

GEM OPTIMAL

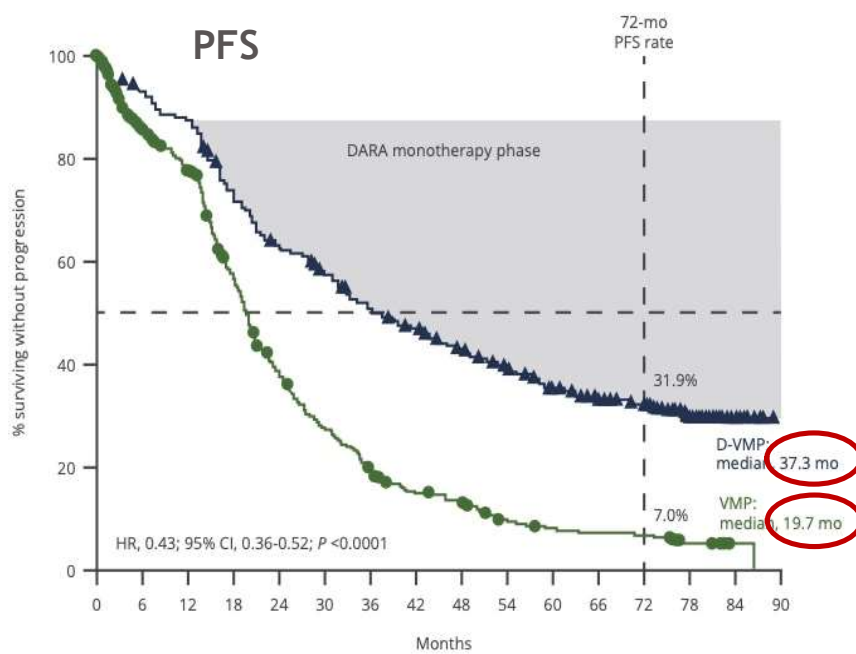
• Justificación para el GEM OPTIMAL

Daratumumab + VMP VS. VMP: PHASE III ALCYONE STUDY

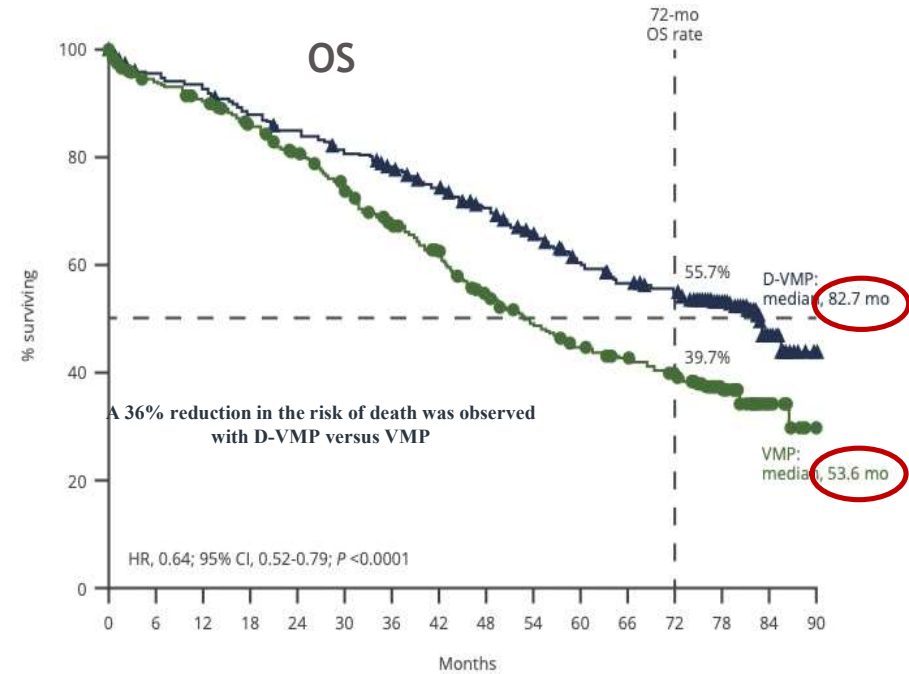
Median follow-up of 78.8 months

ORR: 91% vs 74% (sCR/CR rate: 46% vs 25%);

MRD -ve rate: 28% vs 7%



No. at risk		0	6	12	18	24	30	36	42	48	54	60	66	72	78	84	90
VMP	356	284	253	178	117	84	58	42	36	23	19	17	16	8	1	0	
D-VMP	350	315	295	245	209	188	165	150	131	116	99	86	76	38	7	0	

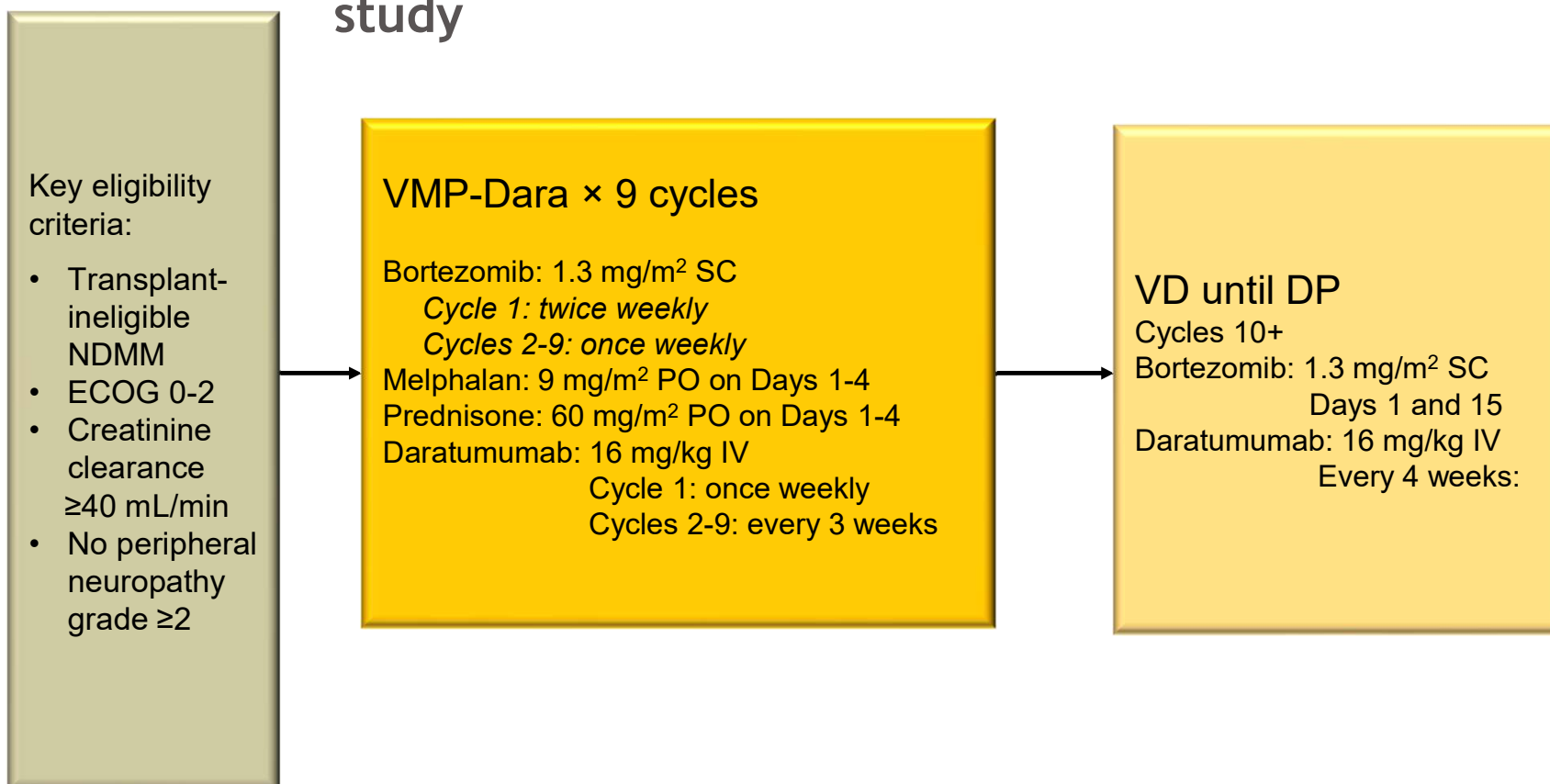


No. at risk		0	6	12	18	24	30	36	42	48	54	60	66	72	78	84	90
VMP	356	324	311	291	268	242	216	197	167	148	133	124	112	70	15	0	
D-VMP	350	327	318	301	288	275	258	244	227	205	183	170	162	112	24	0	

D-, daratumumab; MRD, minimal residual disease; NGS, next-generation sequencing; PFS, progression-free survival; OS, overall survival; VMP, bortezomib, melphalan, prednisone.

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Modified-ALCYONE Scheme Design Observational study

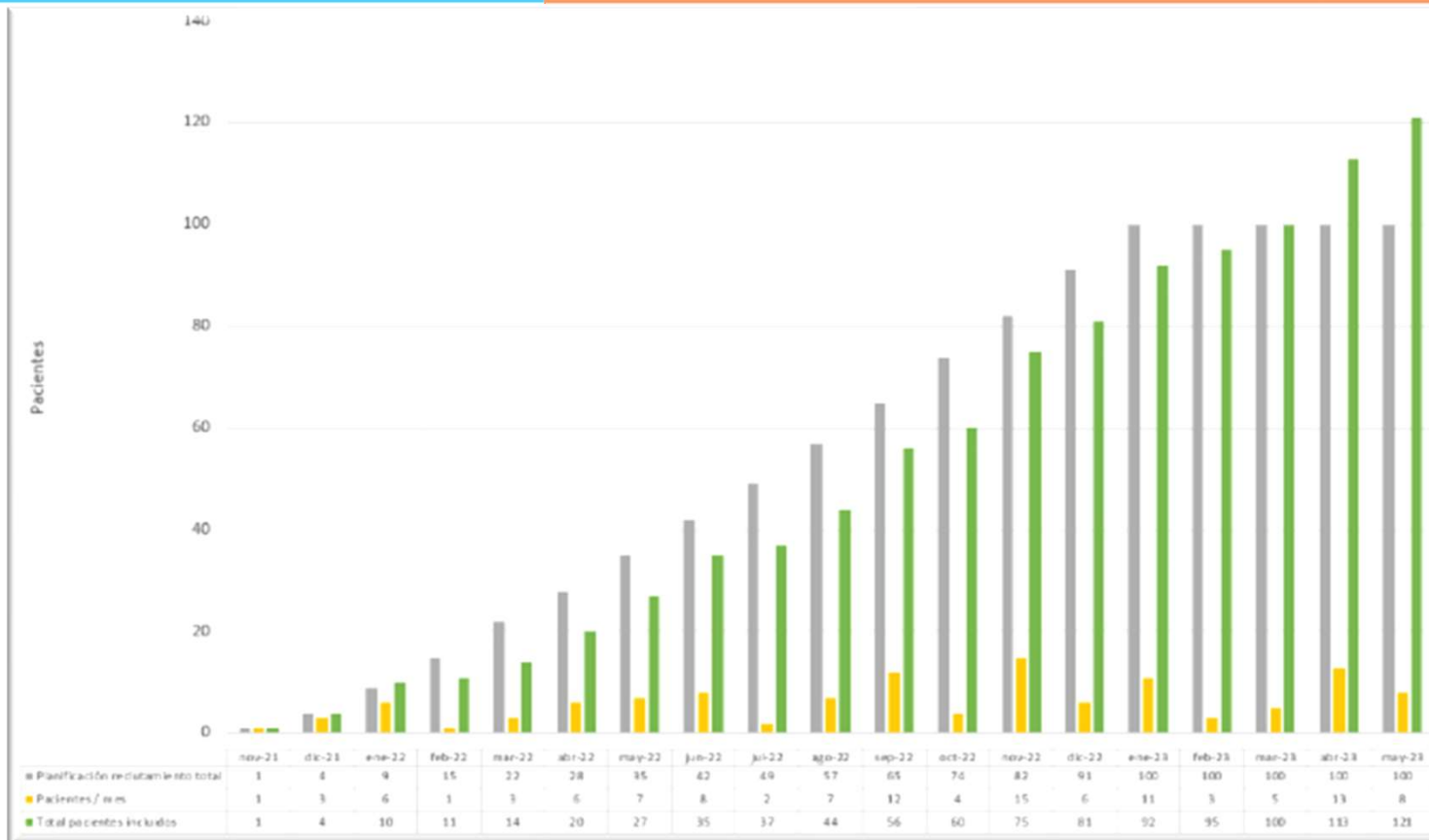


NDMM, newly diagnosed multiple myeloma; ECOG, Eastern Cooperative Oncology Group; ISS, International Staging System; EU, European Union; VMP, bortezomib/melphalan/prednisone; SC, subcutaneously; PO, orally; D, daratumumab; IV, intravenously; PD, progressive disease; PFS, progression-free survival; ORR, overall response rate; VGPR, very good partial response; CR, complete response; MRD, minimal residual disease; NGS, next-generation sequencing; OS, overall survival.

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Recruitment period:
119 Patients enrolled

3-4 years Follow up



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Second interim analysis:

Prospective follow-up of 1 year after the start of the study.

