Scientific Abstract

SU2C Canada-Lustgarten Foundation-Pancreatic Cancer Canada PASS Convergence Dream Team:

"PASS-01-Pancreatic Adenocarcinoma Signature Stratification for Treatment-01"

[This abstract was provided by the scientists when their application was accepted.]

Primary Objective:

- To determine the PFS benefit of modified FOLFIRINOX (mFFX) compared to Gemcitabine/ nab-paclitaxel (GA) as first line treatment in metastatic pancreatic ductal adenocarcinoma (PDAC) in a randomized phase II trial. (If standard of care regimens change during this trial the protocol will be amended to reflect this change)

Secondary Objectives:

- To determine the objective response rate (ORR) by RECIST 1.1 and duration of response (DOR) in patients receiving mFFX or GA.
- To determine the overall survival (OS) associated with mFFX or GA.
- To explore GATA6 as a biomarker of response to mFFX or GA.

The two chemotherapy regimens GA and mFFX remain standard treatment options without biomarkers to predict response. PASS-01 will for the first time explore PFS differences in the two standard backbone regimens used in the advanced setting. Biomarker driven strategies in PDAC are lacking perhaps accounting for a large number of failed phase II studies. Early work from the COMPASS study and PDO work at CSHL suggests that the basal-like phenotype which can be detected by *GATA6* RNA ISH are resistant to mFFX. This study will not just evaluate mFFX as a superior regimen, but will also explore chemotherapy sensitivity signatures, *GATA6* and other putative biomarkers as predictors of response to chemotherapy. In addition, the use of PDO models for personalized medicine in PDAC will continue to develop within this study.