




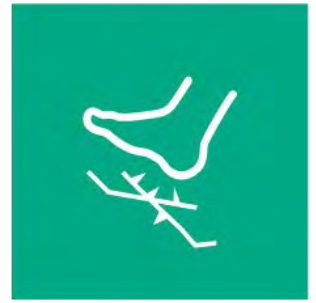
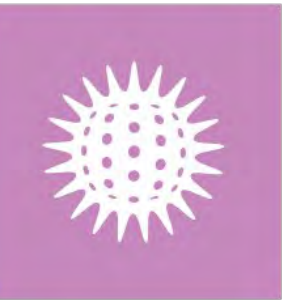
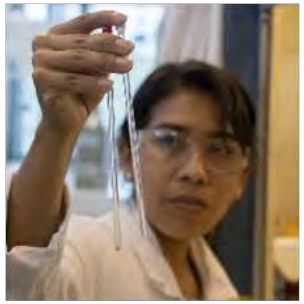




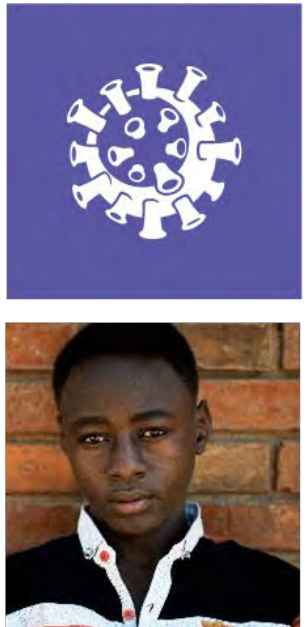




Poster 00721

LIVING: 48-week data on LPV/r pellets in 990 children in resource-limited settings

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DNDi
Drugs for Neglected Diseases *initiative*

BACKGROUND

- LPV/r-based regimens remain an important treatment for children living with HIV (CLHIV), with established safety and efficacy. Treatment outcome data from large cohorts of CLHIV in resource-poor settings are limited. LIVING (NCT02346487) addresses this data gap across pediatric age groups.

AIM

Test the effectiveness, safety, and acceptability of LPV/r 40/10mg pellets given in combination with ABC/3TC (or AZT/3TC) dispersible tablets to CLHIV under field conditions.

METHODS

- **Design:** single-arm phase IIIb implementation studies in Kenya, Uganda and Tanzania; open-label, prospective, non-randomized, non-comparative
- **Key Eligibility Criteria:**
  - CLHIV;
  - ≥ 3 to <25kg;
  - ARV naïve, on liquid LPV/r or failing NNRTI based ART.

- **Clinical/Other assessments:** Baseline, Week 2, 4, 12, and 12-weekly thereafter
- **Acceptability:** via caregiver questionnaire
- **Primary endpoint = effectiveness**, a composite of
  - Being alive;
  - Being on study drug;
  - Viral load < 1000cp/ml at Week 48.

  (analyzed in all children who received study drugs)

- **Dosing:** twice daily by WHO weight bands

WHO Weight Band Dosing

Drug	Strength	Number of doses by weight band morning & evening									
		3-5.9 kg		6-9.9 kg		10-13.9 kg		14-19.9 kg		20-24.9 kg	
LPV/r	Pellets 40mg/10mg	2	2	3	3	4	4	5	5	6	6
ABC/3TC	Tablet 60mg/30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3
AZC/3TC	Tablet 60mg/30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3

RESULTS

- **Key disposition data:** 990/1003 received study drugs (ITT). 82% received ABC/3TC. 852 had VL at W48 (mITT).
- **At Baseline:** 51% female; age range from 2 to 148 months with 32% aged < 24 months; 91% ART exposed; 19% had VL ≥100,000cp/ml; 32% with advanced/severe disease.
- **Median treatment duration:** 72.1 weeks (IQR 48.3-96.1).
- **Effectiveness and Efficacy:**

	ITT population n (%, 95% CI)
Primary endpoint at **W48**	
VL<1,000copies/ml	683/990 (**69**, 66-72)
VL≥1,000copies/ml	169/990 (17, 15-20)
No VL	138/990 (14, 12-16)

	mTT population n (%, 95% CI)	**PP population** n (%, 95% CI)
Secondary efficacy endpoints		
VL<1,000copies/ml at **W48**	683/852 (**80**, 77-83)	569/692 (82, 79-85)
VL<1,000copies/ml at **W96**	296/337 (88, 84-91)	235/265 (**89**, 84-92)
Immunological failure by **W48**	No	No
Clinical failure by **W48**	49/887 (6, 4-7)	21/686 (3, 2-5)

- **Safety:** 14% children had Gr3/4 AEs. Most frequent: malaria, pneumonia, gastroenteritis, anemia.
- 8% had treatment-related AEs (most frequent diarrhea) with 1 being a SAE. 17 deaths reported during entire study period (one related to AZT).
- **Acceptability:** at last assessment, **93%** caregivers described the pellets as *easy/very easy* to administer and **94%** reported their children *accepted pellets well*.

CONCLUSIONS

- **LPV/r pellets plus ABC/3TC or AZT/3TC were effective, well-tolerated, and well-accepted in a large CLHIV cohort, with a significant proportion of children < 24 months and with advanced/severe disease.**
- This combination remains a good treatment option for CLHIV, as an alternative 1st line or following failure on Dolutegravir-based ART.

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