



The Patient Impact of 10 Years of Ocrelizumab Treatment in Multiple Sclerosis: Long-Term Data from the Phase III OPERA and ORATORIO Studies

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STUDY AIMS

To assess the long-term (10-year) impact of OCR on disability accumulation in patients with relapsing and primary progressive MS

CONCLUSIONS

After long-term (10 years) continuous ocrelizumab treatment:

Almost 8 out of 10 PwRMS and a third of PwPPMS were progression-free on EDSS >90% of PwRMS did not need a walking aid and >80% of PwPPMS did not need a wheelchair

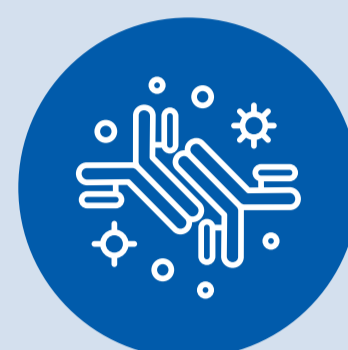
Early treatment with ocrelizumab extends the progression-free event window by almost 10 years in PwRMS, compared with a lower-efficacy DMT

The notable impact of a decade of ocrelizumab treatment in reducing disability accumulation reinforces the role of early treatment in preserving patient function across the MS spectrum

BACKGROUND



Preserving patient function, by optimally slowing disease progression, is the key treatment goal across the MS continuum¹⁻³



OCR, the only anti-CD20 monoclonal antibody approved for the treatment of both RMS and PPMS,^{4,5} has a decade of safety and efficacy experience in clinical trials, and over 300,000 patients have been treated in trial and post-marketing settings⁶⁻⁹

METHODS

Disability Measures^a

CDW-EDSS

Defined as ≥ 1.0 increase in EDSS from baseline (or 0.5 increase in EDSS if baseline EDSS >5.5) confirmed at 48 weeks

CDW-T25FW

Defined as $\geq 20\%$ increase in T25FW from baseline confirmed at 48 weeks

CDW-9HPT

Defined as $\geq 20\%$ increase in 9HPT from baseline confirmed at 48 weeks

REPEATED CDW-EDSS

Defined by expanding the first-event definition such that the EDSS was rebaselined at the onset of a 48-week confirmed event

Annualised repeated events rate
i.e. the average number of events per year, used to establish the time between two disability progression events

Time to key disability milestones

RMS: Requiring a walking aid EDSS ≥ 6 from baseline ≤ 5.5

PPMS: Requiring a wheelchair EDSS ≥ 7 from baseline ≤ 6.5

Composite measure: **cCDW^b**

Defined as 48-week CDW-EDSS, CDW-T25FW or CDW-9HPT

EDSS ≥ 6 CDW EDSS ≥ 7 CDW

Patient Populations, Baseline Demographics and Disease Characteristics^a

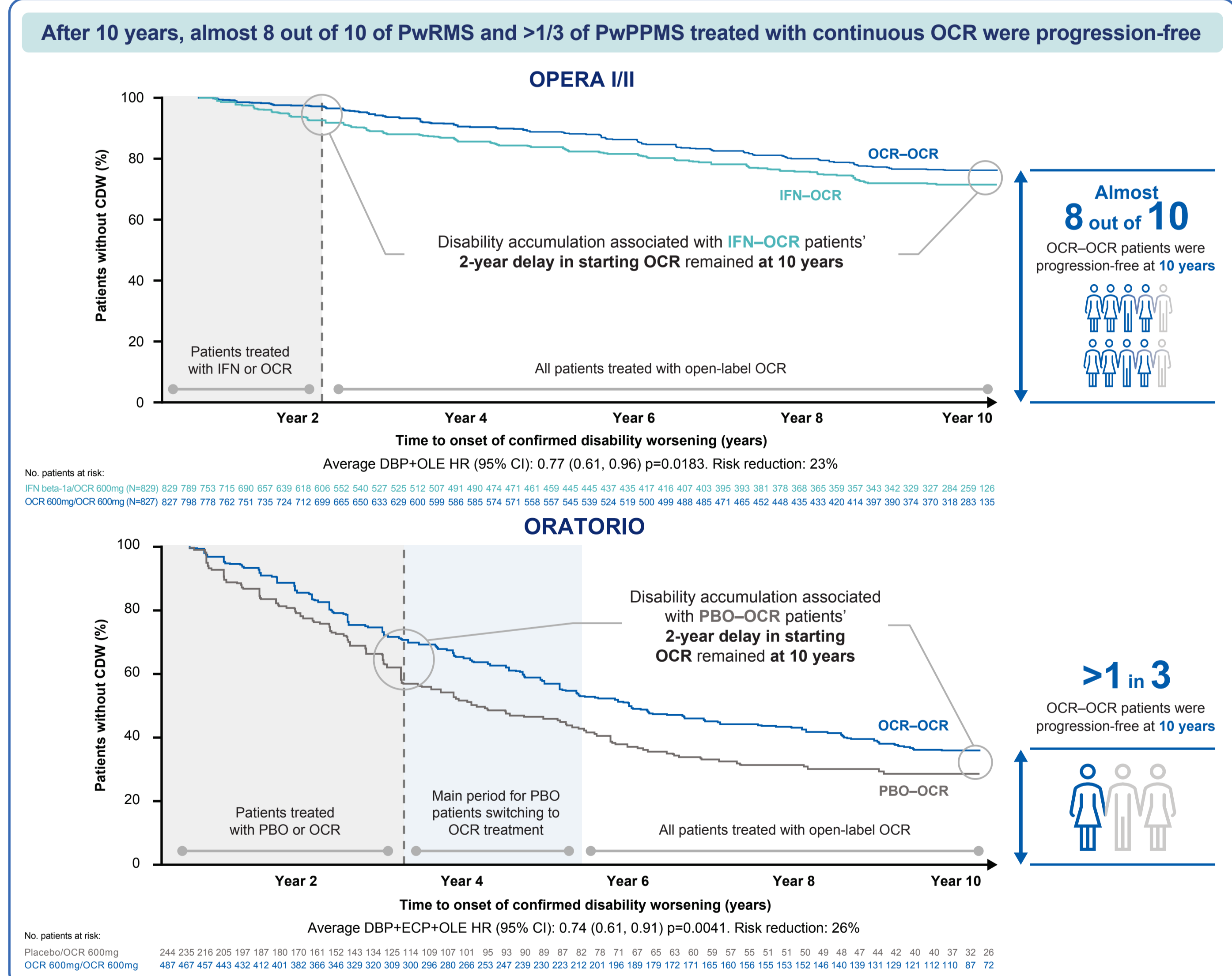
	OPERA III RMS (OCR; N=827)	OPERA III RMS (IFN; N=828)	ORATORIO PPMS (OCR; N=488)	ORATORIO PPMS (PBO; N=514)
Age (years, mean±SD)	37.1±9.2	37.2±9.2	44.7±7.9	44.4±8.3
Female n (%)	541 (65.4)	552 (66.6)	237 (48.6)	124 (24.1)
Time since symptom onset (years, mean±SD)	6.7±5.2	6.5±5.1	6.7±4.0	6.1±3.6
EDSS score	2.8±1.3	2.8±1.3	4.7±1.2	4.7±1.2
T25FW (seconds, mean±SD)	7.9±9.9	7.2±9.2	14.8±21.2	12.9±15.5
9HPT (seconds, mean±SD)	24.6±13.1	24.0±8.3	31.9±23.3	30.6±13.4

Baseline demographics and disease characteristics were representative of relapsing and primary progressive MS disease, and were similar between treatment and comparator arms

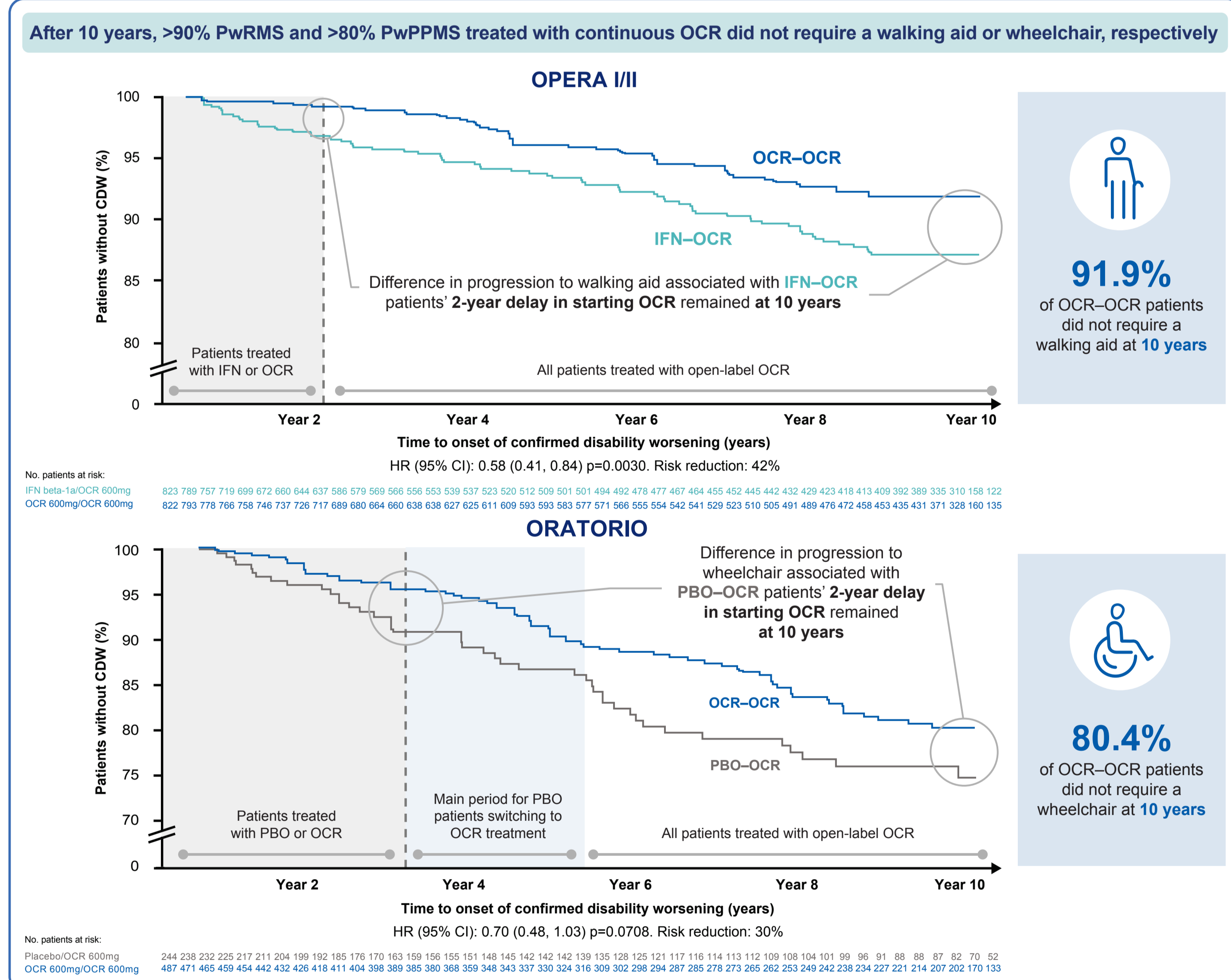
^aData shown for DBP; clinical cut-off date for the analyses was 25 November 2022; for OPERA III (NCT01247324/NCT01412333) and ORATORIO (NCT01194570), data from patients up to Week 528 were used for the 10-year analyses. Patient disposition is available in the Supplementary Materials.

RESULTS

Effect of a Delay in OCR Initiation on 48W-CDW on EDSS^a

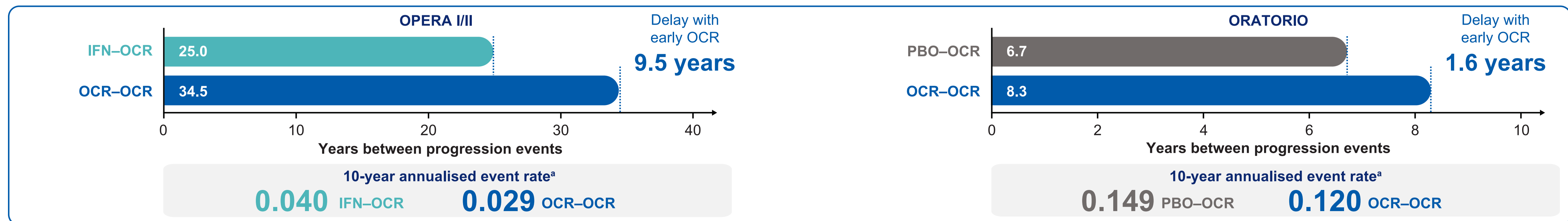


Time to Walking Aid (RMS) and Time to Wheelchair (PPMS)



Disability Event Rate Expressed as Annualised Repeated 48W-CDW-EDSS

Starting OCR 2 years earlier saves almost 10 years of disease progression in PwRMS



Over 10 years, the annualised, repeated 48W-CDW-EDSS event rate patients would be expected to be progression-free for the next 34.5 and 8.3 years after the last event, in PwRMS and PwPPMS