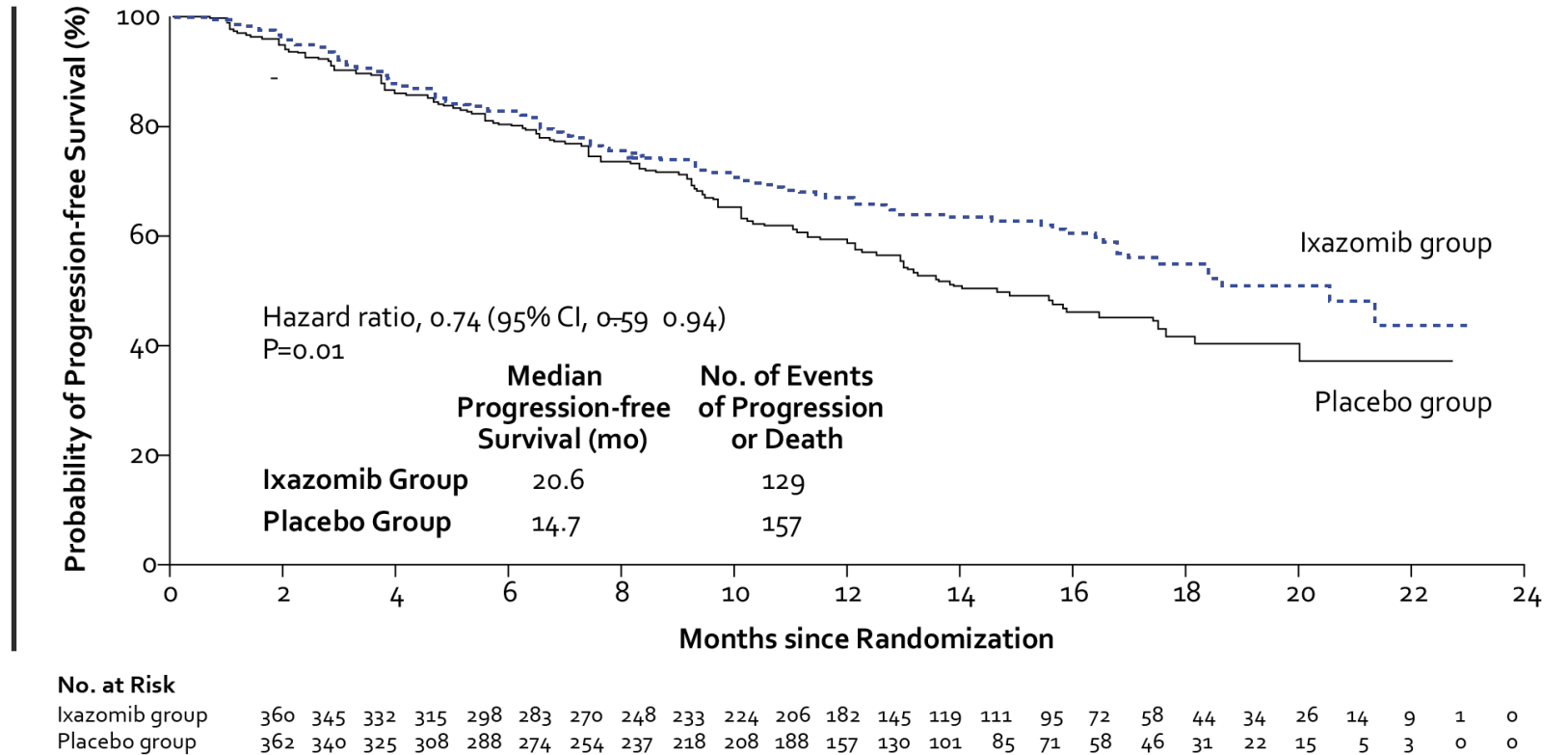


METHODS

- Double-blind, placebo-controlled, phase 3 trial
- 722 patients at 147 sites in 26 countries
- Inclusion criteria:
 - Adult patients with relapsed AND/OR refractory multiple myeloma
 - Measurable levels of disease
 - ECOG = 0-2
 - 1-3 prior therapies
 - Adequate hematologic/hepatic function, renal function ≤ 30 mL/min
- Treatment regimen:
 - 1:1 ratio of treatment to control
 - 28-day cycles, 4 mg of oral ixazomib OR placebo on days 1, 8, and 15
 - 25 mg of oral lenalidomide on days 1 through 21
 - 10 mg for patients with CrCL ≤ 60 OR ≤ 50 mL/40 mg of oral dexamethasone on days 1, 8, 15, 22

EFFICACY DATA

Progression-free Survival in the Intention-to-Treat Population



SAFETY DATA

Overall Safety Profile at the 23-Month Analysis in the Safety Population.*		
Variable	Ixazomib Group (N=361)	Placebo Group (N=359)
Median follow-up — mo [†]	23.3	22.9
Median treatment cycles (range) — no.	17 (1–34)	15 (1–34)
Any adverse event — no. (%)	355 (98)	357 (99)
Any grade ≥ 3 adverse event — no. (%)	267 (74)	247 (69)
Any serious adverse event — no. (%)	168 (47)	177 (49)
Adverse event resulting in dose reduction of any drug — no. (%)	203 (56)	181 (50)
Adverse event resulting in discontinuation of any agent — no. (%) [‡]	91 (25)	73 (20)
Adverse event resulting in discontinuation of the study regimen — no. (%) [§]	60 (17)	50 (14)
Death during the treatment period — no. (%) [¶]	15 (4)	23 (6)

- Thrombocytopenia occurred more frequently in treatment group:
 - Grade 3 (12% treatment, 7% control)
 - Grade 4 (5% treatment, 4% control)

- No adverse effect on QoL

CONCLUSIONS

Median duration of progression-free survival (months)



Ixazomib



Placebo

- Significantly longer (35%) progression-free survival for ixazomib group
- Limited additional toxic effects, no adverse effect on QoL
- May improve prognosis for patients with high-risk cytogenetic features
- Responses were rapid and durable, and deepened with increasing duration of treatment
- All-oral ixazomib regimen was as easy as placebo to follow