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Long-term efficacy and safety of maintenance with lenalidomide in patients with chronic lymphocytic leukaemia and a high risk of progression after first-line immunochemotherapy

Updated results of the CLLM1 study of the German CLL Study Group

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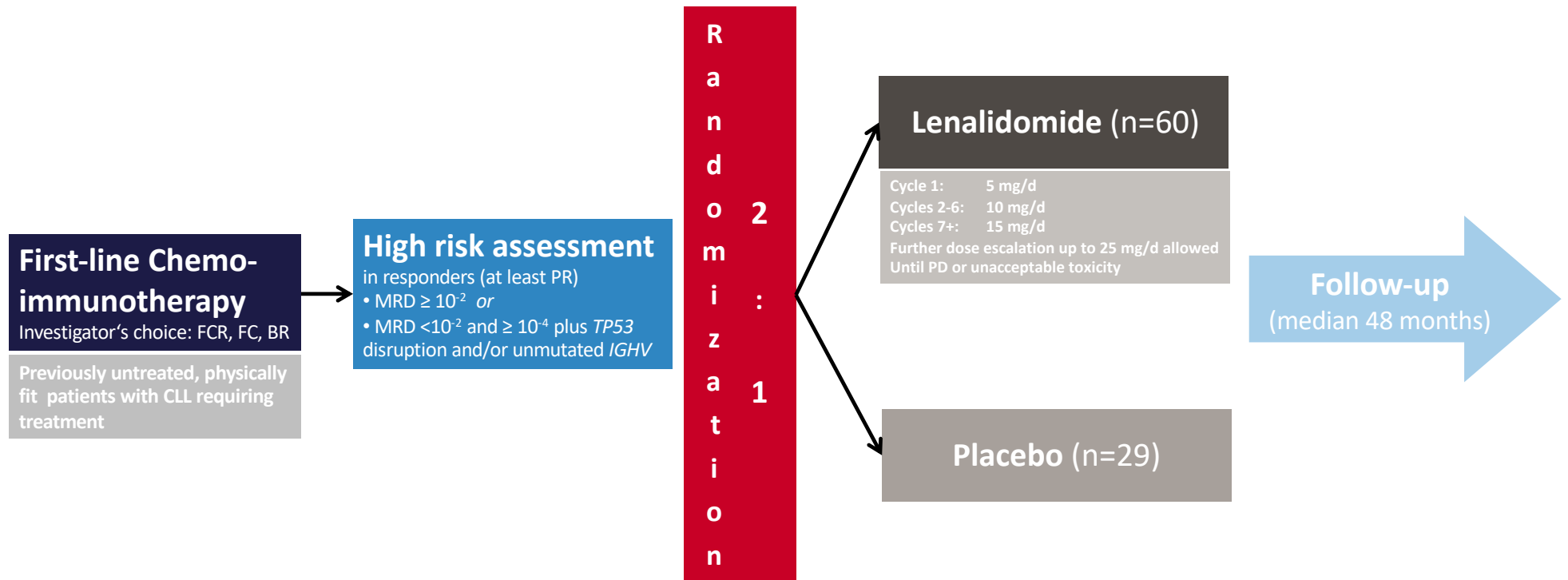


Disclosures

The German CLL Study Group has received research funding from Celgene.

Moritz Fürstenau has nothing to disclose.

CLLM1 study design



Safety: patients with AEs

Lenalidomide arm (n and % of patients with event)

SOC	CTC 1+2	CTC 3	CTC 4	CTC 5
Blood disorders	5 (8.9)	14 (25.0)	9 (16.1)	0 (0.0)
Gastrointestinal disorders	27 (48.2)	11 (19.6)	1 (1.8)	0 (0.0)
General disorders	27 (48.2)	6 (10.7)	0 (0.0)	2 (3.6)
Infections	24 (42.9)	8 (14.3)	3 (5.4)	3 (5.4)
Musculoskeletal disorders	22 (39.3)	3 (5.4)	0 (0.0)	0 (0.0)
Neoplasms	4 (7.1)	7 (12.5)	2 (3.6)	2 (3.6)
Respiratory disorders	23 (41.1)	2 (3.6)	1 (1.8)	0 (0.0)
Skin disorders	33 (58.9)	4 (7.1)	0 (0.0)	0 (0.0)
All categories	11 (19.6)	26 (46.4)	11 (19.6)	7 (12.5)*

* One case of each of the following: acute lymphoblastic leukemia, death of unknown origin, endocarditis bacterial, gastrointestinal infection, general physical health deterioration, renal cell carcinoma, septic shock

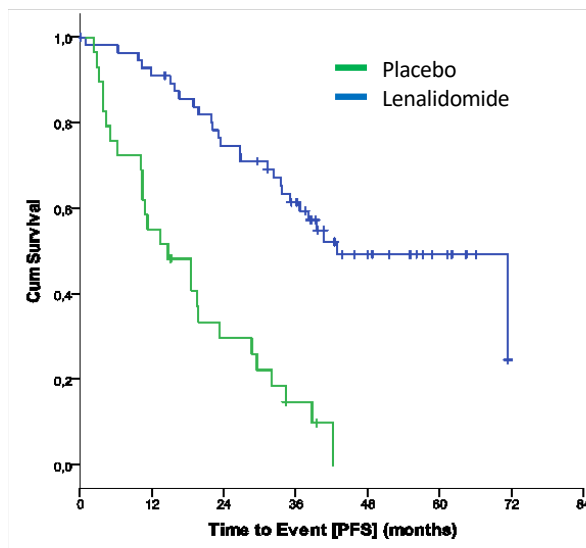
Placebo arm (n and % of patients with event)

SOC	CTC 1+2	CTC 3	CTC 4	CTC 5
Blood disorders	1 (3.4)	3 (10.3)	1 (3.4)	0 (0.0)
Gastrointestinal disorders	8 (27.6)	0 (0.0)	0 (0.0)	0 (0.0)
General disorders	10 (34.5)	0 (0.0)	0 (0.0)	0 (0.0)
Infections	15 (51.7)	3 (10.3)	1 (3.4)	1 (3.4)
Musculoskeletal disorders	31 (36.5)	3 (3.5)	0 (0.0)	0 (0.0)
Neoplasms	1 (3.4)	5 (17.2)	0 (0.0)	0 (0.0)
Respiratory disorders	4 (13.8)	1 (3.4)	0 (0.0)	0 (0.0)
Skin disorders	11 (37.9)	0 (0.0)	0 (0.0)	0 (0.0)
All categories	14 (48.3)	9 (31.0)	2 (6.9)	1 (3.4)*

*Progressive multifocal leukoencephalopathy (n=1)

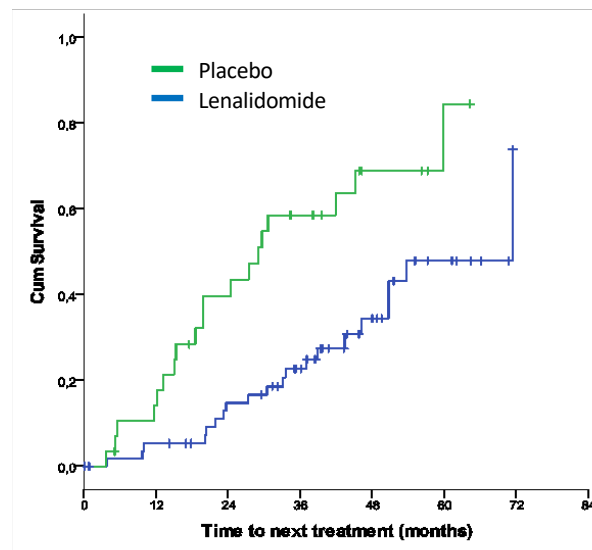
Efficacy

Progression free Survival



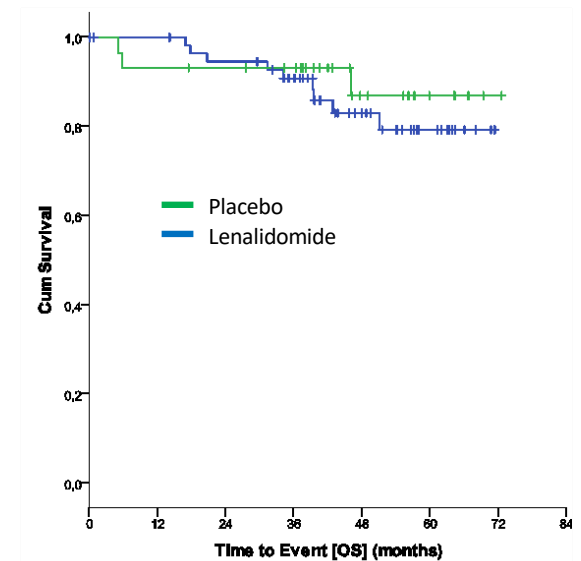
HR 0.226 | 95% CI 0.128-0.399 | P<0.001

Time to Next Treatment



HR 0.351 | 95% CI 0.185-0.665 | P=0.001

Overall Survival



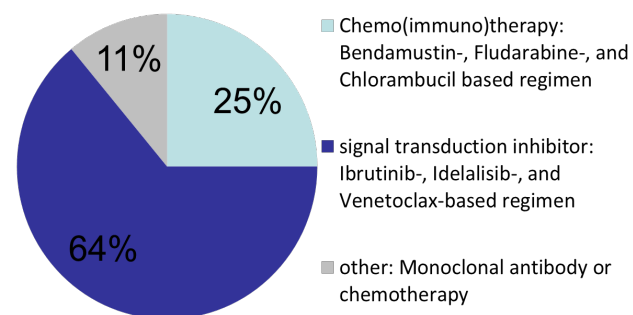
HR 1.534 | 95% CI 0.415-5.669 | P=0.521

MRD results

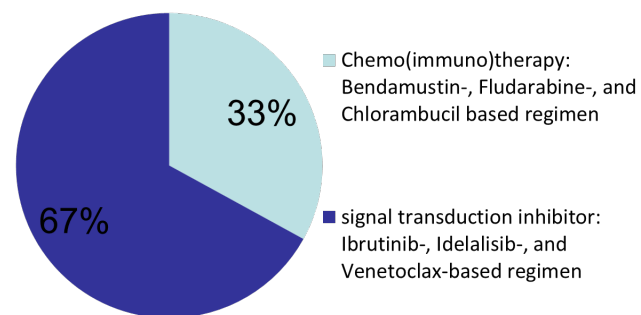
Best achieved MRD Status during treatment	Lenalidomide	Placebo
All patients	60	29
Undetectable ($<10^{-4}$)	8 (13.3)	0 (0.0)
Intermediate ($<10^{-2}$ and $\geq 10^{-4}$)	23 (38.3)	8 (27.6)
Positive ($\geq 10^{-2}$)	14 (23.3)	12 (41.4)
Missing	15 (25.0)	9 (31.0)

Subsequent therapies

Lenalidomide arm:
28 subsequent treatments in 20 patients



Placebo arm:
24 subsequent treatments in 19 patients



Conclusions

Lenalidomide maintenance in high-risk CLL

Update after median observation time of 48 months

60 high-risk patients in the lenalidomide arm and 29 in the placebo arm

- Substantial improvement in PFS, EFS and TTNT
- Lack of overall survival benefit
- 8 patients (13.3%) achieved undetectable MRD during lenalidomide maintenance
- 3 lenalidomide-treated patients (5.4%) developed a B-cell acute lymphoblastic leukaemia
- Majority of subsequent therapies consisted of targeted agents

Questions? comments?



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