LNH2009-1B study

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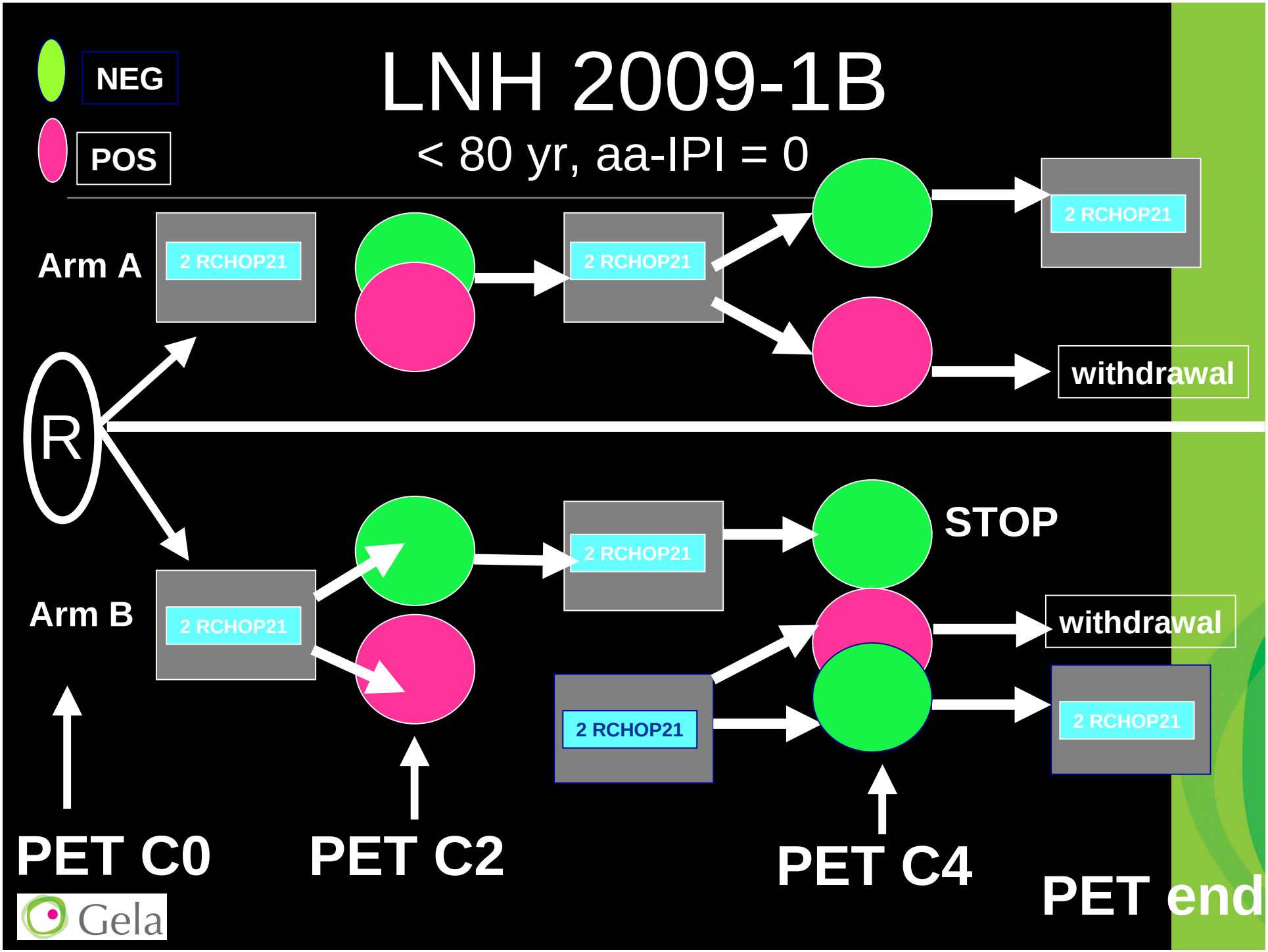
On behalf of the GELA

LNH2009-1B

Randomized Phase III study evaluating the potential non-inferiority of a treatment, adapted to the early response evaluated with PET compared to a standard treatment, for patients aged from 18 to 80 y with low risk (aa IPI = 0) DLBCL


NEG
POS
LNH 2009-1B
< 80 yr, aa-IPI = 0
Arm A
2 RCHOP21
2 RCHOP21
2 RCHOP21
withdrawal
R
Arm B
2 RCHOP21
2 RCHOP21
STOP
withdrawal
2 RCHOP21
2 RCHOP21
PET C0
PET C2
PET C4
PET end
Gela

Primary endpoint

- **PFS at 3 years**
- **4 or 6 cycles** of R-CHOP 21, decided according to early response assessed by PET after 2 cycles, **non inferior** to 6 cycles of R-CHOP 21?

To note: randomization stratified according to:

- **age (≤ 60y / > 60y)**
- **bulk (>10 cm)**

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Secondary endpoints

- **CR rate** after 2 cycles on the basis of PET
- Evaluate the **overall response rate** according to IWC (International Harmonization Project – Cheson 2007) (CR, PR) after 4 or 6 cycles according to the treatment arm.
- **EFS, PFS, DFS, OS**
- Determine the Δ **SUV max** between PET at baseline, PET after C2 and PET after C4
- Identify the **biological factors** on blood samples and on tumor biopsy influencing treatment response and prognosis.

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LNH 2009-1B - Sample size calculation

- Non inferiority hypothesis (clinically acceptable difference: 10%)
  - 3y- PFS : 80% (control arm)

- Accrual rate: ~11 patients per month
- Accrual period = 3 y
- Study duration = 6 y

- n = 420 patients randomised for 114 events

The approximate schedule of the interim and final analyses will be 42 months and 6 years after the first patient randomized, respectively.

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LNH 2009-1B study

- **International study:**

  France, Belgium, Suisse, Portugal (to be confirmed) and …

- GELARC for Coordination :
  - Randomisations, Monitoring, DataM,, PV, Biostatistics, logistics of PETs review, Pathological review (GELA-P) and logistic of biology samples

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PET Review (1/2)

- Baseline PET (PET0) is mandatory before inclusion, the result of which being faxed to allow patient randomization.
- PET0, PET2 and PET4 should performed **on the same machine** for both arms
- **PET2, PET4 and PET6 should be done 16 +/- 2 days after D1 of the last cycle**
- **PET0, PET2 and PET4 will be reviewed (3 expert reviewers) and results should be transmitted on time in order to determine the treatment strategy (including the number of cycles in Arm B)**
- All these requirements will be sent either by transfer (positoscope or internet) or CD-ROM shipment according to the process available on site.

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PET Review (2/2)

- Local and centralized interpretations of the PET should be done according
  - **to the 5PS for the interim PET2 (adapted ?)**
  - **to the 5PS and to the IHP (Juweid, J Clin Oncol 2007) for PET4.**
- SUVmax will be determined by the expert reviewers for secondary endpoints

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