

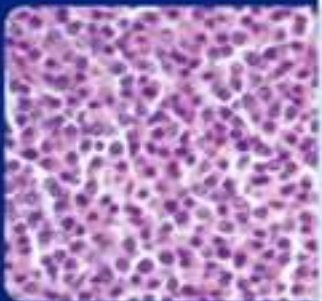
Newly Diagnosed Myeloma > 65 years

Facts and Questions

IFM perspectives

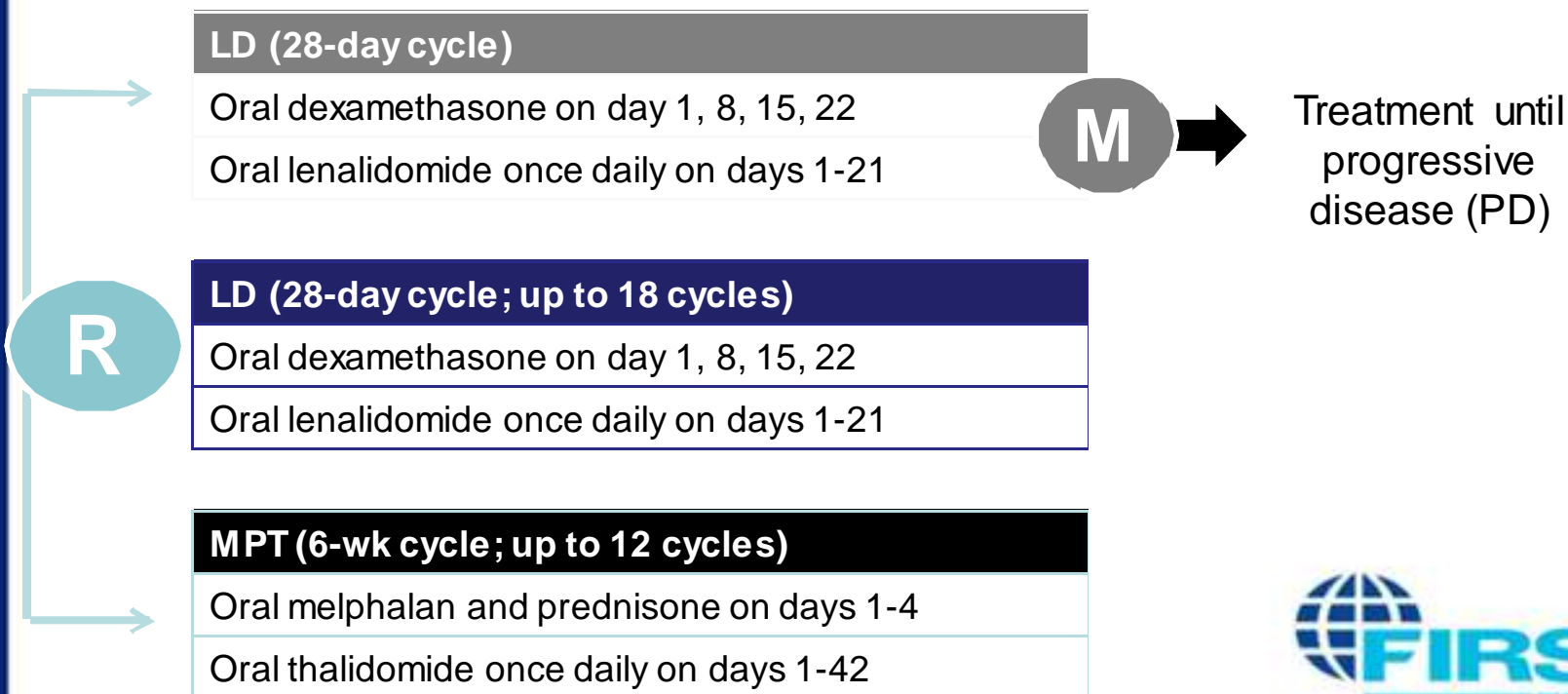
Thierry FACON
On behalf of IFM

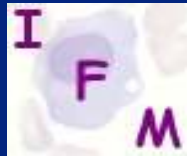
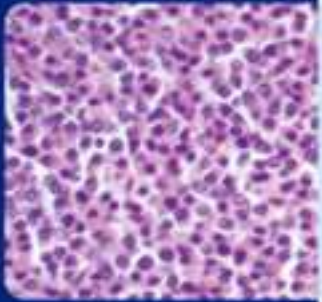




FIRST: Lenalidomide + LD-dex vs. MPT (IFM 07-01)

- **Pts:** Previously untreated MM pts **>65 yrs old** or not a candidate for ASCT
- **Primary Endpoint:** *Progression-free survival (PFS)*





Enrollment Summary

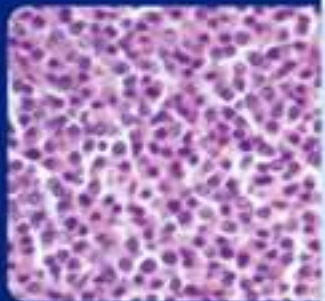
- EU (196 centers) 1112
- NA (55 centers) 311
- APAC (45 centers) 200



23-May-11

Confidential Information

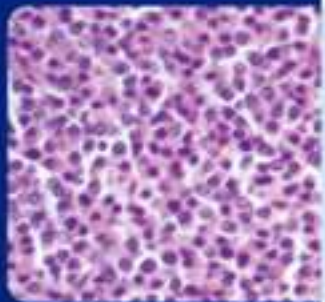




Enrollment By Country EU

Country	# sites screening	# patients screened	# patients randomized
Austria	10	51	41
Belgium	11	62	52
France	64	555	459
Germany	14	132	97
Greece	2	103	86
Italy	17	178	148
Ireland	0	0	0
Portugal	5	34	27
Spain	18	108	87
Sweden	3	23	19
Switzerland	6	28	26
UK	16	101	72





Enrollment By Country AsiaPac



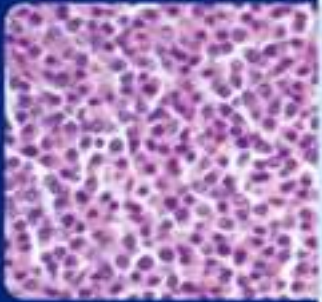
Country	# sites screening	# patients screened	# patients randomized
Australia	17	103	72
New Zealand	3	16	12
China	3	52	49
South Korea	15	71	56
Taiwan	3	16	11



23-May-11

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Enrollment By Country NA



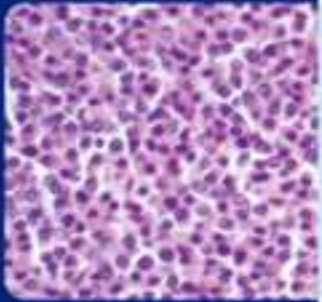
Country	# sites screening	# patients screened	# patients randomized
Canada	22	322	251
US	21	79	60



23-May-11

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FIRST: Lenalidomide + LD-dex vs. MPT (IFM 07-01/MM020)

1623 patients randomized in 296 centers

- . 537 patients in IFM centers***

The population is as close to the real life population as possible

- . 569 patients > 75 years (36%)***

- . Med age 73 years***

- . Patients with renal insufficiency were enrolled
(only pts receiving dialysis were excluded)***



CARMYSAP (1) Trial

Phase I/II trial of **carfilzomib plus melphalan and prednisone** in elderly untreated with MM

Primary objective : to identify the most appropriate dose of carfilzomib in combination with a standard MP regimen (Phase I), and to evaluate the efficacy of CMP in terms of response rates (Phase II)

Nine 6-week cycles of carfilzomib (20. 20/27, 20/36...) on days 1,2,8,9,22,23,29,30 in combination with MP on days 1-4.

After identification of the MTD, up to a total of 20 pts at the MTD for the phase II part of the study

CARMYSAP 2 Trial proposal

Multicenter open-label phase II randomized study of CMP in untreated symptomatic elderly MM patients

The study would investigate **weekly carfilzomib** in combination with MP

Primary endpoint : VGPR+CR rate

Patients randomly allocated to :

- Arm A: MTD demonstrated in the phase I/II Carmysap trial
- Arm B: A weekly Carfilzomib regimen with Carfilzomib used at a higher dose level

Using Rd as a platform for a next step forward

- VRd ; new standard of care in the US, part of IFM/DFCI trial in younger pts. Modified (little) VRd in the elderly is worthwhile, using weekly Bz, and likely SC Bz
- CRd and Rd + oral proteasome inhibitors also promising
- Rd and HDAC inhibitors (Rd-Vorinostat)
- Rd-Elotuzumab (IFM commitment in the upcoming randomized phase 3)



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