Ci sono novità nelle terapie?

MATTEO DELLA PORTA

AIPaSIM

Trattamenti per l’anemia: Luspatercept

- Esperienze real-life

- Luspatercept nelle MDS senza sideroblasti ad anello

- Luspatercept nel trattamento dell’anemia NON severa

Table 1: Endpoints in FISIM real-life multicenter study (Italian compassionate program) and data from the MEDALIST trial

	FISIM Multicenter Study (n=184)	MEDALIST Trial[a] (n=153)
RBC-TI ≥ 8 weeks during weeks 1–24, n (%)	59 (32.0)	58 (37.9)
RBC-TI ≥ 8 weeks during weeks 1–48, n (%)	71 (38.6)	69 (45.1)
Longest transfusion independence duration (weeks), median	27.9	30.6
RBC-TI ≥ 12 weeks during weeks 1–24, n (%)	36 (19.6)	43 (28.1)
RBC-TI ≥ 12 weeks during weeks 1–48, n (%)	52 (28.3)	51 (33.3)
Reduction of ≥ 4 RBC units/8 weeks during weeks 1-24[b], n (%)	66/164 (40.2)	52/107 (48.6)
AML evolution, n (%)	4 (2.2)	3 (1.9)
Patients with ≥ 1 SAEs, n (%)	28 (15.2)	48 (31.3)

[a] Fenaux P, Platzbecker U, Mufti GJ, et al. Luspatercept in Patients with Lower-Risk Myelodysplastic Syndromes. N Engl J Med. 2020;382(2):140-151
[b] analysis was based on patients with base transfusion burden ≥ 4/8 weeks
RBC-TI: red blood cells transfusion independence
AML: acute myeloid leukemia
SAEs: serious adverse events

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Table 2: response rate and dose at first response, stratified by baseline transfusion burden in FISIM multicenter study

	Baseline Transfusion Burden (RBC units/8 weeks)			
	≤ 4 (n = 52)	5 – 7 (n = 54)	≥ 8 (n = 78)	p-value[a]
RBC-TI ≥ 8 weeks during weeks 1–24	27 (51.9)	19 (35.2)	13 (16.7)	< 0.01
RBC-TI ≥ 8 weeks during weeks 1–48	29 (55.8)	22 (40.7)	20 (25.6)	< 0.01
RBC-TI ≥ 12 weeks during weeks 1–24	16 (30.8)	13 (24.1)	7 (9.0)	< 0.01
RBC-TI ≥ 12 weeks during weeks 1–48	22 (42.3)	18 (33.3)	12 (15.4)	< 0.01
Reduction ≥70% in total RBC units transfused during weeks 1-24	16 (30.8)	18 (33.3)	16 (20.5)	0.19
Dose at first RBC-TI ≥ 8 weeks during weeks 1–48				
1.00 mg/kg	17/30 (56.7)	10/21 (47.6)	5/20 (25.0)	
1.33 mg/kg	7/30 (23.3)	5/21 (23.8)	7/20 (35.0)	*NA*
1.75 mg/kg	6/30 (20.0)	6/21 (28.6)	8/20 (40.0)	

[a] Fisher's exact test
RBC-TI: red blood cells transfusions independence
NA: not applicable

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Bristol Myers Squibb Announces Positive Topline Results of Phase 3 COMMANDS Trial

10/31/2022

- ***Luspatercept, the first erythroid maturation agent, met primary and key secondary endpoints in the first-line treatment of patients with very low/low/intermediate-risk myelodysplastic syndromes***
- PRINCETON, N.J.

BMS today announced the COMMANDS study, a Phase 3, open-label, randomized trial evaluating luspatercept, met its primary endpoint, demonstrating a highly statistically significant and clinically meaningful improvement in red blood cell transfusion independence (RBC-TI) with concurrent hemoglobin (Hb) increase in the first-line treatment of adult patients with very low-, low- or intermediate-risk myelodysplastic syndromes (MDS) who require RBC transfusions

Trattamenti per i pazienti ad alto rischio

COMBINAZIONI CON AZACITIDINA:

- anti BCL2
- immunoterapia
- farmaci mirati (TP53)
- nuove molecole