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Letermovir (LTV) for Secondary Cytomegalovirus (CMV) Prevention in High Risk Hematopoietic Cell Transplant (HCT) Recipients: Interim Results of a Single Center, Open Label Study.

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BACKGROUND

- Letermovir (LTV) is effective for primary CMV prevention (ppx) after hematopoietic cell transplant (HCT).
- Limited data supports the efficacy of LTV as secondary ppx.

OBJECTIVES

- To evaluate the safety and efficacy of letermovir for secondary CMV prevention in high risk patients.

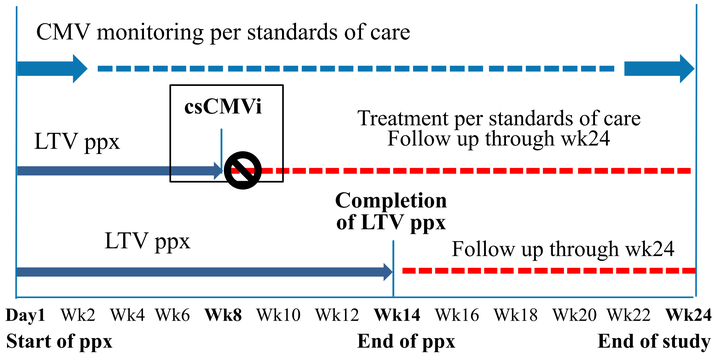
METHOD

- **Study design:** Prospective, single institution, open label study.
- **Study period**: 08/19 to 02/21.
- **Inclusion criteria**

Inclusion criteria	Exclusion criteria
CMV risk factors*	Breakthrough CMV on LTV
Treated csCMV infection	Known LTV resistance
• CMV viral load at enrollment <136 IU/mL • ≥2 consecutive viral loads <300 IU/mL	
* One or more of: T-cell depletion, mismatched donor, GVHD.	

- **Endpoints**
  - **Primary endpoint**: Clinically significant CMV infection (csCMVi) by week 14.
  - **Secondary endpoints:** LTV resistance, CMV end-organ disease (EOD) and adverse events (AE) related to LTV.

Treatment schema



RESULTS

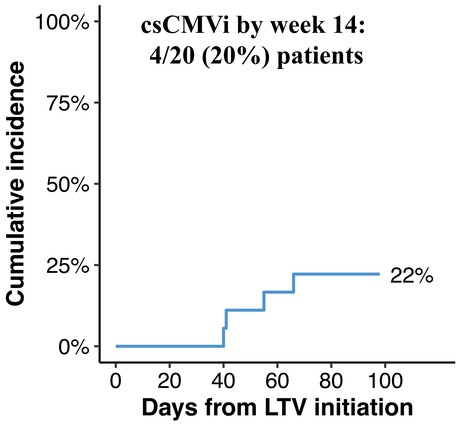
Baseline characteristics

Characteristic		N (%)
Recipient CMV serostatus	R+	17 (85)
	R-	3 (15)
High risk criteria	Ex-vivo T-cell depletion	9 (45)
	Haploidentical	3 (15)
	Mismatched unrelated	4 (20)
	GVHD	9 (45)
	GVHD at enrollment	5 (25)
	Systemic corticosteroids at enrollment	5 (25)
Prior letermovir prophylaxis		14 (70)
Time from HCT to enrollment	Days, median (IQR)	72 (34, 203)

Patient disposition

Events	N (%)
Completed LTV prophylaxis	14 (70)
Did not complete prophylaxis	6 (40)
Primary endpoint csCMVi	4 (20)
Death	1 (5)
Relapse*	1 (5)
Completed study (24 weeks f/u)	16 (80)
Did not complete study	4 (20)
Lost to follow up	0 (0)
Died	4 (20)

* Drug-drug interaction with investigational drug



- 2/4 pts with csCMVi had LTV resistance
- No patient developed CMV EOD

CONCLUSIONS

- Letermovir secondary prophylaxis was safe and prevented recurrent csCMVi in 80% of high risk patients, including patients with prior letermovir exposure.
- Our data supports the utility of letermovir for secondary CMV prevention following HCT.