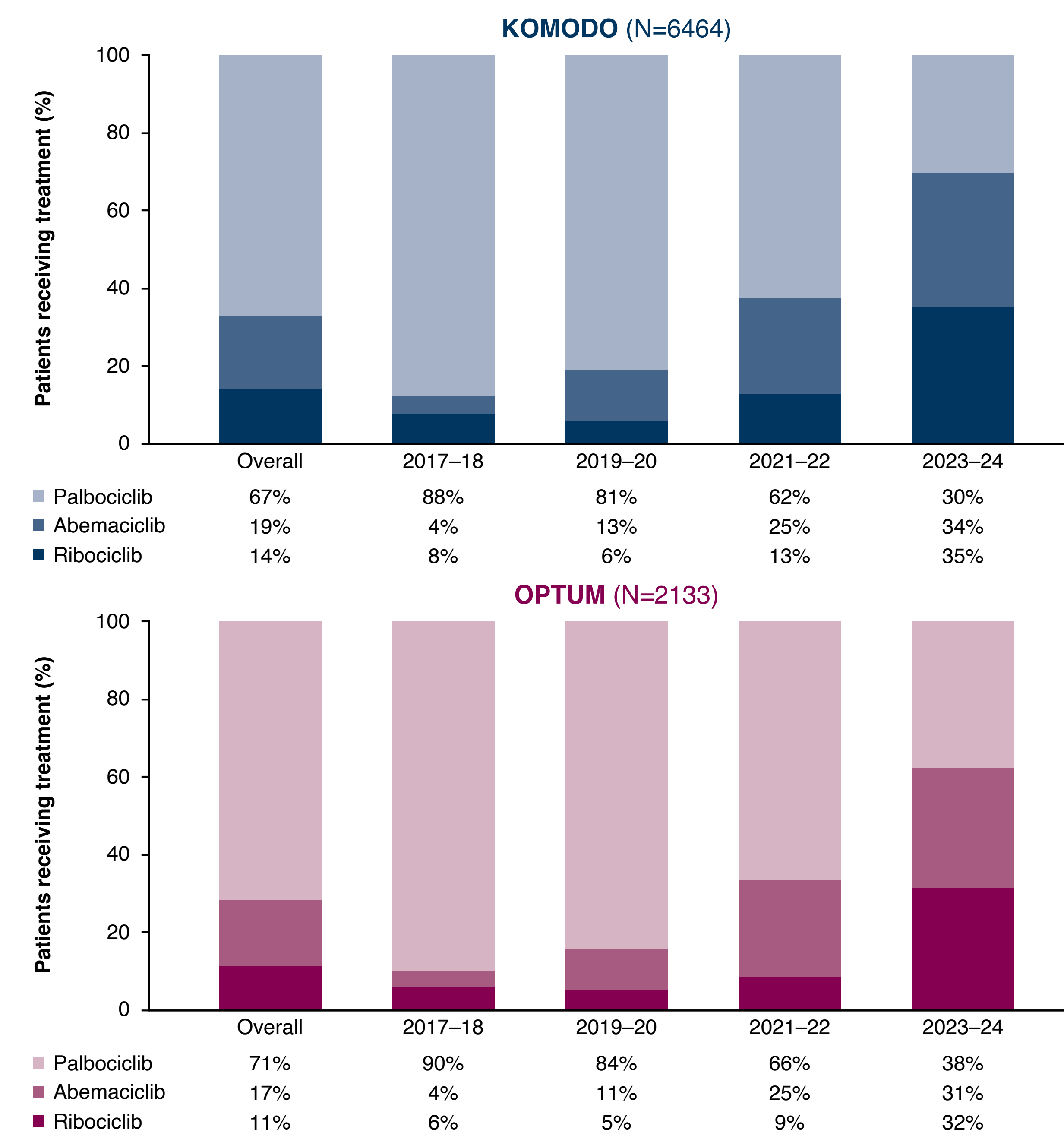
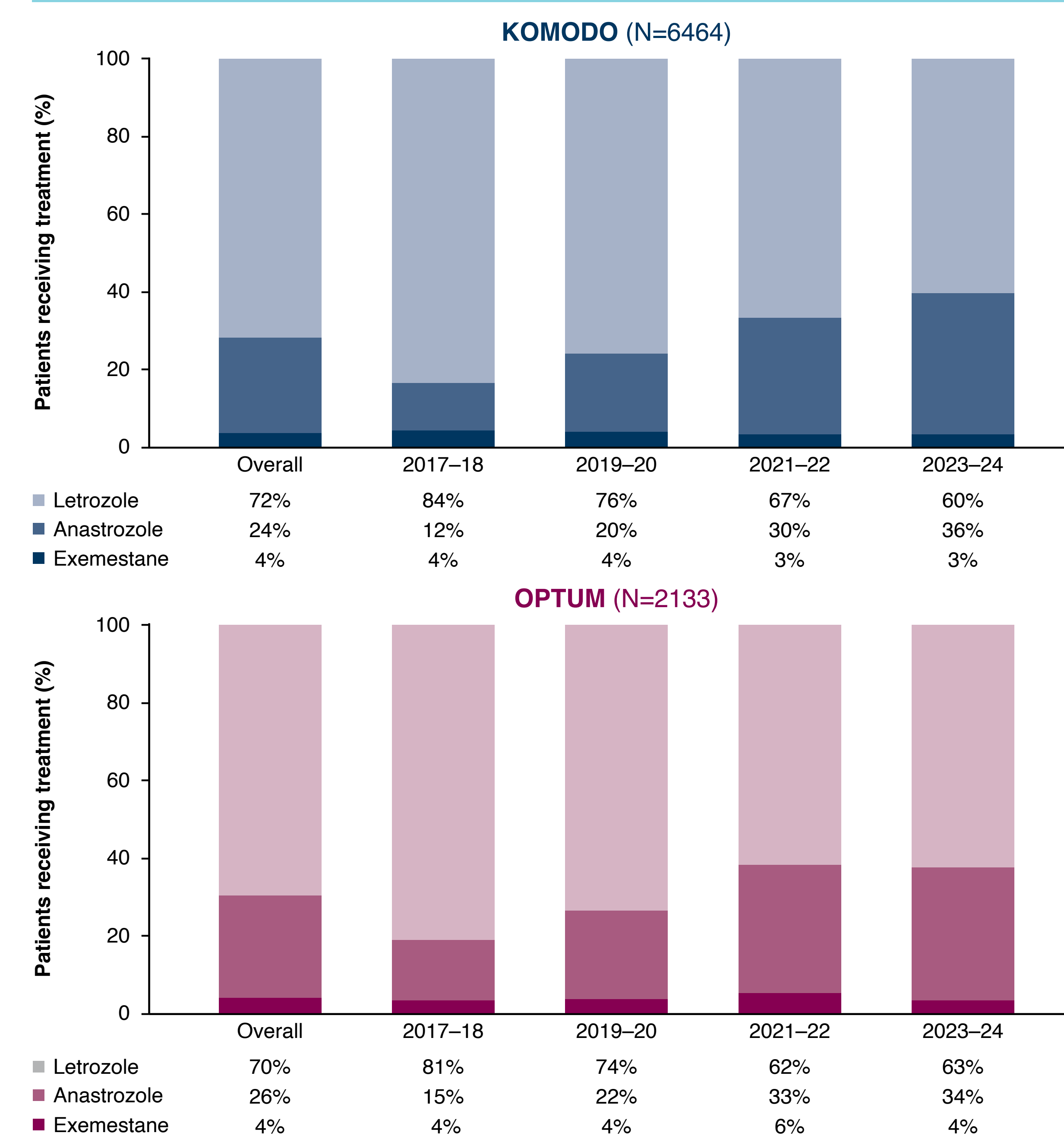


Figure 3. Treatment patterns from 2017 to 2024 (AI backbone)



Treatment outcomes

- Treatment outcomes appeared similar between the two cohorts
 - For KOMODO:
 - Median TTD was 15.9 months (**Figure 4**); 40.5% of patients discontinued treatment within 12 months
 - Median TTNT was 17.6 months (**Figure 5**); 37.3% of patients started subsequent treatment within 12 months
 - For OPTUM:
 - Median TTD was 14.0 months (**Figure 4**); 44.0% of patients discontinued treatment within 12 months
 - Median TTNT was 15.5 months (**Figure 5**); 40.8% of patients started subsequent treatment within 12 months

Figure 4. Time to treatment discontinuation

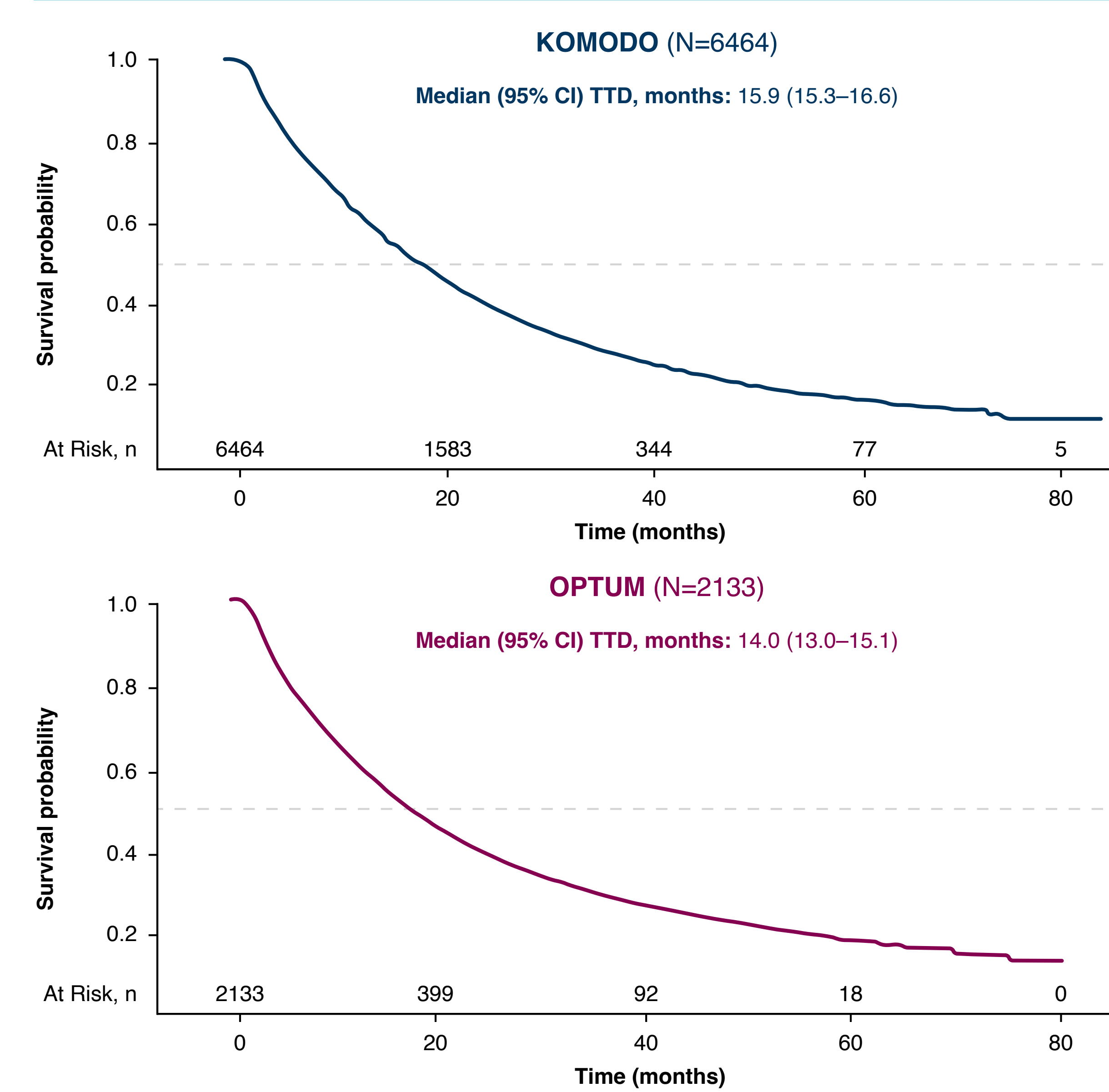
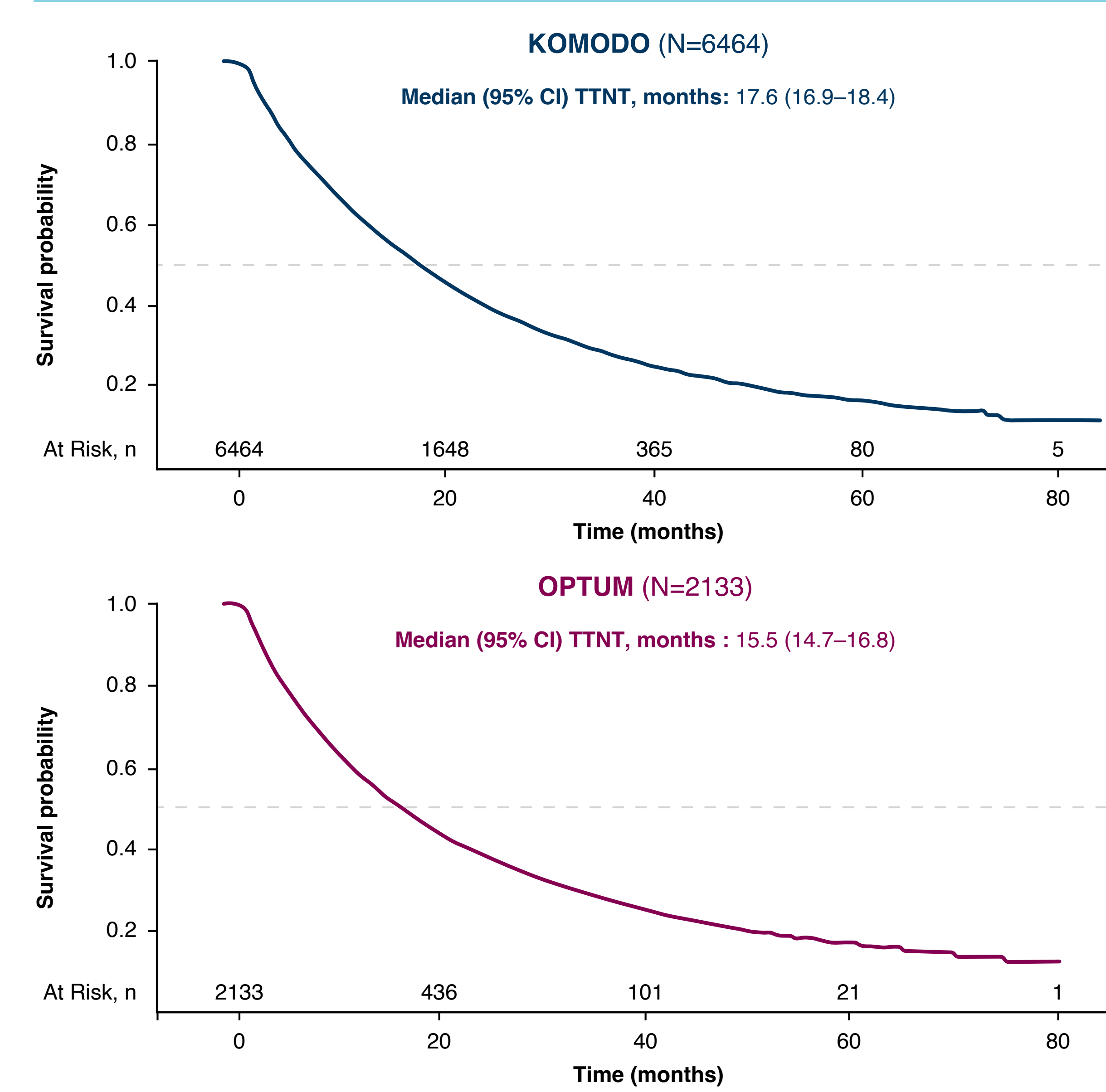


Figure 5. Time to next treatment



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