Abs. 3033: **Diagnostic value of hPG80, as a new multi-cancer blood biomarker, in 16 different cancers: Results of the ONCOPRO prospective study**

Benoit You, Sebastien Couraud, Philippe Ceruse, Lionel Badet, Philippe Paparel, Thomas Walter, Marielle Guillet, Philippe Merle, Charles-André Philip, Francois Ducray, Mathieu Pioche, Lionel Karlin, Jean-Christophe Lifante, Olivier Glehen, Pierre-Adrien Bolze, Marion Chauvenet, Carole Langlois-Jacques, Fabien Subtil, Sara Calattini, Lea Payen

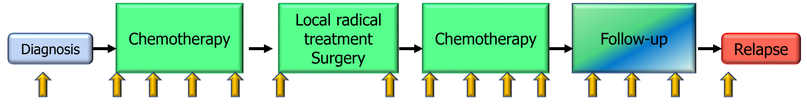
Lyon University Hospital, Hospices Civils de Lyon, IC-HCL, Université Claude Bernard Lyon 1, Univ Lyon 1, Lyon, France

Background:

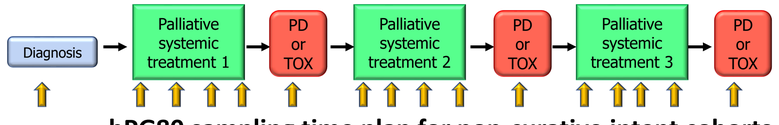
- There is a need for an easy and cheap **multi-cancer blood biomarker**
- **Retrospective analyses** → hPG80 (also called circulating progastrin, *Wnt pathway*) is released from cancer cells to blood at the early step of tumorigenesis in multiple cancers (You et al *eBioMedicine* 2021)
- **Objective**: To prospectively assess the diagnosis value (primary endpoint) and the monitoring value (secondary endpoint) of hPG80 in 16 newly diagnosed types of cancer

Methods:

- **ONCOPRO study is a large prospective case-control study** (NCT03787056)
- **Cancer cases**: **420 patients** with newly diagnosed cancers of **16 origins**
- **Controls**: 330 healthy volunteers with no history of cancer (age & sex ratios matched with the cancer group)
- **hPG80 blood concentration** (*DxPG80.Lab, Biodena care, LLoQ 3.3 pM, no cross reactivity with other progastrin peptides*) at baseline before treatment, and then at each cycle/visit until recurrence for the curative cohorts, or for 3 treatment lines for the non-curative cohorts.
- **Diagnostic accuracy value** at diagnosis in cancer cases vs controls assessed using the **ROC AUC**



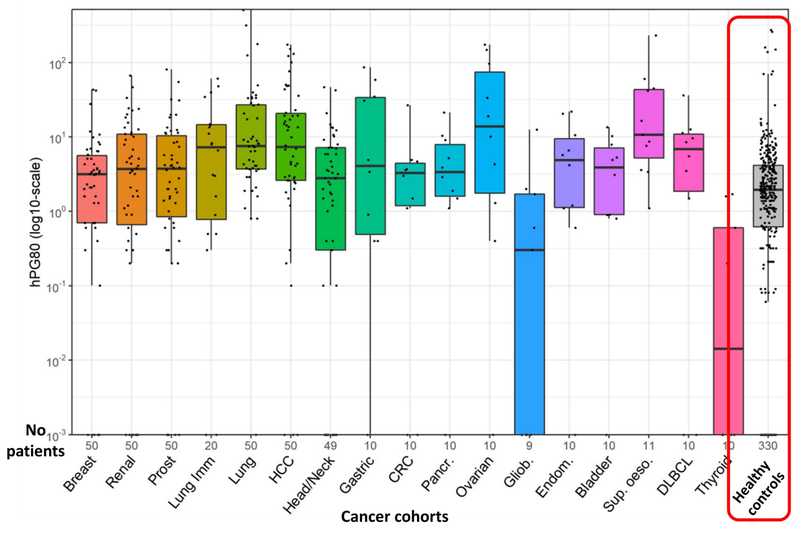
hPG80 sampling time plan for curative intent cohorts

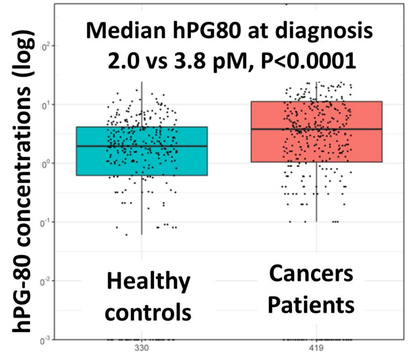


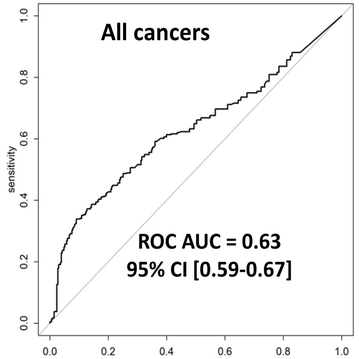
hPG80 sampling time plan for non-curative intent cohorts

Results:

- **Between 2018 and 2022: 499 patients (419 assessable) enrolled with 16 cancers** (17 cohorts) **in 19 departments**
- Median age = 66 [IQR: 58-73], 60% men.
- hPG80 titer not impacted by renal, liver function or inflammation
- hPG80 concentration slightly linked to age







Cohorts of special interest

Lung cancer n= 70

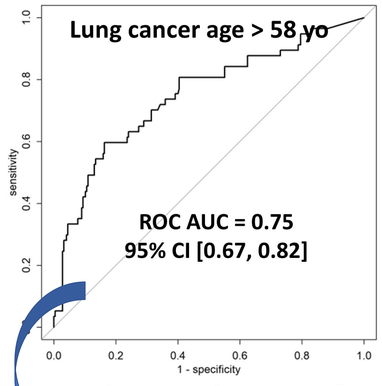
Curative intent (n= 20): St I, 50%; St II, 5%, St III, 35%, st IV, 5%, ND, 5%

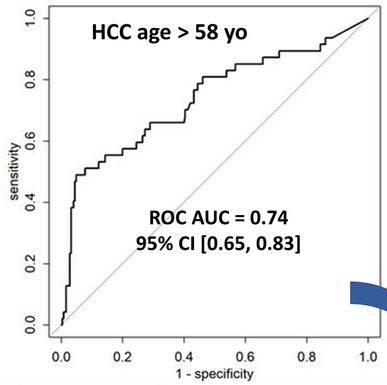
Non-curative intent (n=100): St IV, 100%

Hepatocellular carcinoma (HCC) n= 50

BCLC score

0, 4%; A, 56%; B, 38%, C, 2%





Diagnostic value for a hPG80 value > 7.73 pM

Sensitivity = 0.49
Specificity = 0.90

Sensitivity = 0.48
Specificity = 0.90

Conclusions:

- Large **prospective** study in **16 different cancers** centralized in one center
- **Validation** of **higher values of circulating hPG80 in cancer patients** at diagnosis compared to healthy control subjects
- **High diagnostic accuracy** with **90% Specificity** for NSCLC and HCC

→ Currently on investigation

- Monitoring value during treatments
- Utility of hPG80 for screening programs