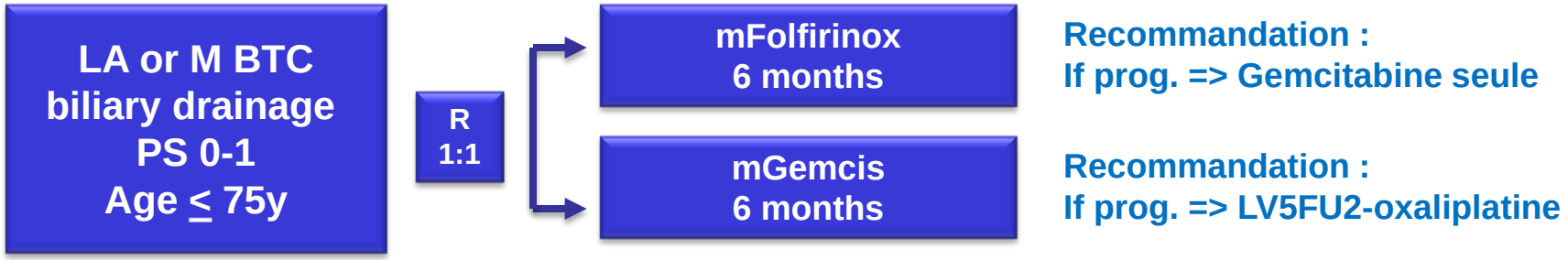
Chemotherapy with mFOLFIRINOX vs GEMCIS for locally advanced or metastatic biliary tract cancers

AMEBICA-01 PRODIGE 38 randomized Phase II-III trial

Coordinating investigator : Phelip JM, D Malka, C Neuzillet



Primary end point for phase II: 6 months mPFS rate (RECIST 1.1). Seuil de 59%. (188 patients)

Actuellement 137 pts inclus

Primary end point for phase III: OS (HR 0,73; mOS from 11 to 15 months (+ 128 patients → **316 patients**)

Stratification :

Center, location of primitive tumor (gallbladder vs intrahepatic + hilar vs extrahepatic), stage (locally advanced, metastatic), biliary drainage (y vs n)

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Treatments :

- Arm A: GEMCIS:

- D1 and D8 of each cycle (every 21 days during 6 months)
- Cisplatine 25 mg/m² over 1h at D1 and D8
- following by gemcitabine 1000 mg/m² over 30 mn at D1 and D8.

- **Arm B: modified FOLFIRINOX modifié** = mFOLFIRINOX (without 5FU bolus at D1):

- D1 of each cycle (every 15 days during 6 months)
- Oxaliplatine 85 mg/m² over 2h at D1
- Irinotécan 180 mg/m² over 2h at D1
- Elvorine 200 mg/m² over 2h
- 5-FU 2400 mg / m² continuous infusion over 46h

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Quality of life : QLQC-30

Biological study :

- Evaluation of tumor tissue will be based upon tumor material collected prior to the patient's entry into the study.

- Biomarkers in serum samples (ie serum DNA mutation).

- These tissue or serum biomarkers will be analyzed in relation to response, stable disease, PFS, OS and adverse events. A correlation between molecular profiling and serum DNA mutations will be performed to assess diagnostic efficiency of blood DNA mutation profiling.