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Pancreatic Cancer

Early Access Program Supplemental Data

Q1 2024

Pancreatic Cancer is a primary focus for Ampligen®'s development given high unmet need, granted FDA and EMA orphan designations, and mechanistic rationale[1]

Compassionate Use/Early Access Program at Erasmus University, The Netherlands (n=57)

Adults with metastatic or locally advanced unresectable pancreatic carcinoma following first-line FOLFIRINOX received Ampligen® 200 mg twice weekly for 2 weeks, then 400 mg twice weekly for a total treatment duration of 18 weeks

- Statistically Significant Increased Overall Survival and Progression-Free Survival Compared to Historical Controls in Treatment of Late-Stage Pancreatic Cancer[2] (i.e., locally advanced or metastatic, post-FOLFIRINOX)
- Data supported IND with FDA to initiate Phase 2 study in locally advanced disease

Actively recruiting studies in Pancreatic Cancer

- Ampligen® following FOLFIRINOX with locally advanced Pancreatic Adenocarcinoma (n=90, NCT05494697)
- Combining Anti-PD-L1 Immune Checkpoint Inhibitor Durvalumab With Ampligen® in Patients With Metastatic Pancreatic Ductal Adenocarcinoma (n=43, NCT05927142)

1. Am J Cancer Res 2023;13(6):2657-2669
2. EL Haddaoui, et al. Rintatolimod (Ampligen®) Enhances Numbers of Peripheral B Cells and Is Associated with Longer Survival in Patients with Locally Advanced and Metastasized Pancreatic Cancer Pre-Treated with FOLFIRINOX: A Single-Center Named Patient Program. Cancers. 2022 Mar 8;14(6):1377. doi: 10.3390/cancers14061377.

Since the compassionate use Pancreatic Cancer study was single-arm, a well-matched historical control group (established by the below p-values) was used to compare outcomes

Variable	Control Group (n=27)	Ampligen® Group (n=57)	p-value
Age, Mean (SD)	64.5 ± 8.4	64.6 ± 8.1	0.9
FOLFIRINOX cycles, Mean (SD)	7.7 ± 3.3	9.1 ± 3.1	0.108
Gender			
Male (n, %) Female (n, %)	18, 67% 9, 33%	36, 63% 21, 37%	0.811
Disease Stages			
LAPC* (n, %) Metastatic (n, %)	5, 19% 22, 81%	15, 26% 42, 74%	0.585

Demographics and Disease Stage of Historical Control Group is similar to Ampligen®-treated Group

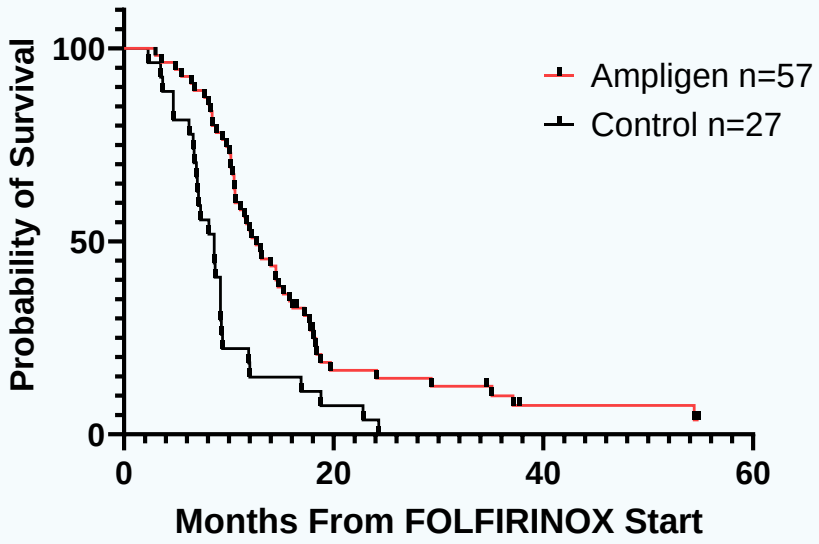
	Time from last FOLFIRINOX dose to progression (months)	Time from last FOLFIRINOX dose to start of Ampligen® (months)
Historical Control (n=27)	Mean:5.84 Median: 3.47	
Ampligen Group (n=57)		Mean: 5.57 Median: 3.93
p-value	p = 0.616	

Time from last FOLFIRINOX dose (Ampligen®-treated Group) and progression-free interval (Historical Control Group) is also similar

*LAPC = Locally Advanced Pancreatic Cancer

Ampligen® demonstrated significant improvement in OS and PFS as compared with historical controls

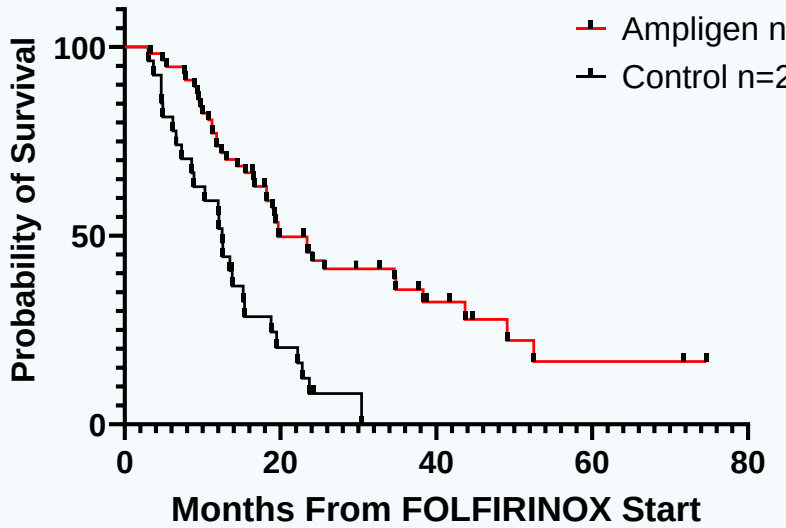
Progression-Free Survival (PFS)



$P_{logrank(mantel\text{-}cox)}$ =.0003
$HR_{logrank}$ = .44 (.25-.78)

Median PFS
Ampligen®: 12.6 months
Historical Control: 8.6 months

Overall Survival (OS)

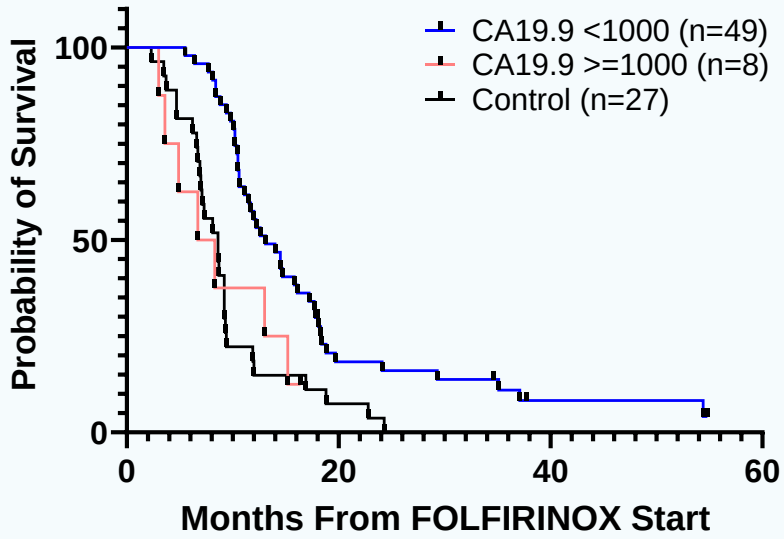


$P_{logrank(mantel\text{-}cox)}$ <.0001
$HR_{logrank}$ = .38 (.20-.70)

Median OS
Ampligen®: 19.7 months
Historical Control: 12.5 months

CA19.9 tumor marker levels appear to be predictive of Ampligen® response

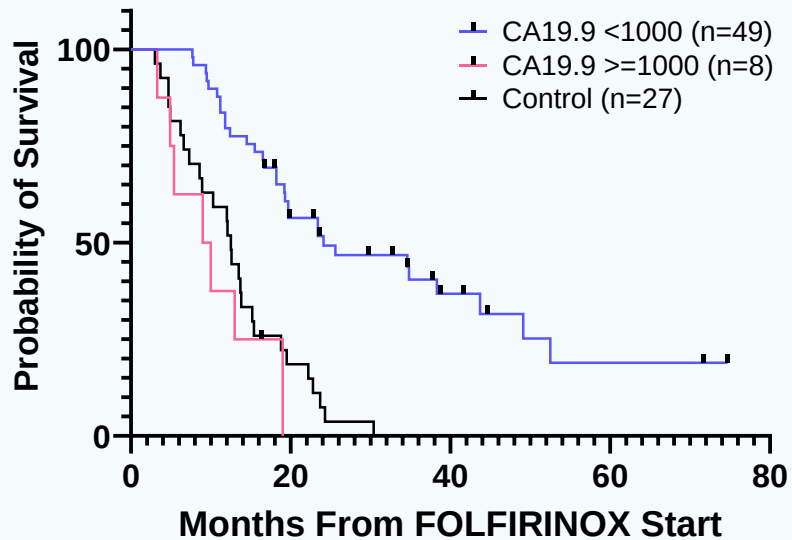
Progression-Free Survival



$P_{logrank(mantel\text{-}cox)}$ <.0001 *CA19.9<1000*
$HR_{logrank}$ = .39 (.22-.71) *vs. Control*

Median PFS (months)
Ampligen® CA 19.9<1000: 13.1
Ampligen® CA 19.9>1000: 7.5
Historical Controls: 8.6

Overall Survival

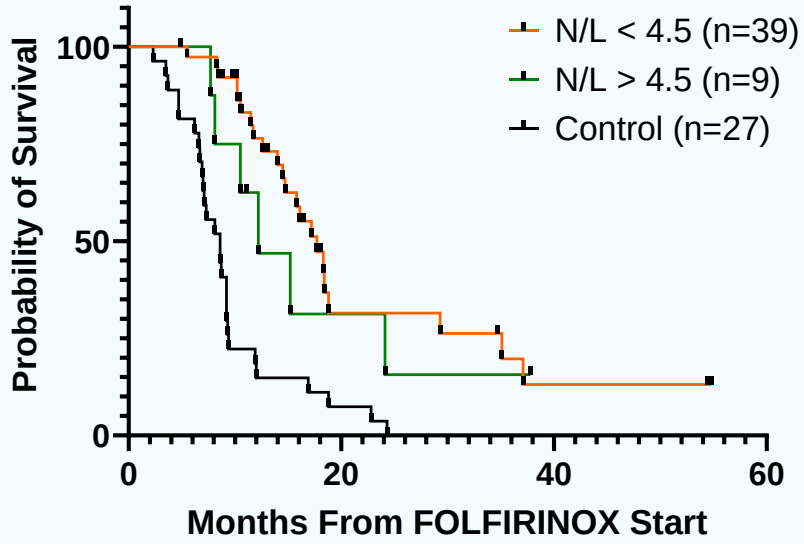


$P_{logrank(mantel\text{-}cox)}$ <.0001 *CA19.9<1000*
$HR_{logrank}$ = .29 (.15-.54) *vs. Control*

Median OS (months)
Ampligen® CA 19.9<1000: 24.1
Ampligen® CA 19.9>1000: 9.5
Historical Controls: 12.5

Baseline Neutrophil/Lymphocyte (N/L) ratio appear to be predictive of Ampligen® response

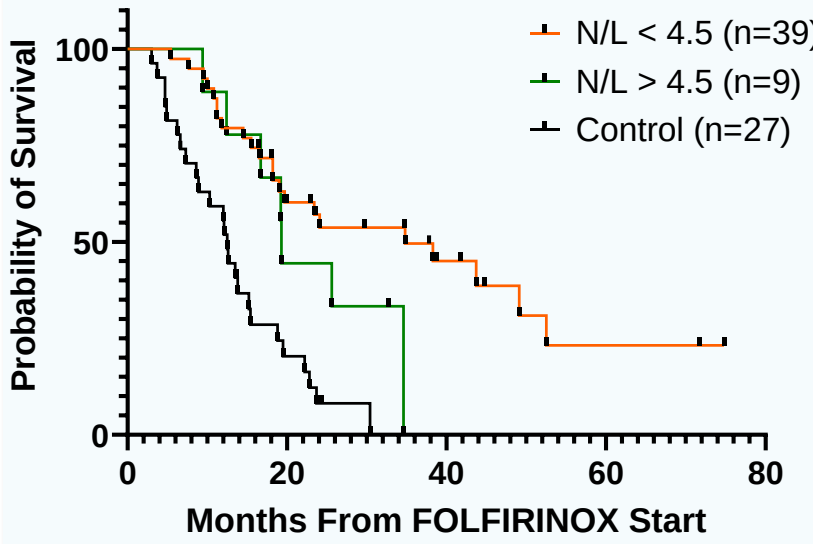
Progression-Free Survival



$P_{logrank(mantel-cox)}$ <.0001 *N/L<4.5*
$HR_{logrank}$ = .26 (.14-.50) *vs. Control*

Median PFS (months)
Ampligen® N/L< 4.5: 17.7
Ampligen® N/L> 4.5 : 12.2
Historical Controls: 8.6

Overall Survival



$P_{logrank(mantel-cox)}$ <.0001 *N/L<4.5*
$HR_{logrank}$ = .29 (.15-.56) *vs. Control*

Median OS (months)
Ampligen® N/L< 4.5: 34.8
Ampligen® N/L> 4.5 : 19.3
Historical Controls: 12.5