A safety and efficacy trial of lethally irradiated pancreatic tumor cells transfected with the GM-CSF gene in combination with adjuvant chemoradiotherapy for the treatment of adenocarcinoma of the pancreas : Abstract 3010

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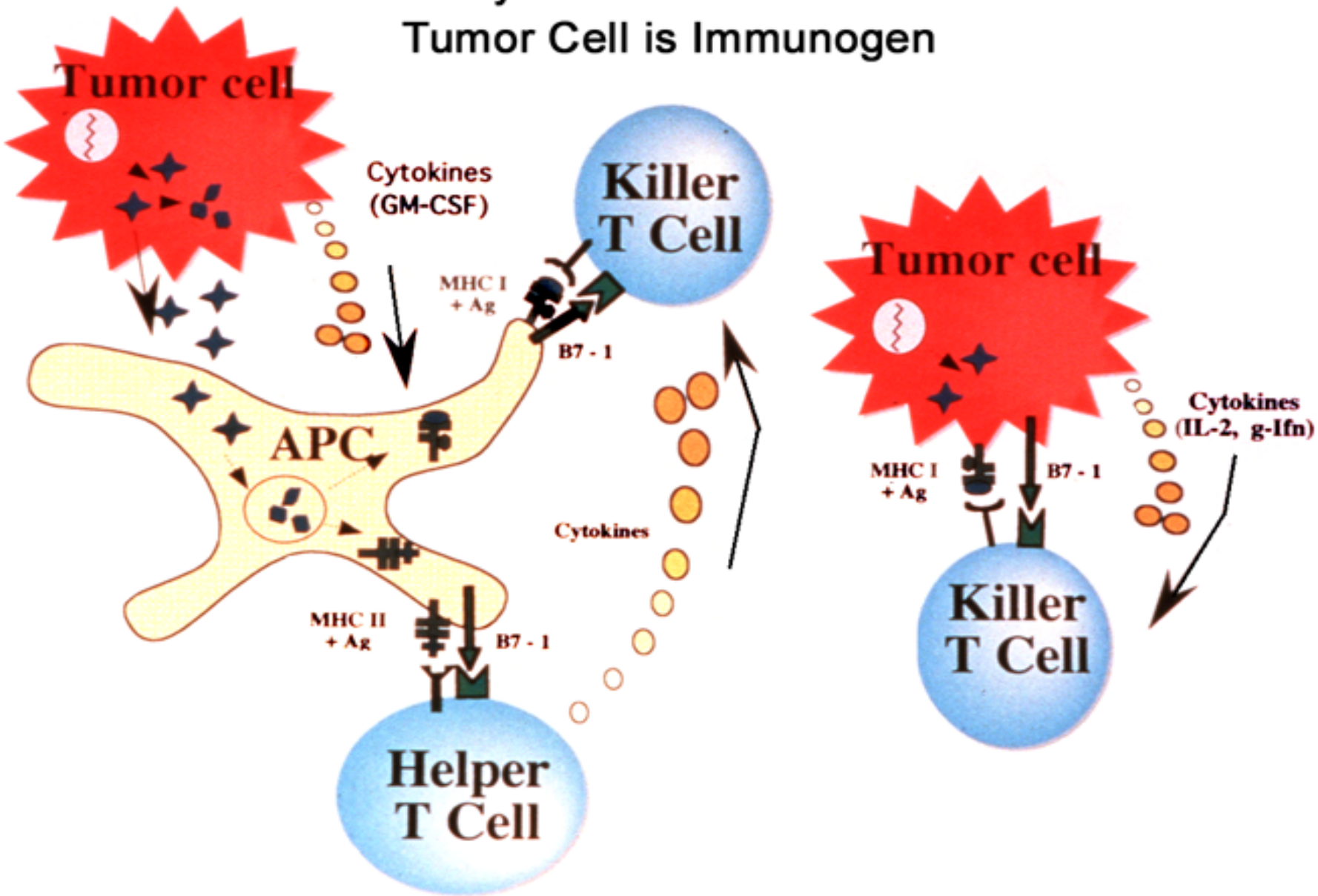
Conflict of Interest Statement

Under a licensing agreement between Cell Genesys and the Johns Hopkins University, the University is entitled to milestone payments and royalty on sales of the vaccine product described in this presentation. The terms of this arrangement are being managed by the Johns Hopkins University in accordance with its conflict of interest policies.

Pancreas Cancer

- 4th leading of cause of cancer related death in US in 2006/2007
- Surgery is the only known cure for early pancreas cancer
- Majority of patients under these best of circumstances will recur
- A standard adjuvant treatment approach for patients with resected disease has not been determined

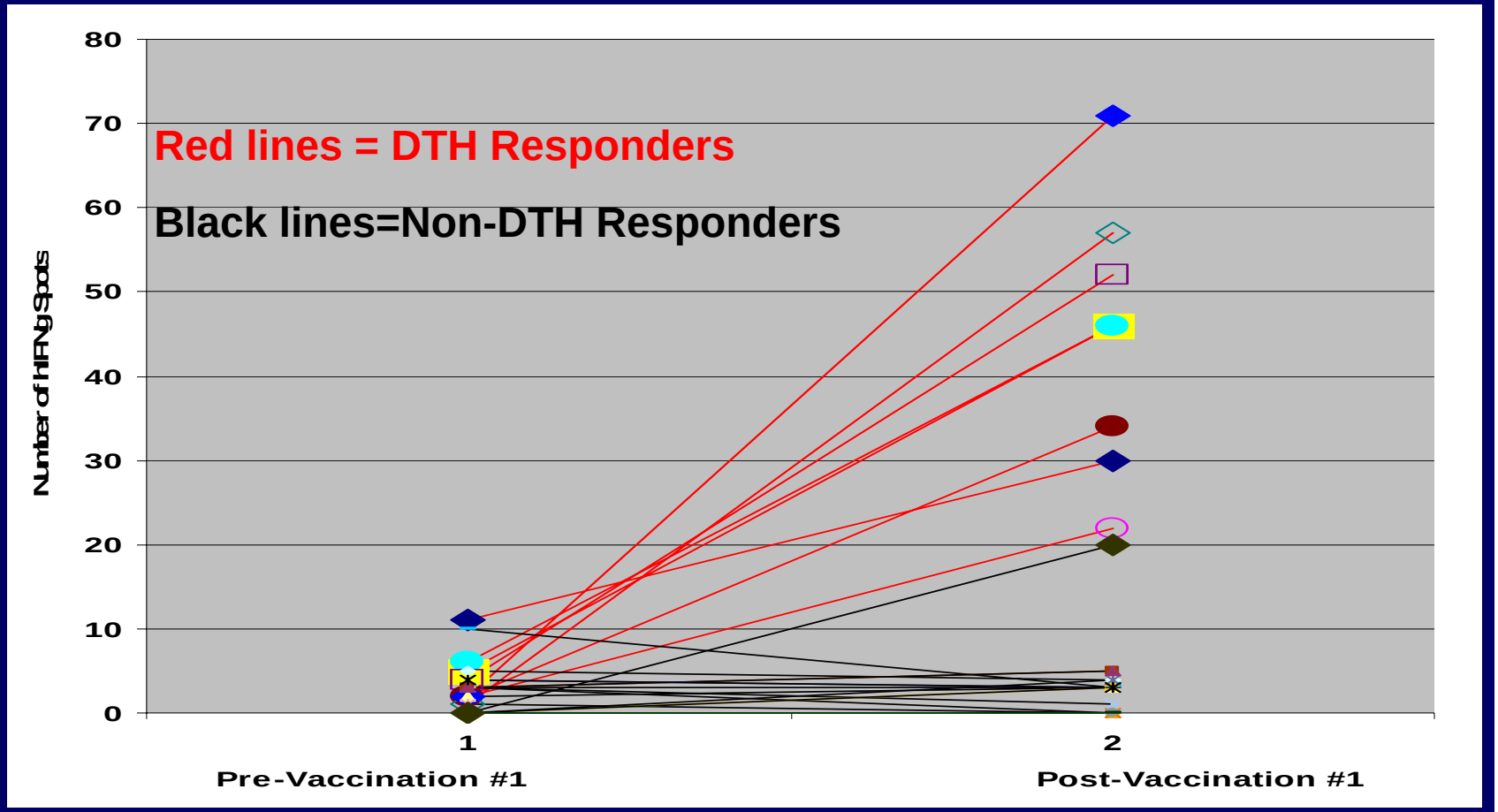
Genetically Modified Tumor Vaccines:
Tumor Cell is Immunogen



Summary of Phase I study using Gene Modified pancreas tumor cells in combination with chemoradiotherapy for resected pancreas cancer

- Immunotherapy treatment is well tolerated
- Dose-dependent Delayed Type Hypersensitivity responses to autologous tumor for responding patients
- Possible dose-dependent improvement in DFS
- T cell responses to mesothelin may serve as *in-vitro* predictors of clinical response

Summary of Mesothelin-specific CD8+ T Cell Responses for 14 Patients From Phase I study



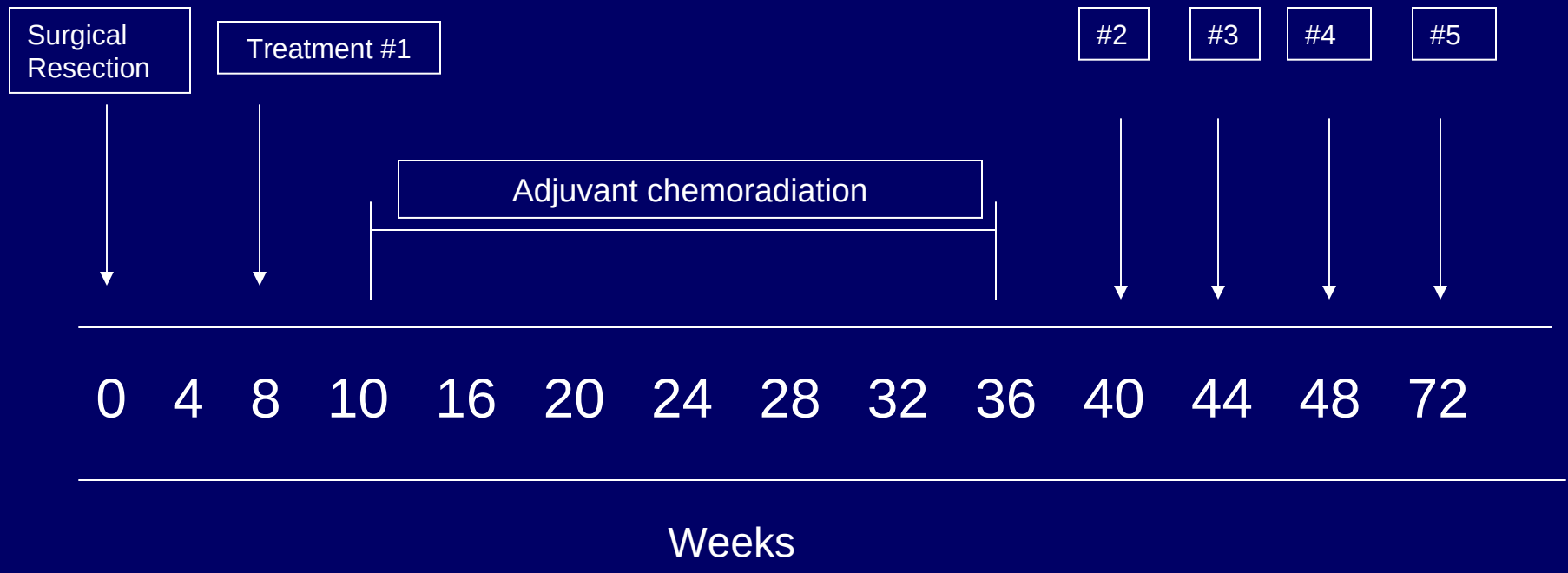
Peptide Symbol Legend

■=MesothelinA2$_{(20\text{-}29)}$
□=MesothelinA3$_{(83\text{-}92)}$
◊=MesothelinA24$_{(435\text{-}444)}$
♈=TyrosinaseA24$_{(206\text{-}214)}$

❍=MesothelinA2$_{(530–539)}$
●=MesothelinA3$_{(225\text{-}234)}$
♦=MesothelinA24$_{(475\text{-}484)}$

♦=HIVGAGA
Δ=HIVNEFA3$_{(9}$

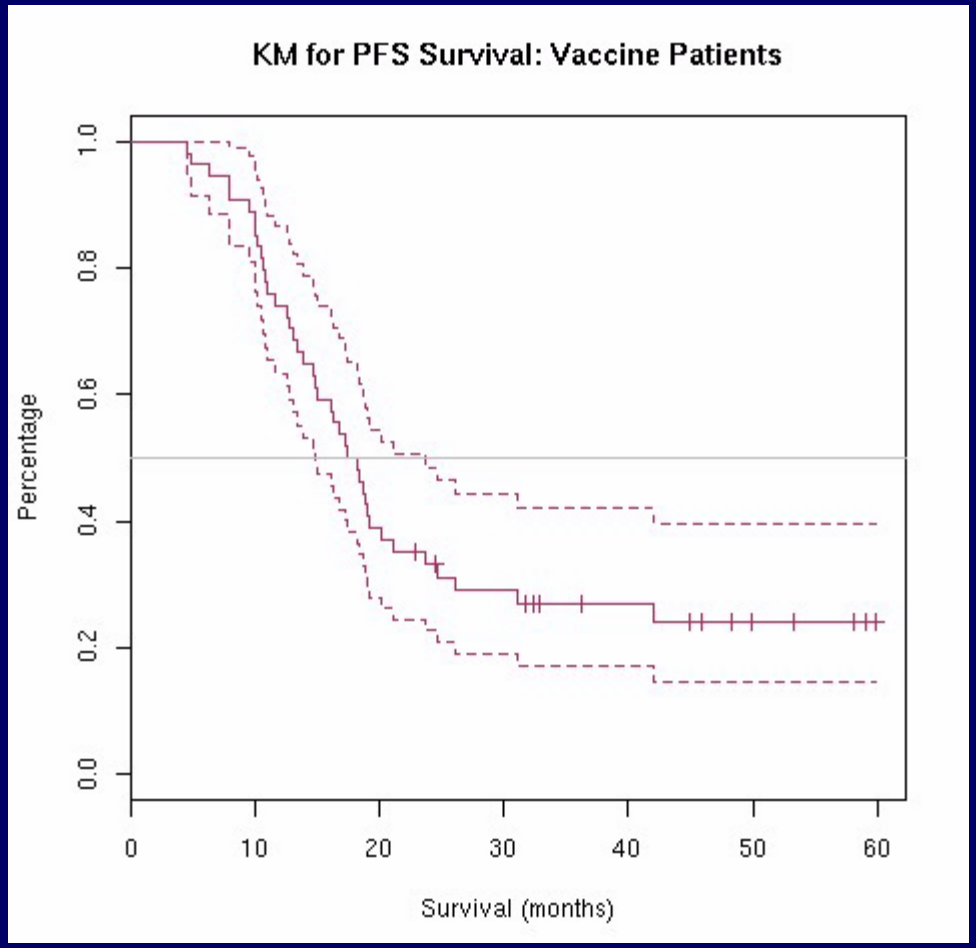
Design of Follow-up Phase II Study



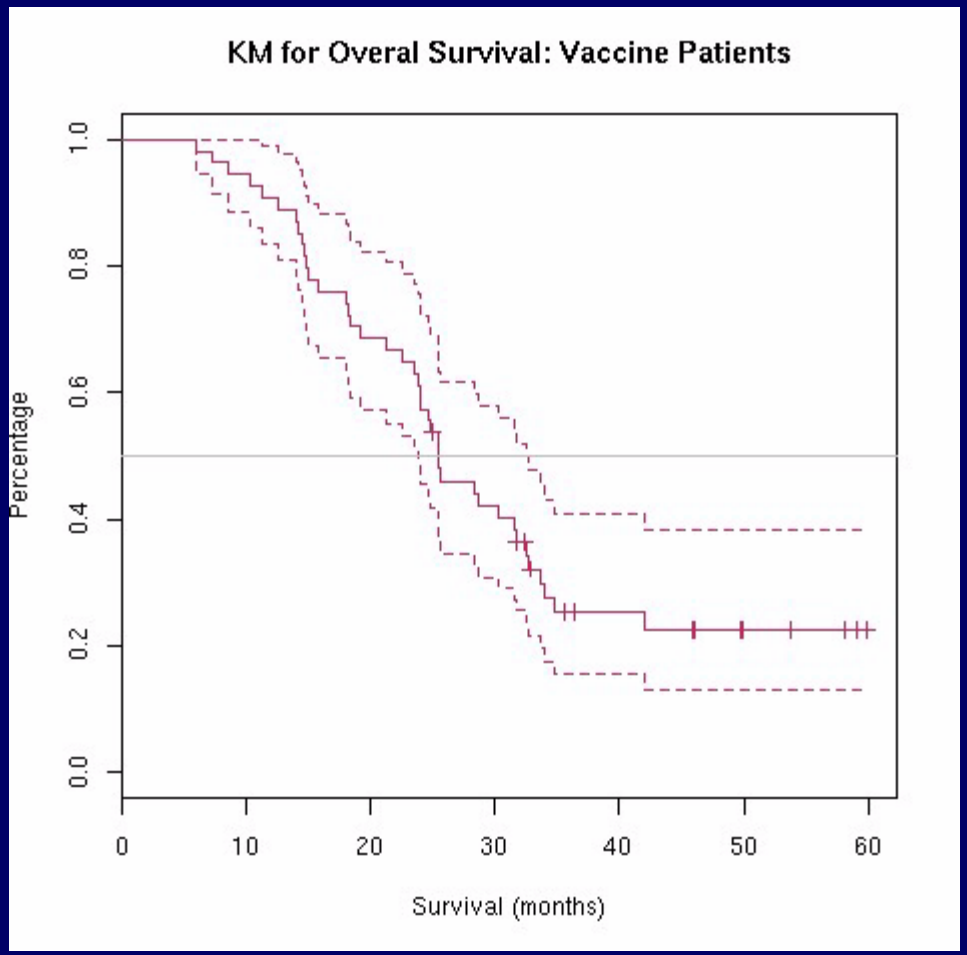
Patient Characteristics

Male	37
Female	23
Median age (yrs)	56.7
Range (yrs)	41-83
Node + (%)	53 (88)
Margin + (%)	18 (30)
Node+ /Margin + (%)	18 (30)

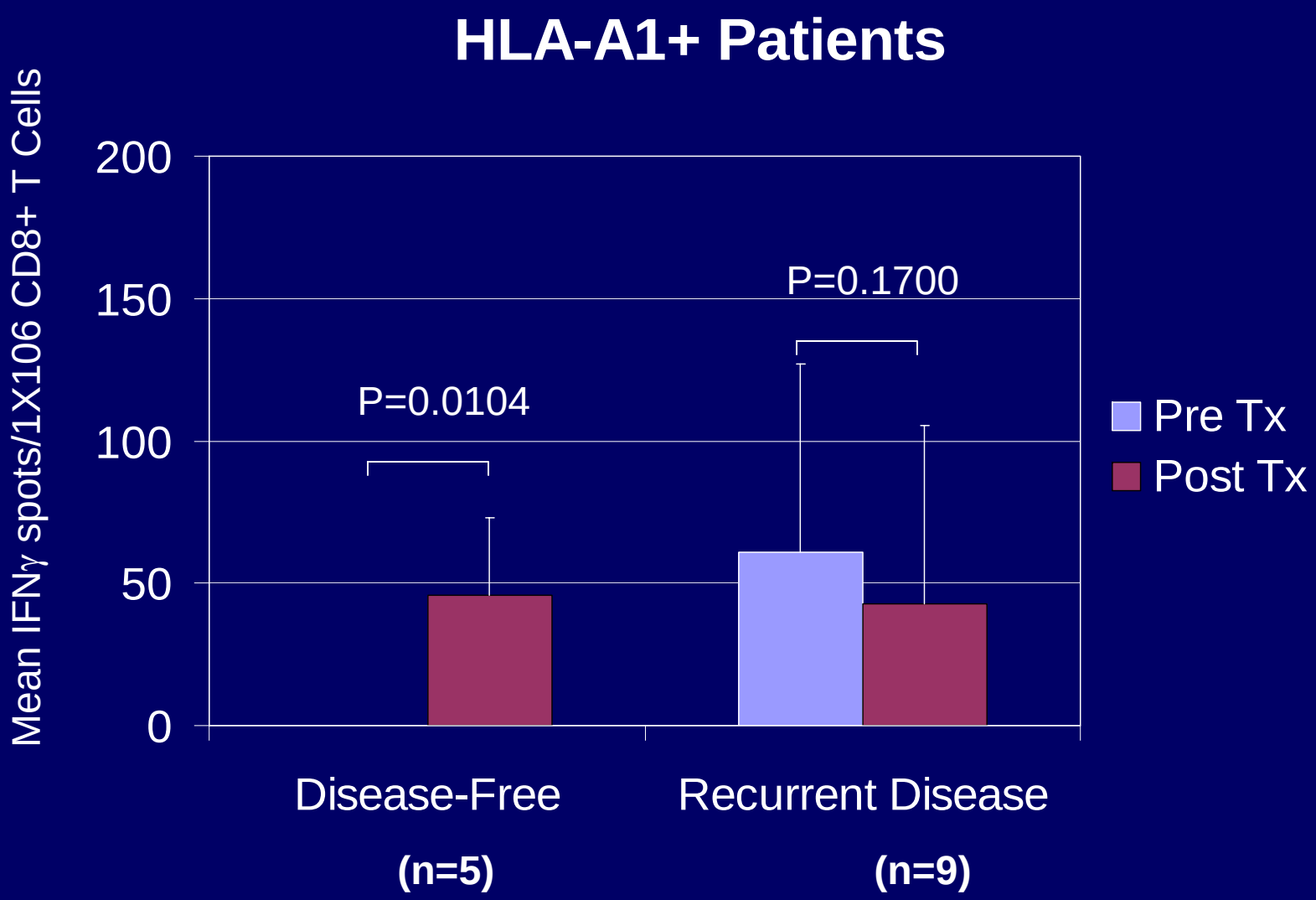
DFS


KM for PFS Survival: Vaccine Patients
Percentage
0.0
0.2
0.4
0.6
0.8
1.0
0
10
20
30
40
50
60
Survival (months)

Overall Survival



Post- Immunotherapy Induction of CD8+ T Cells to Mesothelin



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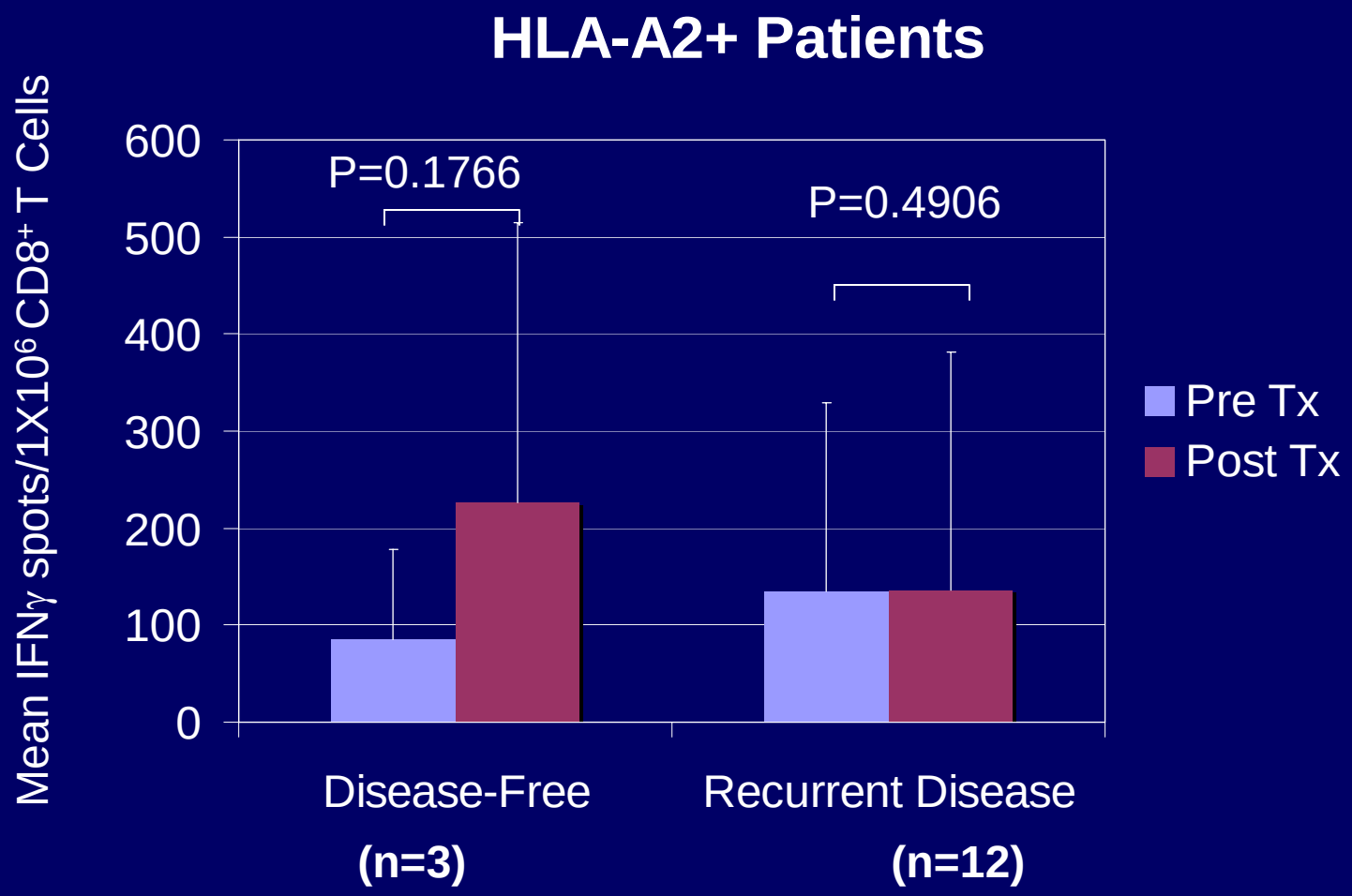
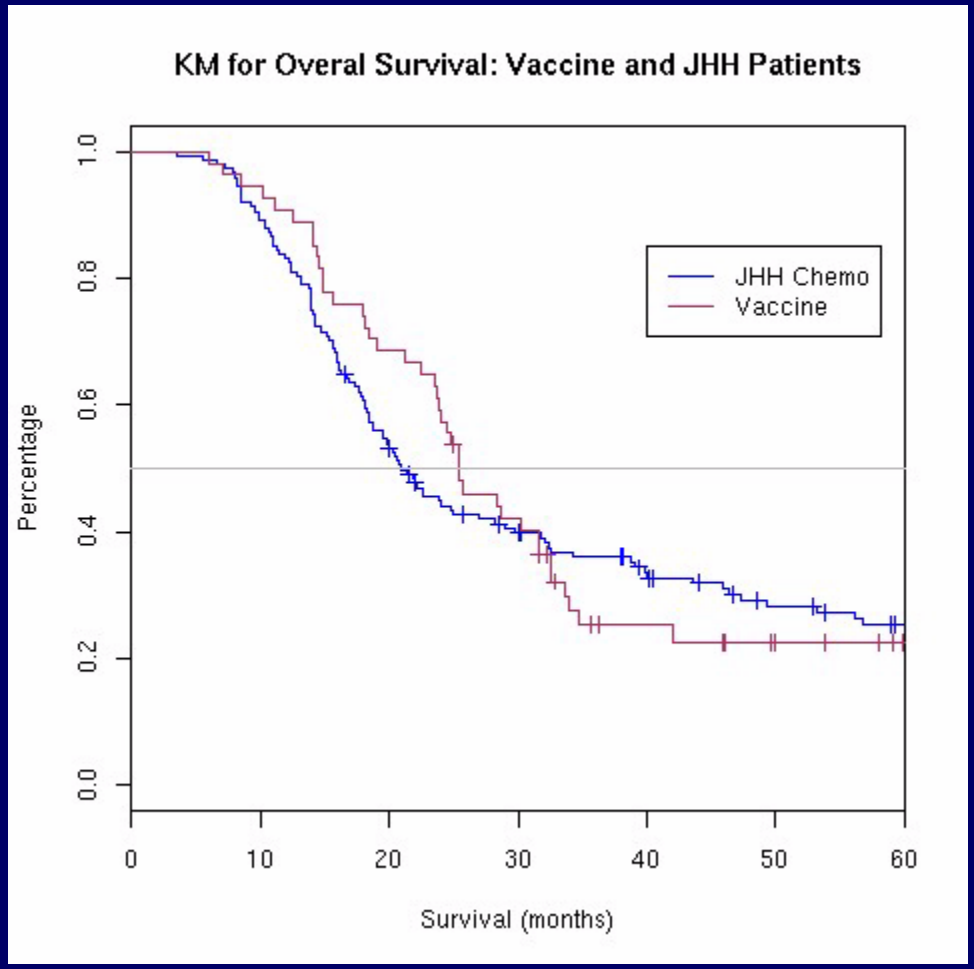


Comparison of patient cohort resected at JHH and who received chemotherapy alone versus immunotherapy study patients



Study Summary

- The administration of a gene modified pancreas tumor cells is well tolerated.
- With over 3 year median follow-up, the overall survival in this study is approximately 26 months. The survival compares very favorably with published data for resected pancreas cancer.
- Comparison to cohort of patients resected at Johns Hopkins who received chemoradiation without immunotherapy (median survival approximately 21 months) indicates that the effect of the immunotherapy is of additional benefit over chemoradiation alone for first 3 years of study but that this benefit is not maintained.
- Post-immunotherapy induction of mesothelin-specific $CD8^+$ T cells correlates with DFS. Immune correlates to HLA-A3 and A24 patients are in progress.
- The data supports additional boost immunotherapies beyond one year post surgery in future studies