**Background**

- Overall survival (OS) for the FOLFIRINOX arm was 11 months versus 8 months for Gem alone (HR=0.75, p=0.003).
- Better survival for FOLFIRINOX compared to Gem: deterioration free rate of global health status at 3 months 83% with FOLFIRINOX vs 69% with Gem; at 6 months 66% vs 44%.
- Median PFS for FOLFIRINOX was 7 months compared to 3 months for Gem (HR=0.51, p=0.002).

**Study Design**

- **Eligibility**: Locally advanced or metastatic pancreatic adenocarcinomas.
- **Tumor Factors**: Histologically and histopathologically confirmed, resectable disease.
- **Consent**: Previously untreated patients, able to receive nab-P+Gem.

**Endpoints**

- **Primary Endpoints**: At least 2 QLQ completed or baseline and survival data available; PFS median time:
  - nab-P+Gem: 7 months
  - Gem: 3 months

**Quality of Life**

- At least 2 QLQ completed N (%): 137 (97%)
  - nab-P+Gem: 134 (97%)
  - Gem: 13 (9%)

**TARGET POPULATION**

- Unresectable locally advanced or metastatic pancreatic adenocarcinomas.

**TREATMENT EXPOSURE**

- **treatment**: nab-P+Gem 1000 mg/m2 q3wks 4 cycles

- **Monitoring**: 2 cycles q4wks 4 cycles q4wks

**TARGET SAFETY**

- nab-P+Gem: 11 (7.7%)
  - Gem: 9 (5.5%)

**ESMO 2018 Congress, Munich, Germany – Poster 2822 / 7409**

**FINAL RESULTS OF A PHASE II QUALITY OF LIFE RANDOMIZED, CROSS-OVER STUDY WITH GMCITABINE AND NAB-PACLITAXEL IN LOCALLY ADVANCED OR METASTATIC PANCREATIC ADENOCARCINOMA: QOLINPAC**


**Conclusions**

- Patients receiving the combination nab-P/Gem seem to report better quality of life scores for longer duration compared to patients on Gem monotherapy.
- In an intent to treat analysis, deterioration free rates of all QOL scores were higher in the combination arm than in the Gem arm.
- Median survival time in the cross-over study was 11 months for all QOL scores compared to 9 months in the baseline group.
- The value of baseline QOL scores as indicators of survival probability will be further explored in subsequent analyses including clinical variables.
- Median survival was long in all groups. Patients receiving nab-P/Gem had better outcomes than those receiving Gem monotherapy, without reaching statistical significance. The effect of covariates will be further explored.
- Response rates were significantly higher in the combination group. Two complete responses were seen in the cross-over group. Two patients were successfully reassessed post treatment with long survival.
- Treatment-related toxicities were manageable with slighter higher incidences in the combination groups. As expected neutropenia, parastomal symptoms, anaemia, fatigue and abdominal pain were the most common. Thromboembolic events were noted.
- Translational studies are ongoing.

**Acknowledgments**

- The Belgian Group of Digestive Oncology network
- The Belgian Group of Oncology Research
- The Belgian Group of Digestive Oncology network
- The Belgian Group of Oncology Research
- The Belgian Group of Digestive Oncology network
- The Belgian Group of Oncology Research
- The Belgian Group of Digestive Oncology network
- The Belgian Group of Oncology Research

**References**


**UH Leuven**

**ADDRESS**

UZ Leuven, 2000 Leuven, Belgium www.uzl.ac.be tel. +32 16 33 23 11

**FUNDING**

The study was supported by the Belgian Group of Digestive Oncology (BGDO)

**COMPETING INTERESTS**

No competing interests were declared.