



The Tetravalent Death Receptor 5 Agonist Ozekibart (INBRX-109) in Conventional Chondrosarcoma: Results From the Randomized, Registrational, Phase 2 ChonDRAGON Study

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Presented at BSG Annual Conference 2026, Oxford Town Hall, Oxford, UK. 25-26 February 2026.



Presenter Disclosures

R.L. Jones reports receipt of grants/research support from MSD and GSK, and has received consultancy fees from Adaptimmune, Adcendo, Advenchen, Agenus, Astex, Athenex, Avacta, Ayala, Bayer, Boehringer Ingelheim, Blueprint, Cogent, Clinigen, Eisai, Epizyme, Daichii Sankyo, Deciphera, GSK, IDRx, Immunodesign, Immunicum, Incyte, Inhibrx Biosciences, Inc., Karma Oncology, Lilly, Merck, Mundipharma, Newbay, Orion, Pfizer, Pharmamar, Pharma Essentia, PTC, Rain Therapeutics, Servier, SpringWorks, SynOx, Traccon Pharmaceuticals, and UpToDate

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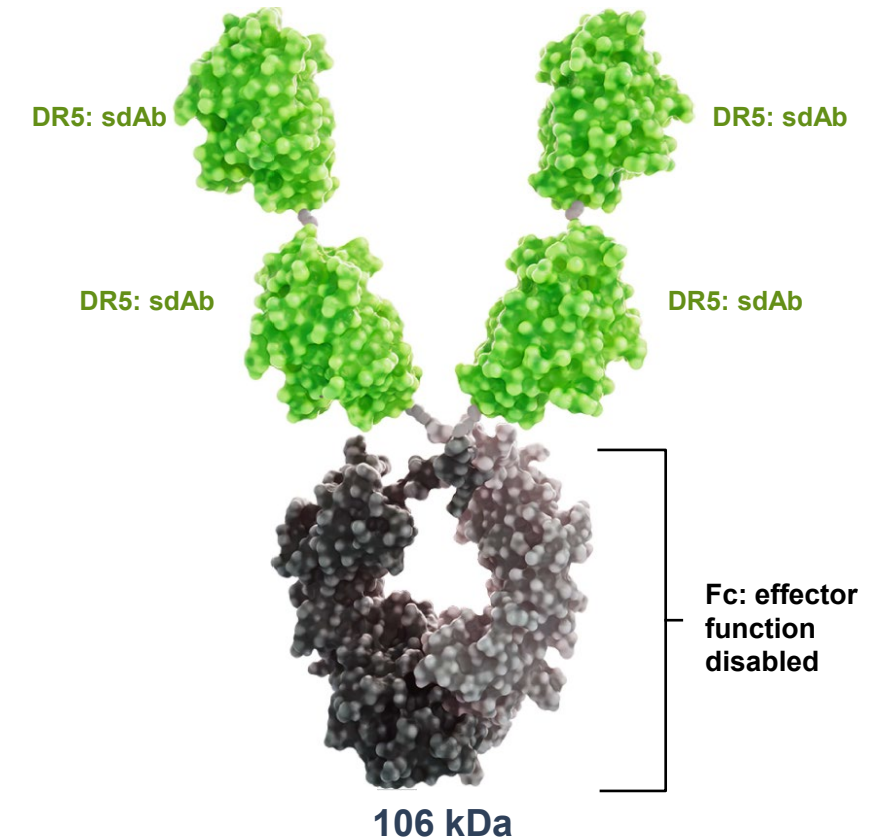
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Background

- **Unresectable or metastatic chondrosarcoma** is associated with **poor outcomes** (mPFS of 2-4 months)¹; systemic treatment options are limited
- **Ozekibart** (INBRX-109) is a next-generation, recombinant, humanized, tetravalent **DR5 agonist**
 - **DR5** is a member of the TNFR superfamily that binds the trimeric ligand TRAIL, resulting in receptor multimerization and induction of apoptosis³
 - High DR5 expression and resistance to intrinsic apoptosis have been observed in chondrosarcoma cell lines, providing a clear mechanistic rationale^{2,4}
- In a **phase 1** clinical trial (NCT03715933), **ozekibart** demonstrated **encouraging clinical efficacy** and a **manageable safety profile** in patients with **chondrosarcoma**²
 - Hepatotoxicity was limited; most liver-related AEs were low grade, and only few patients reported grade ≥ 3 hepatic events²
- These findings supported further evaluation of ozekibart in the randomized ChonDRAgon study (NCT04950075)

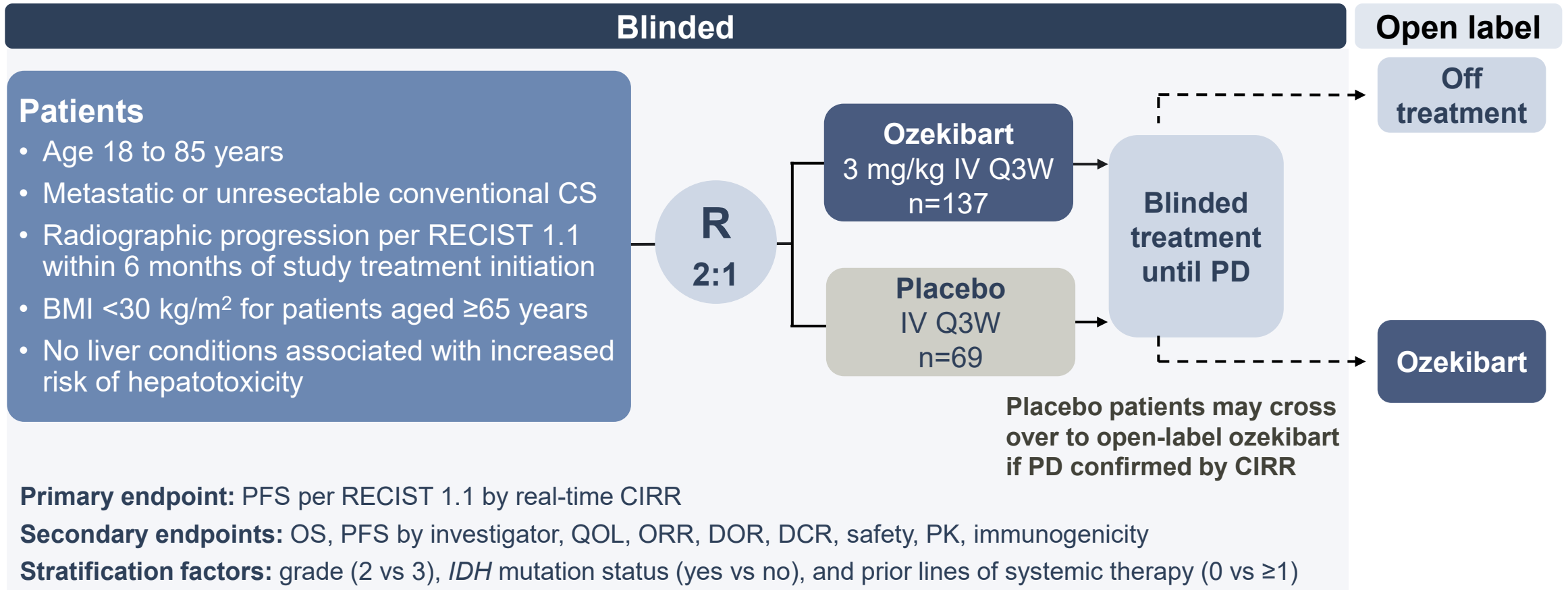
Structure of Ozekibart



AE, adverse event; DR5, death receptor 5; mPFS, median progression-free survival; sdAb, single-domain antibody; TNFR, tumor necrosis factor receptor; TRAIL, tumor necrosis factor–related apoptosis-inducing ligand.

1. Duffaud F, et al. *Eur J of Cancer*. 2021;150:108-118. 2. Subbiah V, et al. *Clin Cancer Res*. 2023;29:2988-3003. 3. Wajant H. *Cancers (Basel)*. 2019;11:954. 4. Tomek S, et al. *Eur J Cancer*. 2003;39:1318-1329.

ChonDRAGON Study Design



Statistical assumptions: The study was powered to detect a HR of 0.571; with 90% power; 1-sided family-wise α of 0.025

Protocol version 7.0; October 21, 2024.

BMI, body mass index; CIRR, central independent radiology review; CS, chondrosarcoma; DCR, disease control rate; DOR, duration of response; HR, hazard ratio; IDH, isocitrate dehydrogenase; IV, intravenous; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PK, pharmacokinetics; Q3W, every 3 weeks; QOL, quality of life; R, randomized; RECIST, Response Evaluation Criteria in Solid Tumors.

Baseline Characteristics

Patient characteristic	Ozekibart (n=137)	Placebo (n=69)
Age, median (range), years	54.0 (20-82)	50.0 (19-91)
Sex, n (%)		
Male	96 (70.1)	42 (60.9)
Female	41 (29.9)	27 (39.1)
Race, n (%)		
White	114 (83.2)	47 (68.1)
Other ^a	23 (16.8)	22 (31.9)
Histological grade, n (%)		
2	96 (70.1)	48 (69.6)
3	41 (29.9)	21 (30.4)
Disease status at trial entry, n (%)		
Unresectable nonmetastatic	15 (10.9)	13 (18.8)
Metastatic	122 (89.1)	56 (81.2)
<i>IDH1/2</i> mutation status, n (%)		
Wild type	93 (67.9)	47 (68.1)
<i>IDH</i> mutant	44 (32.1)	22 (31.9)
Region, n (%)		
US	65 (47.4)	32 (46.4)
Outside of US	72 (52.6)	37 (53.6)
Prior systemic therapy, n (%)	58 (42.3)	28 (40.6)

Data cutoff: September 30, 2025. Data from the double-blind period of the study are presented.

IDH, isocitrate dehydrogenase.

^a Includes patients with race listed as “not reported.”

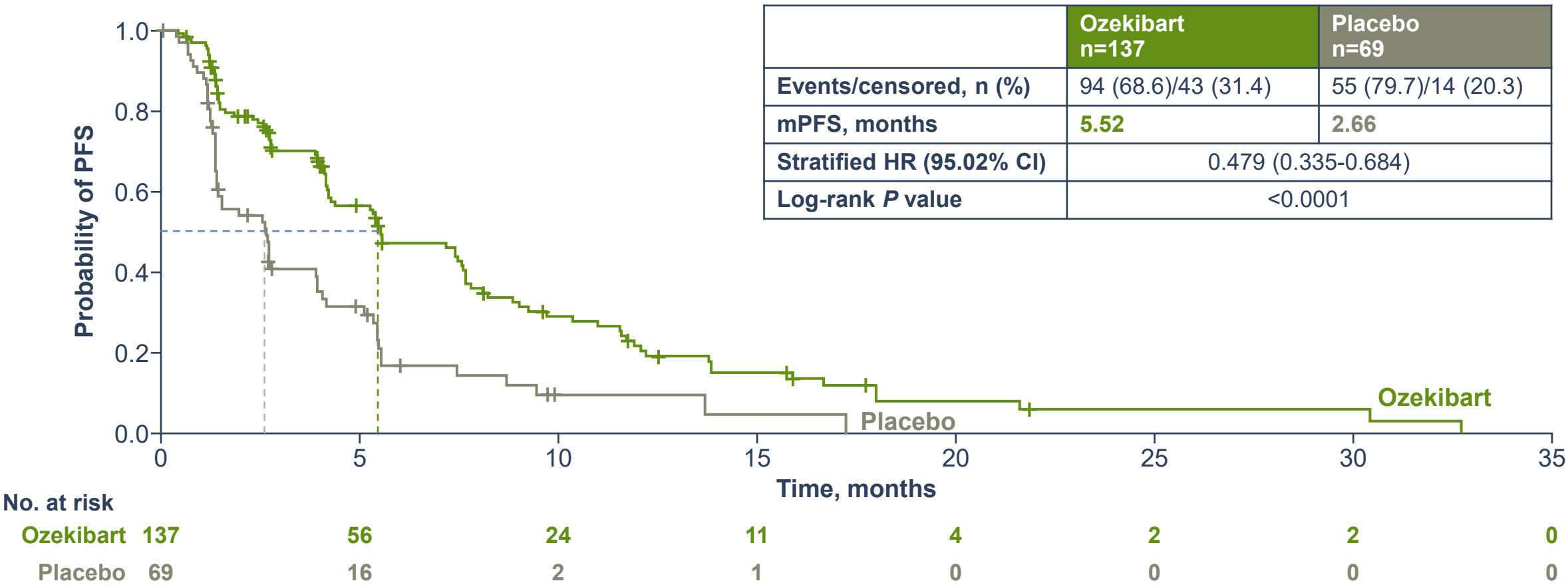
Patient Disposition

Patient characteristic	Ozekibart (n=137)	Placebo (n=69)
ITT	137 (100)	69 (100)
Patients treated	136 (99.3)	67 (97.1)
Ongoing treatment	25 (18.2)	3 (4.3)
Discontinued treatment	112 (81.8)	66 (95.7)
Crossed over to receive ozekibart	N/A	44 (63.8)
Reasons for discontinuation		
Disease progression per CIRR	91 (66.4)	49 (71.0)
Adverse event	9 (6.6)	3 (4.3)
Disease progression per investigator	6 (4.4)	6 (8.7)
Withdrawal of consent	4 (2.9)	4 (5.8)
Other	2 (1.5)	4 (5.8)
Long-term safety follow-up	36 (26.3)	16 (23.2)
Median follow-up, months	10.2	9.0

- As of the data cutoff, 18.2% of patients in the ozekibart arm and 4.3% of patients in the placebo arm remained on study treatment
- 63.8% of patients crossed over from placebo to ozekibart after progression

Data cutoff: September 30, 2025. Data from the double-blind period of the study are presented. CIRR, central independent radiological review; ITT, intention to treat; N/A, not applicable.

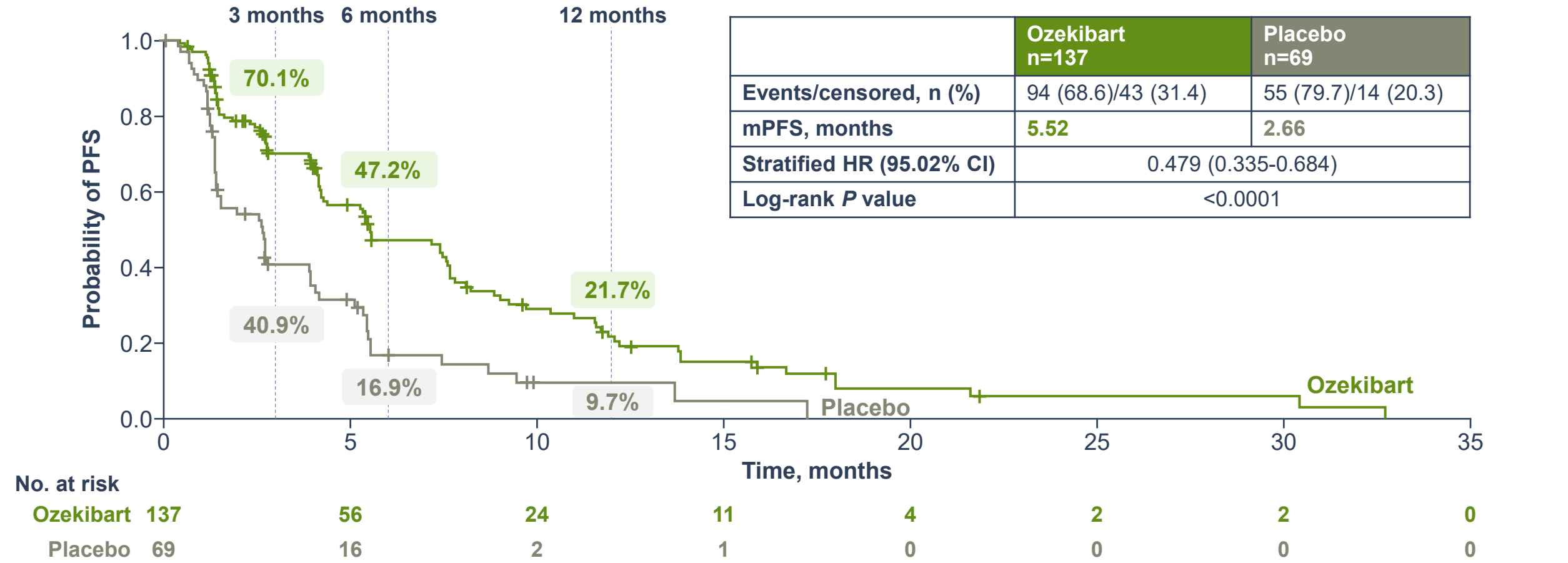
Primary Endpoint: Progression-Free Survival by CIRR



Ozekibart significantly prolonged mPFS vs placebo and led to a 52% reduction in the risk of disease progression or death

Data cutoff: September 30, 2025. Crosses indicate censored patients. Data from the double-blind period of the study are presented.
CIRR, central independent radiology review; HR, hazard ratio; mPFS, median progression-free survival; PFS, progression-free survival.

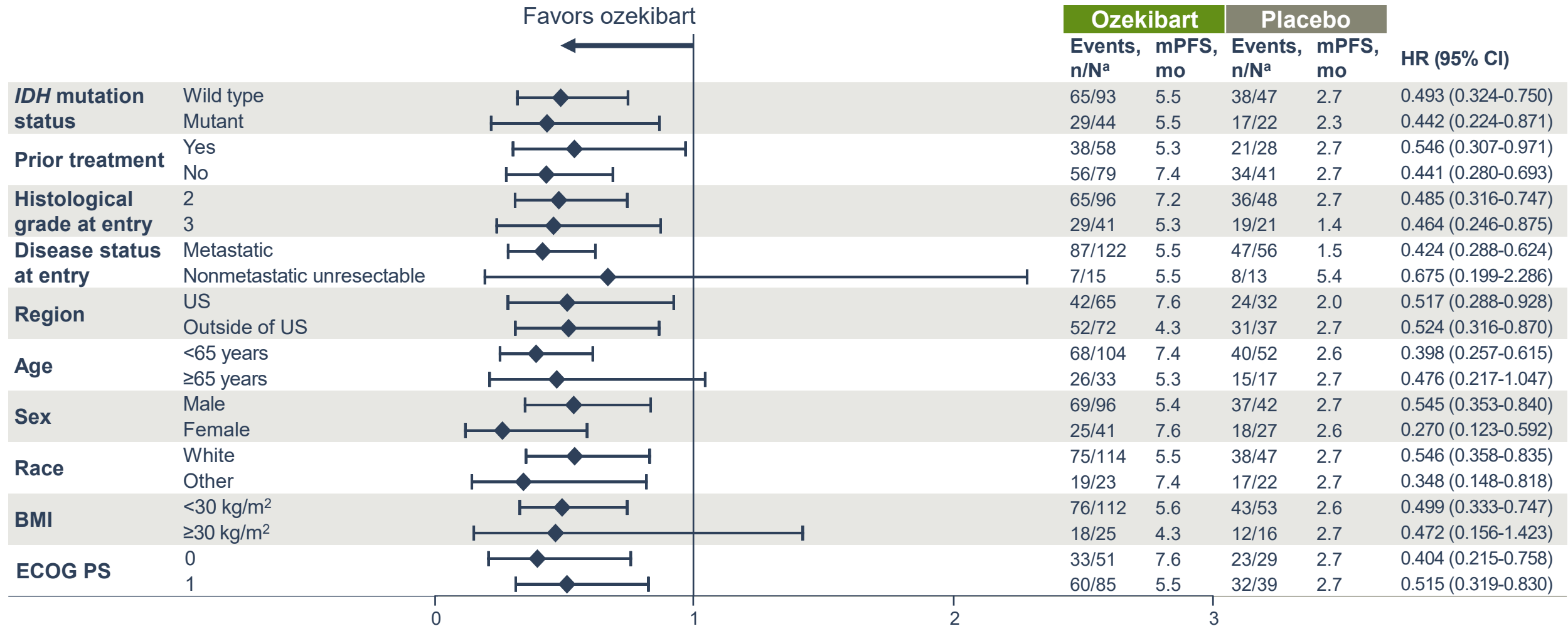
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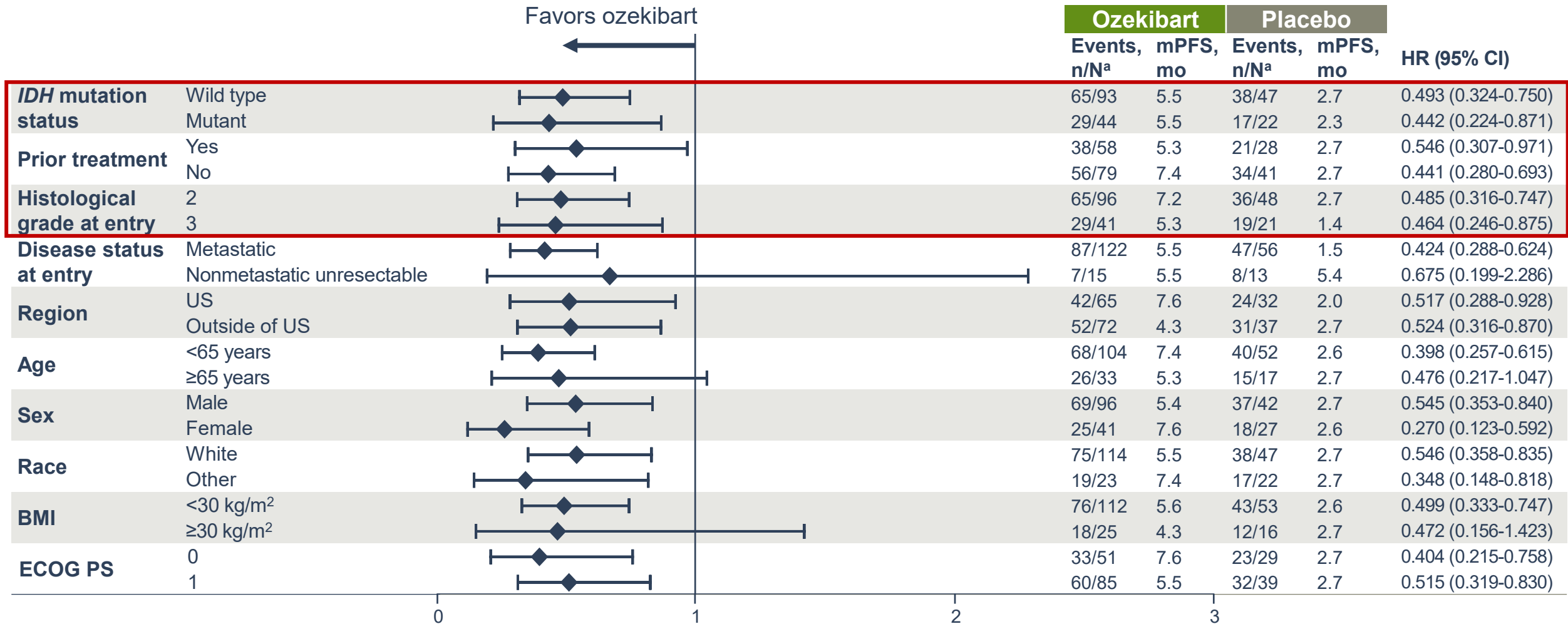
Progression-Free Survival by CIRR: Subgroup Analyses



PFS benefit was consistent across key prespecified subgroups, including *IDH* mutation status and prior therapy

Data cutoff: September 30, 2025. Data from the double-blind period of the study are presented. ^a N values represent the number of patients with available data for each parameter. BMI, body mass index; CIRR, central independent radiology review; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; IDH, isocitrate dehydrogenase; mPFS, median progression-free survival.

Progression-Free Survival by CIRR: Subgroup Analyses



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Overall Safety

	Ozekibart (n=136)	Placebo (n=67)
Patients with ≥ 1 AE (including unrelated AEs), n (%)	129 (94.9)	62 (92.5)
Grade ≥ 3	53 (39.0)	17 (25.4)
SAE	38 (27.9)	12 (17.9)
HAE	21 (15.4)	9 (13.4)
Resulting in death	5 (3.7)	1 (1.5)
Patients with ≥ 1 treatment-related AE, n (%)	77 (56.6)	32 (47.8)
Grade ≥ 3	14 (10.3)	1 (1.5)
SAE	8 (5.9)	0
HAE	16 (11.8)	3 (4.5)
Leading to interruption of study drug	8 (5.9)	2 (3.0)
Leading to discontinuation of study drug	4 (2.9)	0
Resulting in death	1 (0.7)	0

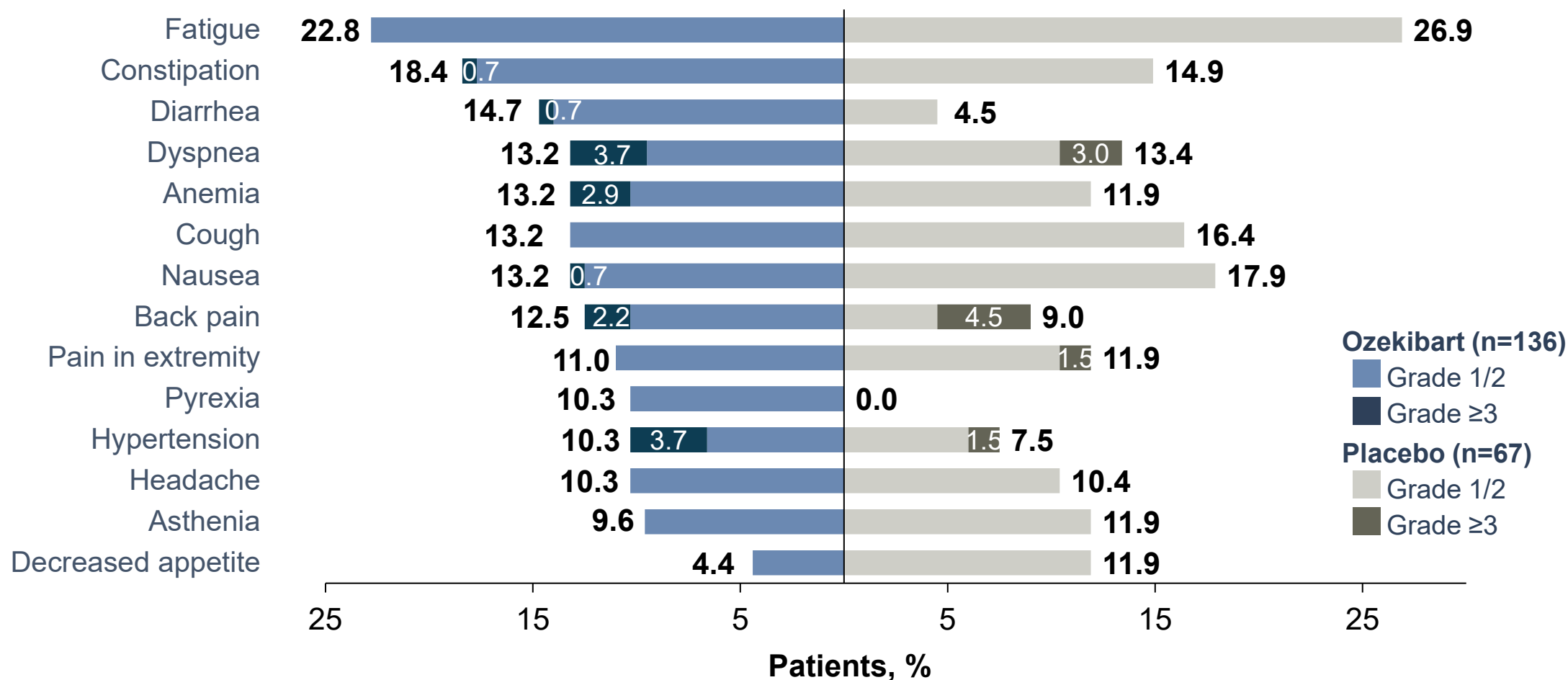
Mean duration of exposure: 5.72 months in the ozekibart arm vs 3.18 months in the placebo arm

Data cutoff: September 30, 2025. Data from the double-blind period of the study are presented.

HAEs included alanine aminotransferase increased, aspartate aminotransferase increased, bile duct stone, bilirubin conjugated increased, blood alkaline phosphatase increased, blood bilirubin increased, feces discolored, gamma-glutamyltransferase increased, hepatic failure, hyperbilirubinemia, hypertransaminasemia, and liver disorder.

AE, adverse event; HAE, hepatic adverse event; SAE, serious adverse event.

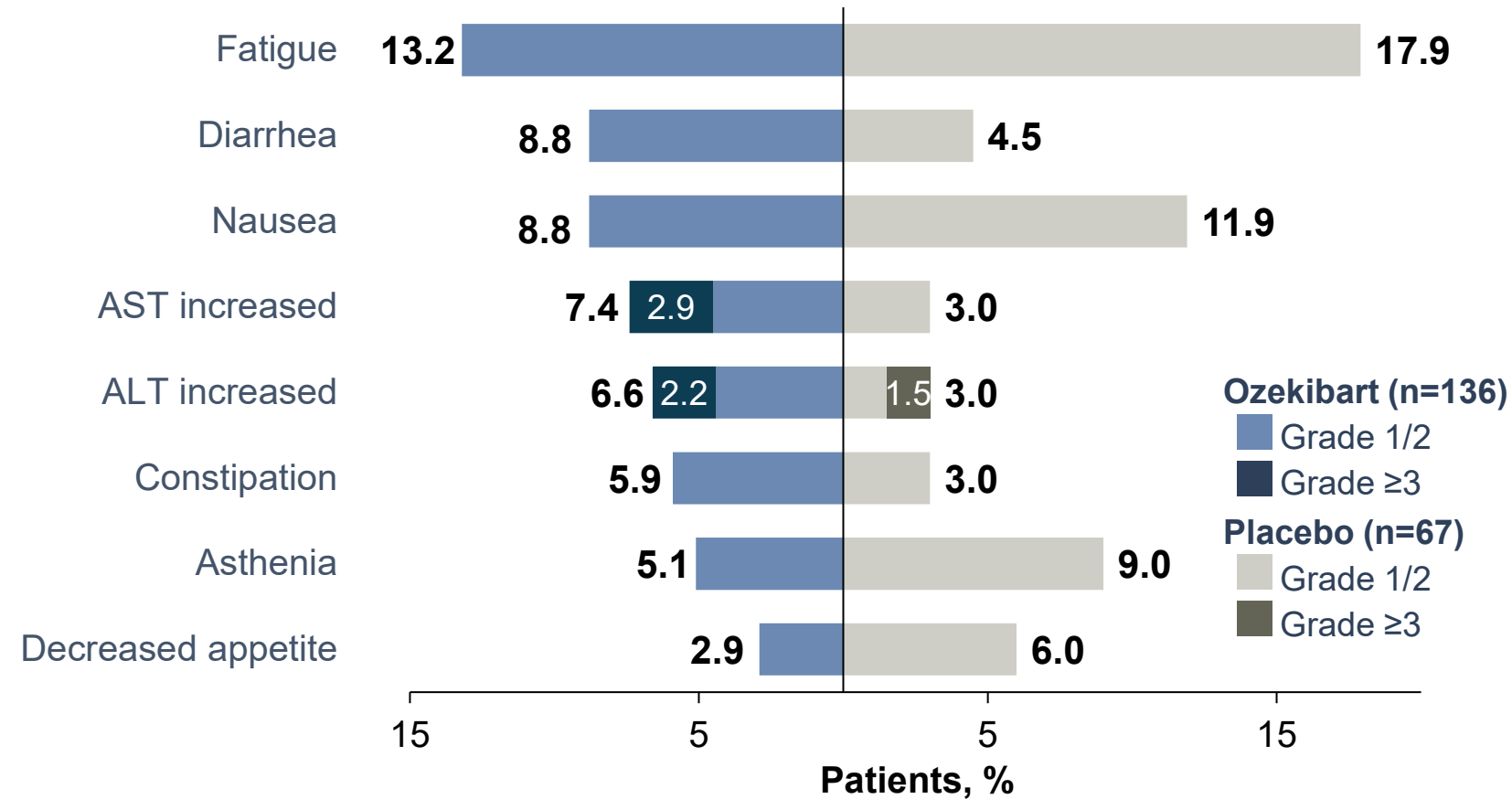
Most Common Adverse Events, including unrelated AEs (in ≥10% of Patients in Either Arm)



Most adverse events were low grade; fatigue, constipation, and diarrhea were the most common adverse events

Data cutoff date: September 30, 2025. Data from the double-blind period of the study are presented.

Most Common Treatment-Related Adverse Events (in $\geq 5\%$ of Patients in Either Arm)



- The most common treatment-related adverse events with ozekibart were fatigue, diarrhea, and nausea
 - Most treatment-related adverse events were grade 1 or 2
- The incidence of treatment-related hepatic events was low
 - The most common treatment-related hepatic events were increased AST and ALT
- Hepatotoxicity risk mitigation:
 - Through frequent monitoring of liver enzymes, especially during the first treatment cycle, and rapid intervention, hepatotoxicity remained low and generally manageable
 - Around 200 patients have been treated across the program since the implementation of the screening, monitoring, and mitigation strategy, with no new treatment-related deaths

Data cutoff: September 30, 2025. Data from the double-blind period of the study are presented.
 ALT, alanine aminotransferase; AST, aspartate aminotransferase.

Conclusions

- **Unprecedented data in chondrosarcoma:** ChonDRAgon is the largest randomized trial in chondrosarcoma and demonstrated that ozekibart significantly reduced risk of disease progression or death by 52% compared with placebo (HR, 0.479; 95.02% CI, 0.335–0.684)
- **Robust and significant PFS improvement:** Median PFS with ozekibart was double that observed with placebo (5.52 vs 2.66 months; $P<0.0001$), with PFS benefits observed early and throughout the course of treatment
- **Consistent and reliable efficacy:** PFS benefits were observed across key subgroups
- **Favorable risk/benefit profile:** Ozekibart had a manageable safety profile, with most adverse events being low grade and reversible; a low incidence of treatment-related hepatic events was observed
- **Supportive secondary endpoints:** Additional outcomes (eg, quality of life) align with primary findings and will be shared in future presentations. At the time of analysis, OS data were not mature
- **Potential new standard of care:** Ozekibart could become the first standard-of-care for a population with a high unmet need

HR, hazard ratio; OS, overall survival; PFS, progression-free survival.

Acknowledgments



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- We thank our patients and participating clinical sites and teams
- This study is sponsored by Inhibrx Biosciences, Inc.
- Medical editorial assistance with this presentation was provided by Jenna M. Gaska, PhD, of Nucleus Global, an Inizio company, and funded by Inhibrx Biosciences, Inc.

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