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Phase 2b Pancreatic Cancer Study
Topline Data
March 28, 2017

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AGENDA

- Pancreatic cancer and eryaspase (GRASPA®)
- Phase 2b study design
- Topline results
- Next steps and upcoming milestones
- Q&A

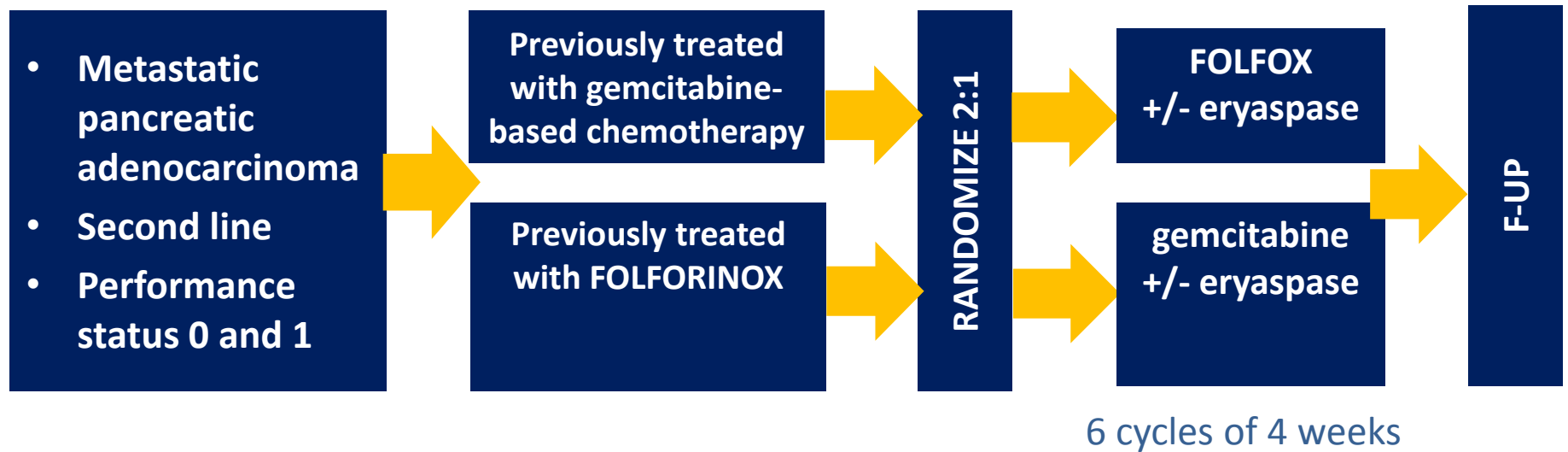
Pancreatic cancer

- Approximately 150,000 new cases of pancreatic cancer are diagnosed in Europe and the United States annually
- Pancreatic cancer is a particularly aggressive cancer, with a five-year survival rate of less than 10%. It is currently the fourth most common cause of cancer-related death in the EU
- Pancreatic cancer affect mainly older people. Median age at diagnosis is 70 years
- Approximately 80% of patients treated with chemotherapy, of which approximately 50% will receive second line treatments

Pancreatic cancer and eryaspase

- L-asparaginase depletes asparagine, a naturally occurring amino acid essential for the survival and proliferation of cancer cells, from circulating blood plasma. L-asparaginases are well established in acute lymphoblastic leukemia (ALL), but their toxicity has limited use in solid tumors
- With eryaspase, the L-asparaginase is encapsulated inside donor-derived red blood cells. The product demonstrated a favorable safety and efficacy profile in different studies in ALL. A Phase 1 study, completed in 2013, also demonstrated a favorable safety profile in pancreatic cancer (*Bachet et al 2015*)
- Asparagine synthetase (ASNS) expression status is believed to play a role in determining sensitivity to asparaginase treatment in several tumor types, such as leukemia, lymphoma and pancreatic cancer.

Phase 2b study design



- N=140 (about 70% ASNS 0/1, 30% ASNS 2/3)
- 2 to 1 randomization (standard of care plus eryaspase versus standard of care alone)
- 16 centers in France
- Study performed with the GERCOR
- Principal investigator: Prof Pascal Hammel, gastroenterologist-oncologist, Head of Oncology Unit at Beaujon Hospital Paris
- IDMC reviewed safety on first 24 patients

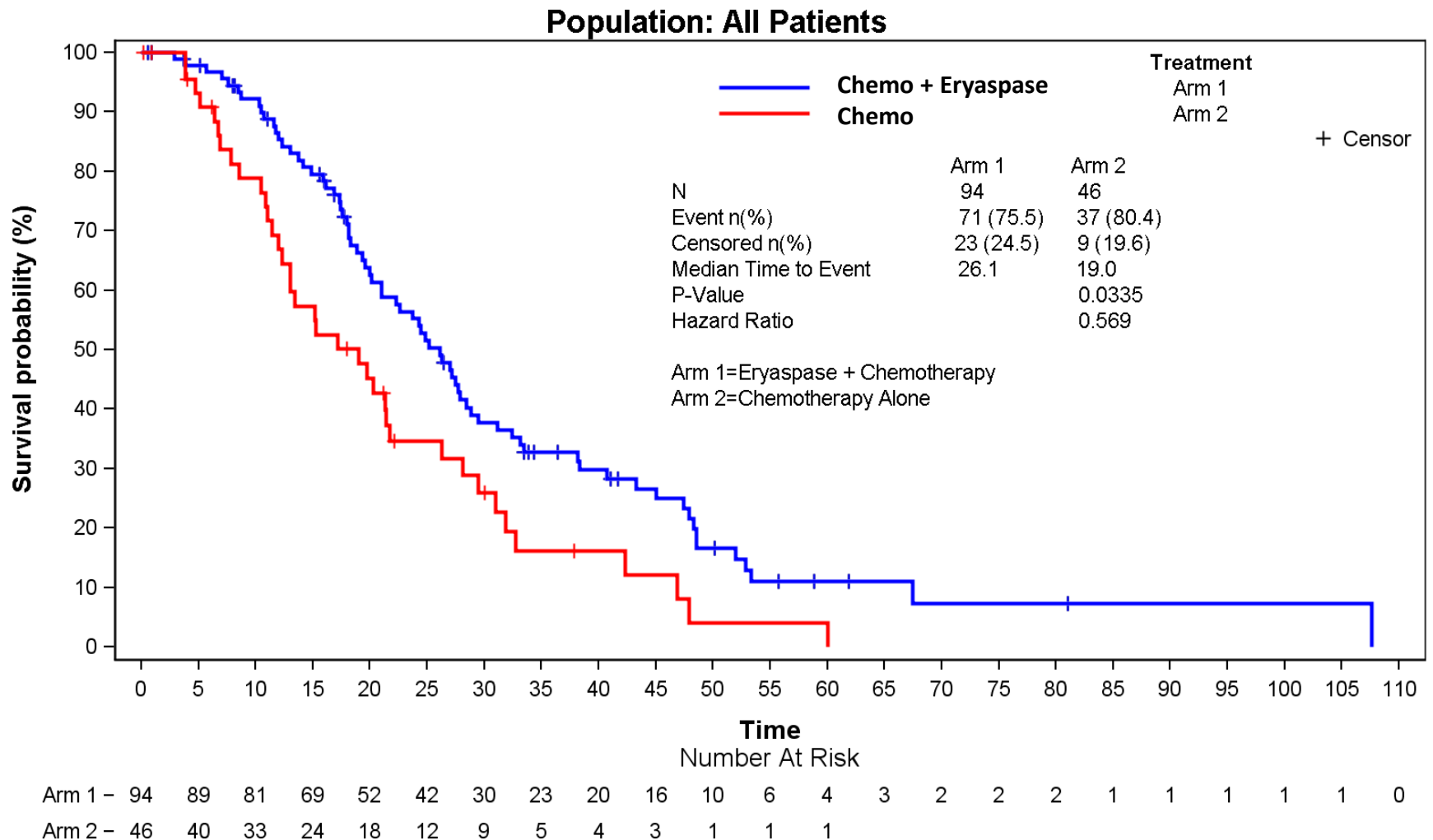
Key study endpoints

- Co-primary endpoints:
 - Progression Free Survival (PFS) and Overall Survival (OS) in ASNS 0/1 patients
 - Positive study if HR <0.85 for either PFS or OS, providing none is >1.0
- Key secondary endpoints:
 - PFS and OS HR in key treatment populations:
 - ASNS 0/1
 - ASNS 2/3
 - Entire population
 - Safety
 - Objective response rate
 - Quality of Life

Primary endpoints met and clear efficacy signal found

- Co-primary endpoints met:
 - PFS in ASNS 0/1+: HR = 0.73
 - OS in ASNS 0/1+: HR = 0.62
- Statistically significant improvement of both PFS and OS across the population
 - OS:
 - HR = 0.57 (p = 0.034) → 43% reduction in risk of death
 - median OS 26.1 (95% CI: 21.0, 28.9) versus 19.0 weeks (95% CI: 12.3, 21.7)
 - Similar results on PFS
- Well balanced baseline and demographic characteristics
- PFS and OS results are consistent and robust across subgroups
- ASNS appears not to be predictive of treatment benefit, but seems to be prognostic. Patients with high ASNS have a worse prognosis
- Treatment is generally well tolerated

Clear survival benefit



Next steps

- Further review and analysis of data
- Presentation of full dataset at medical meeting
- Publication
- Initiate discussions with FDA and EMA regarding next steps

Key upcoming milestones

- Results from Phase 2b pancreatic cancer study**
- MTD defined in US Phase 1 adult ALL study
- Meeting with FDA on further ALL development plan
- Resubmission of EU marketing authorization application for GRASPA in R/R ALL
- Preclinical proof of concept data with ERYMMUNE and ERYZYME programs
- Launch of erymethionase (ERY-MET) Phase 1 study
- Launch of Phase 3 study in pancreatic cancer**
- Results from EU Phase 2b AML study

THANK YOU

QUESTIONS?



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