

# NANOBIOTIX



**Pancreatic Cancer – MDA-2019-1001**

**ESTRO 2025**

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# ESTRO – May 2025 Data on Completed Phase I Trial

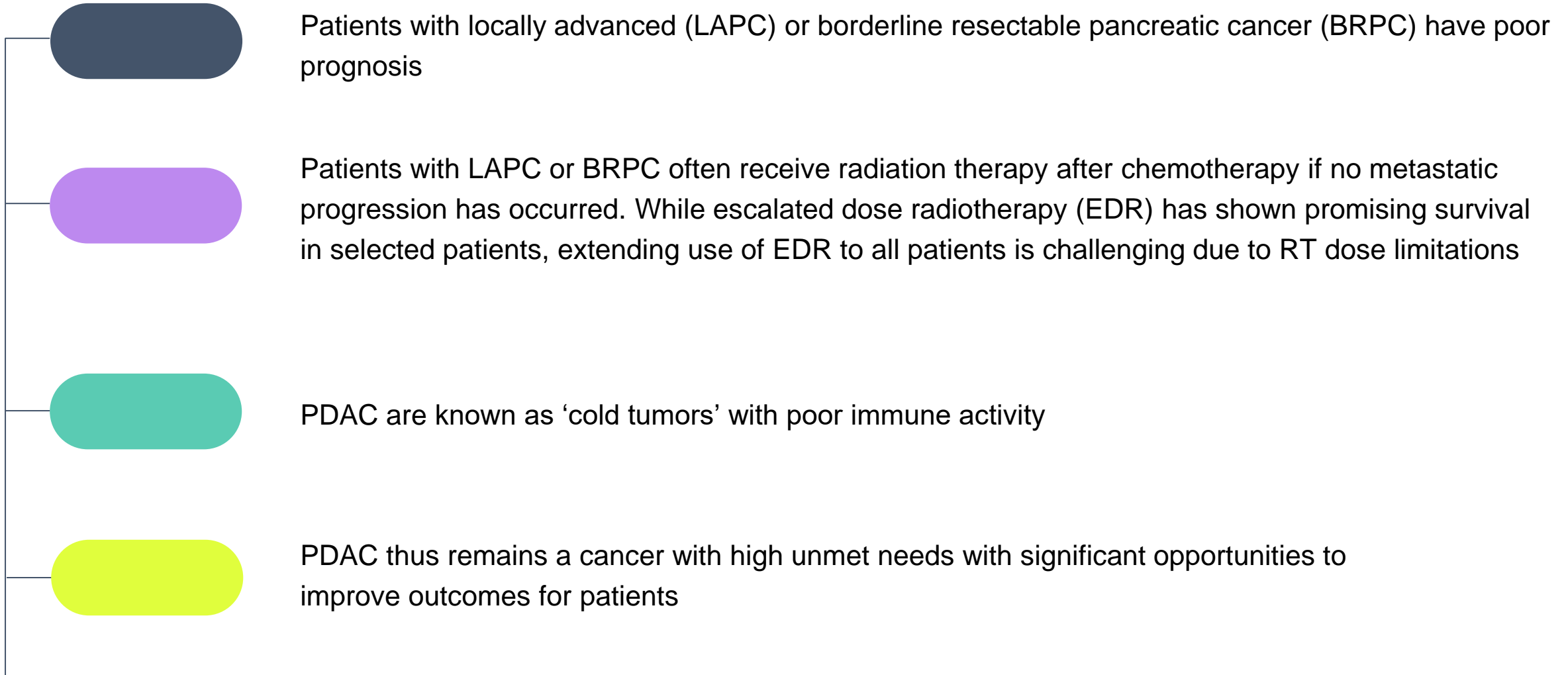
Nanoray Pancreas: A Phase I Study of NBTXR3 activated by Radiotherapy for Locally Advanced or Borderline Resectable Pancreatic Cancer (LAPC or BRPC)

Koay EJ, Liu S, Guerrero P, Stokes E, Katz MHG, Ikoma N, Snyder RA, Tzeng CD, Overman MJ, Pant S, Wolff RA, Javle M, Holliday EB, Ludmir EB, Das P, Noticewala S, Koong AC, Tamm EP, Bhutani M  
The University of Texas MD Anderson Cancer Center

# NANOBIOTIX

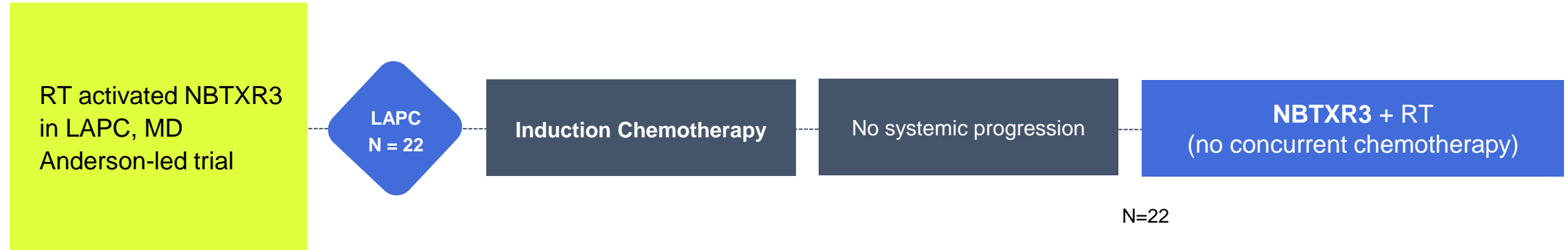
# PDAC is a Cancer with High Unmet Needs with Significant Opportunities to Improve Outcomes for Patients

NBTXR3 could represent an opportunity for this patient population



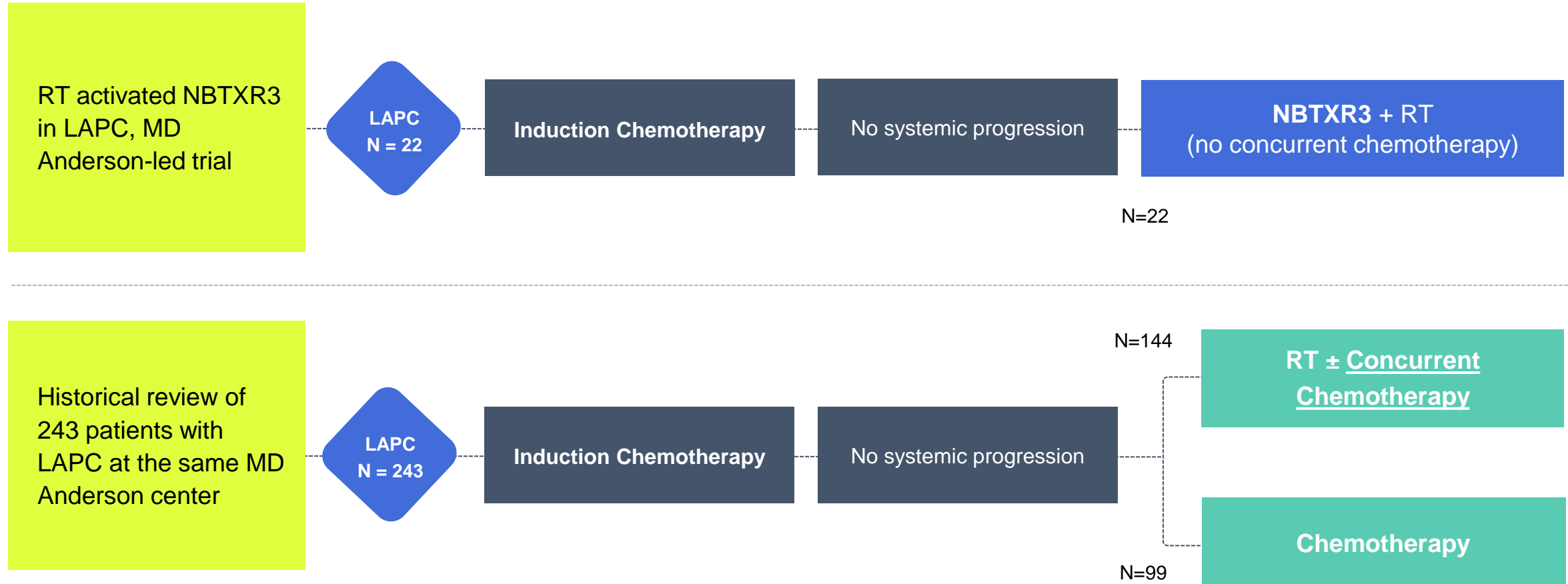
# Pancreatic Cancer Phase 1 Study Design

Single arm trial at MD Anderson, compared to historical data from the same center



# Pancreatic Cancer Phase 1 Study Design

Single arm trial at MD Anderson, compared to historical data from the same center



# Baseline Characteristics

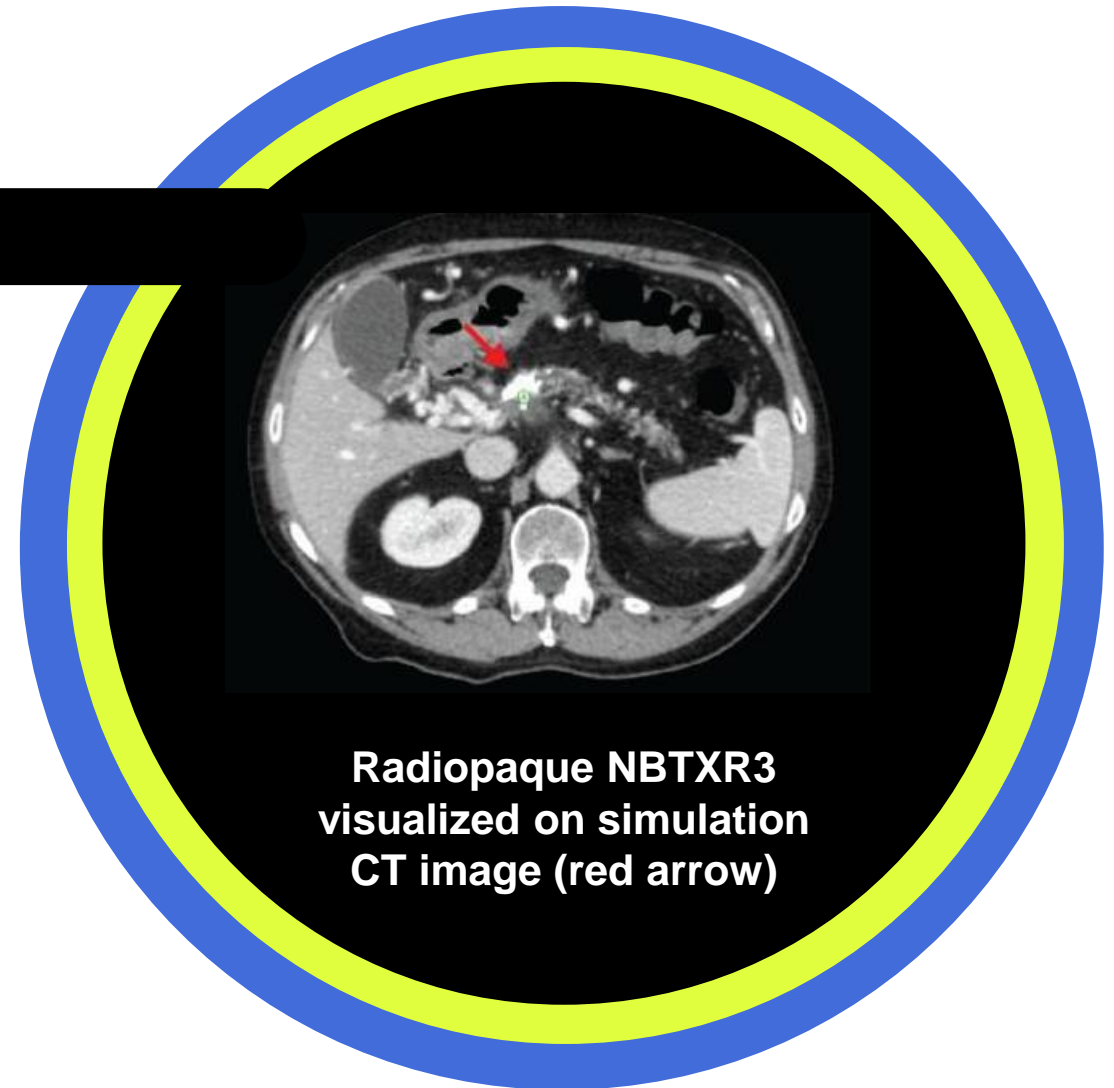
Most patients (20/22) had LAPC

	Dose escalation N=10	Dose escalation N=12	TOTAL N=22
<b>Sex, n (%)</b>			
Female	3 (30)	9 (75)	12 (54,5)
Male	7 (70)	3 (25)	10 (45,5)
<b>Age, years</b>			
Mean	59	65,5	62,5
Median	59	68	62,5
Min ; Max	43 ; 76	39 ; 81	39 ; 81
<b>ECOG/WHO PS, n (%)</b>			
0	5 (50)	3 (25)	8 (36,4)
1	5 (50)	8 (66,7)	13 (59,1)
Missing	0 (0)	1 (8,3)	1 (4,5)
<b>Disease status, n (%)</b>			
Borderline resectable	0 (0)	2 (16)	2 (9,1)
Locally advanced	10 (100)	10 (83)	20 (90,9)

# Injection of NBTXR3 is Safe and Feasible\*

## Methods

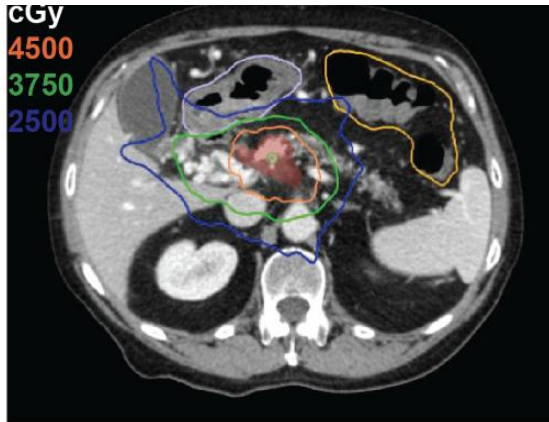
NBTXR3 was intratumorally injected once prior to RT via endoscopic ultrasound guidance.



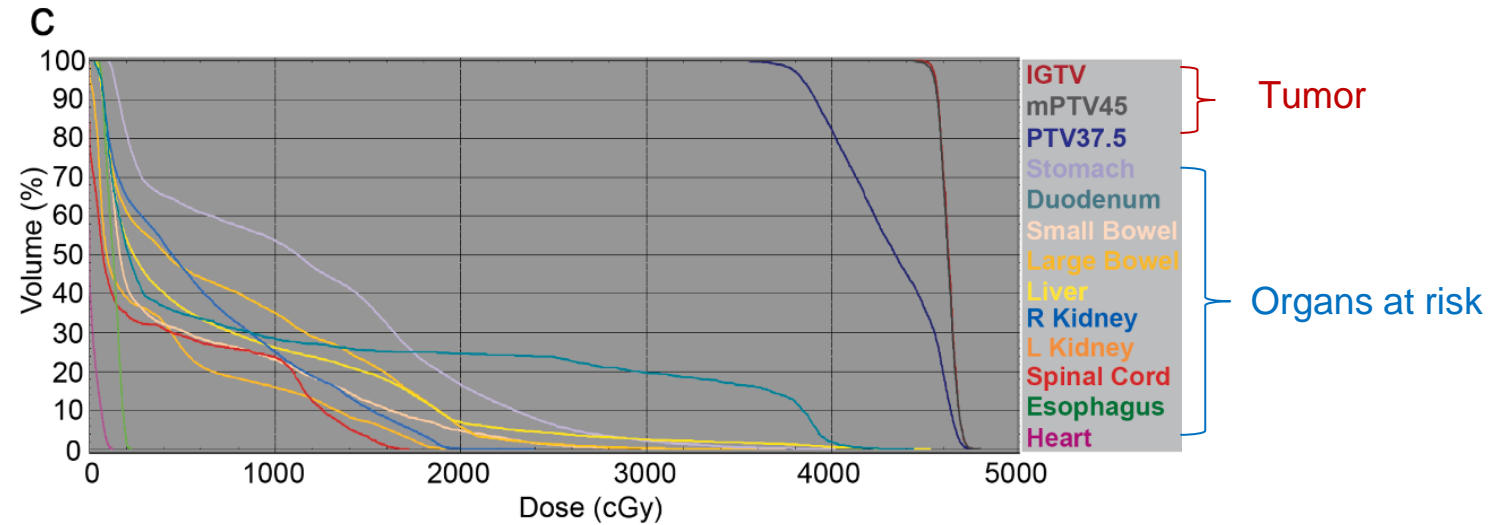
**Radiopaque NBTXR3  
visualized on simulation  
CT image (red arrow)**

# Delivering High Dose of Radiation in PANC is Complex

NBTXR3 + moderate dose RT is feasible for LAPC and BRPC



All pts received **moderate dose** of radiation: **45 Gy in 15 fractions** to GTV (BED of 58.5 Gy<sub>10</sub>) with intensity modulated RT.



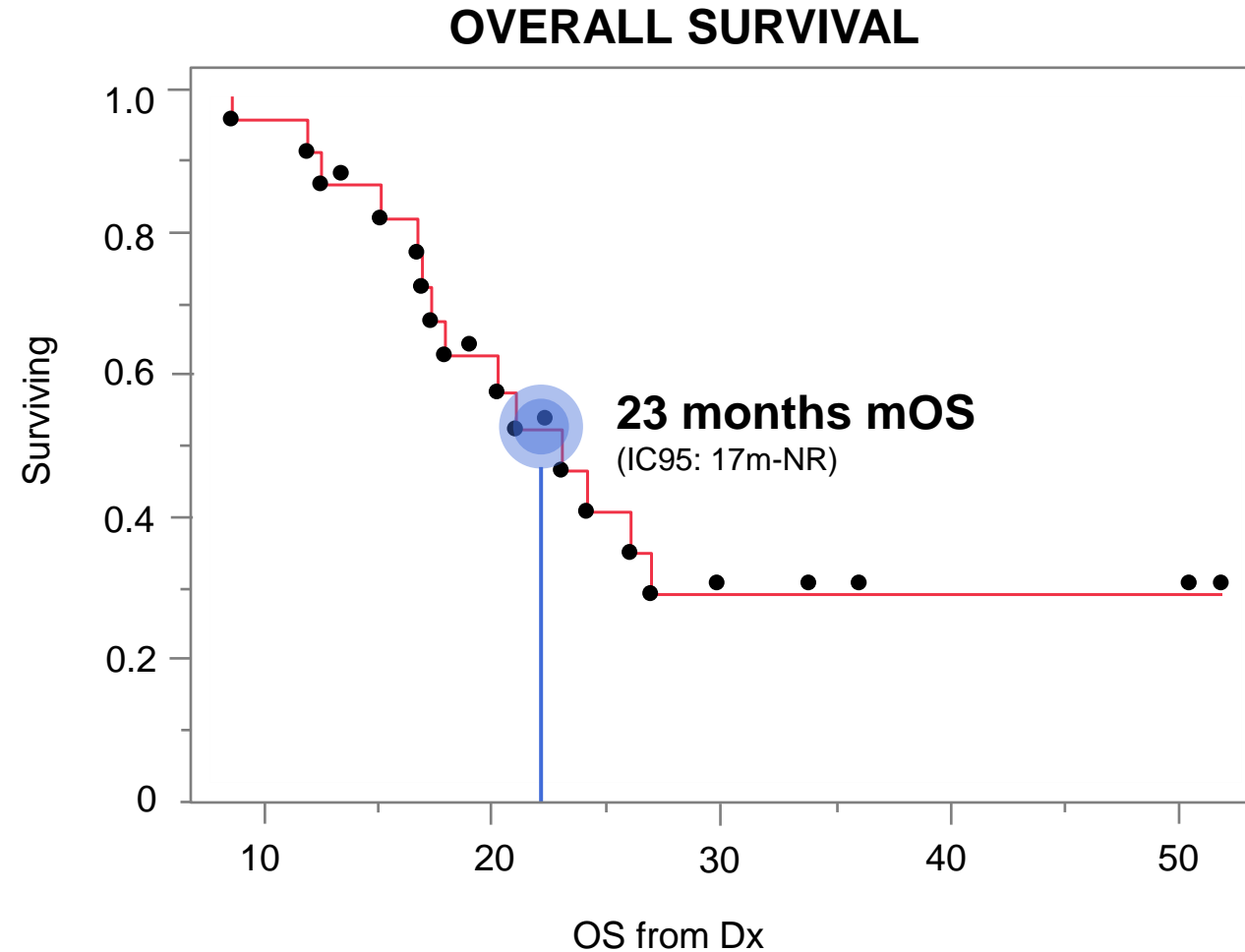
# Safety Assessment

NBTXR3/RT is feasible and safe for LAPC and BRPC

- No DLT observed during the dose escalation
- RP2D of NBTXR3 is 42% of GTV.
- Overall (escalation + expansion), grade 3 AEs were transiently observed in 3 of 12 patients. In part 2 at the level 2 dose:
  - 1 related to NBTXR3
  - 2 related to other treatments

# 23 months Median Overall Survival (from Diagnosis)

Cutoff: May 2025 (n=22)



**NBTR3 Pancreatic Study**

**23 with R3+RT**

mOS (Months)

(IC95: 17m-NR)

**Historical Control from same MDA Center**

**19.2 with CT+RT**

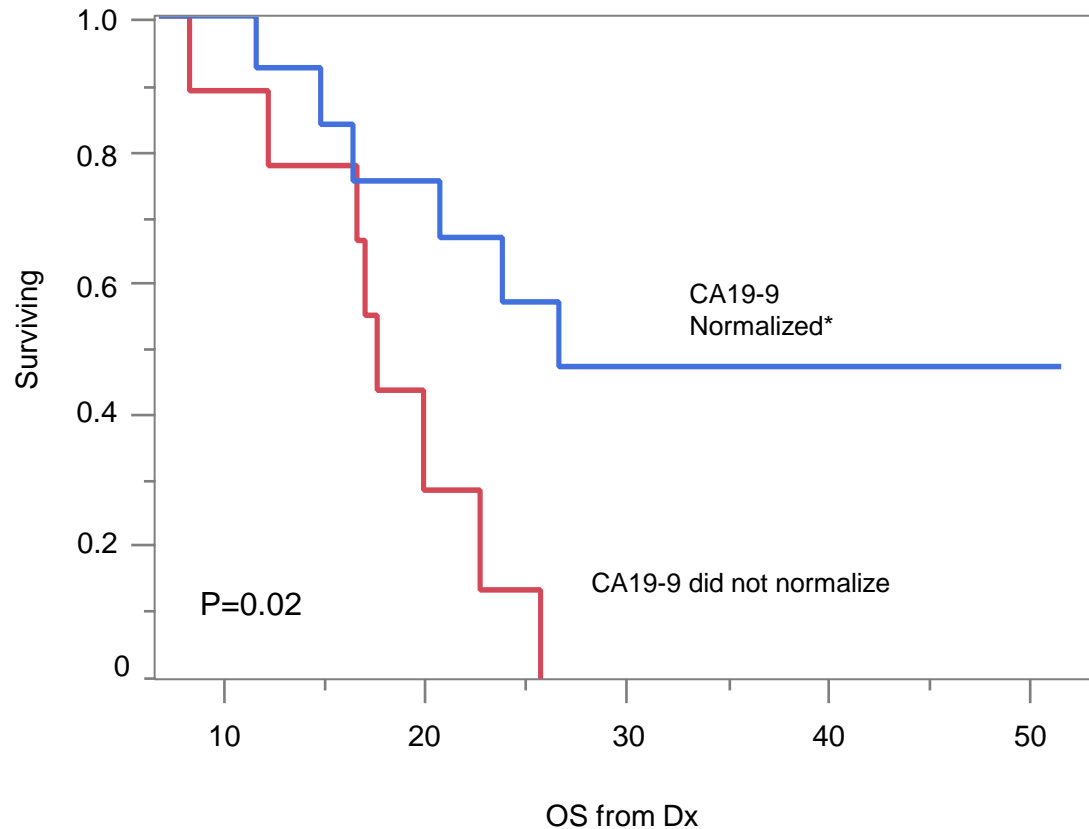
mOS (Months)

11.9 months [3-40.7] median follow up from RT

# 59% of Treated Patients had CA19-9 Normalization and Higher Survival

Cutoff: May 2025 (n=22)

### Improved survival in patients with CA19-9 normalization



## NBTR3 Pancreatic Study

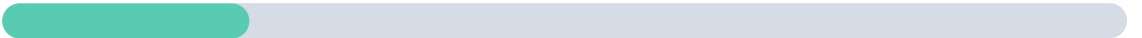
59%



59% of patients (13/22) / Normalized CA19-9\*

## Historical Control from same MDA Center

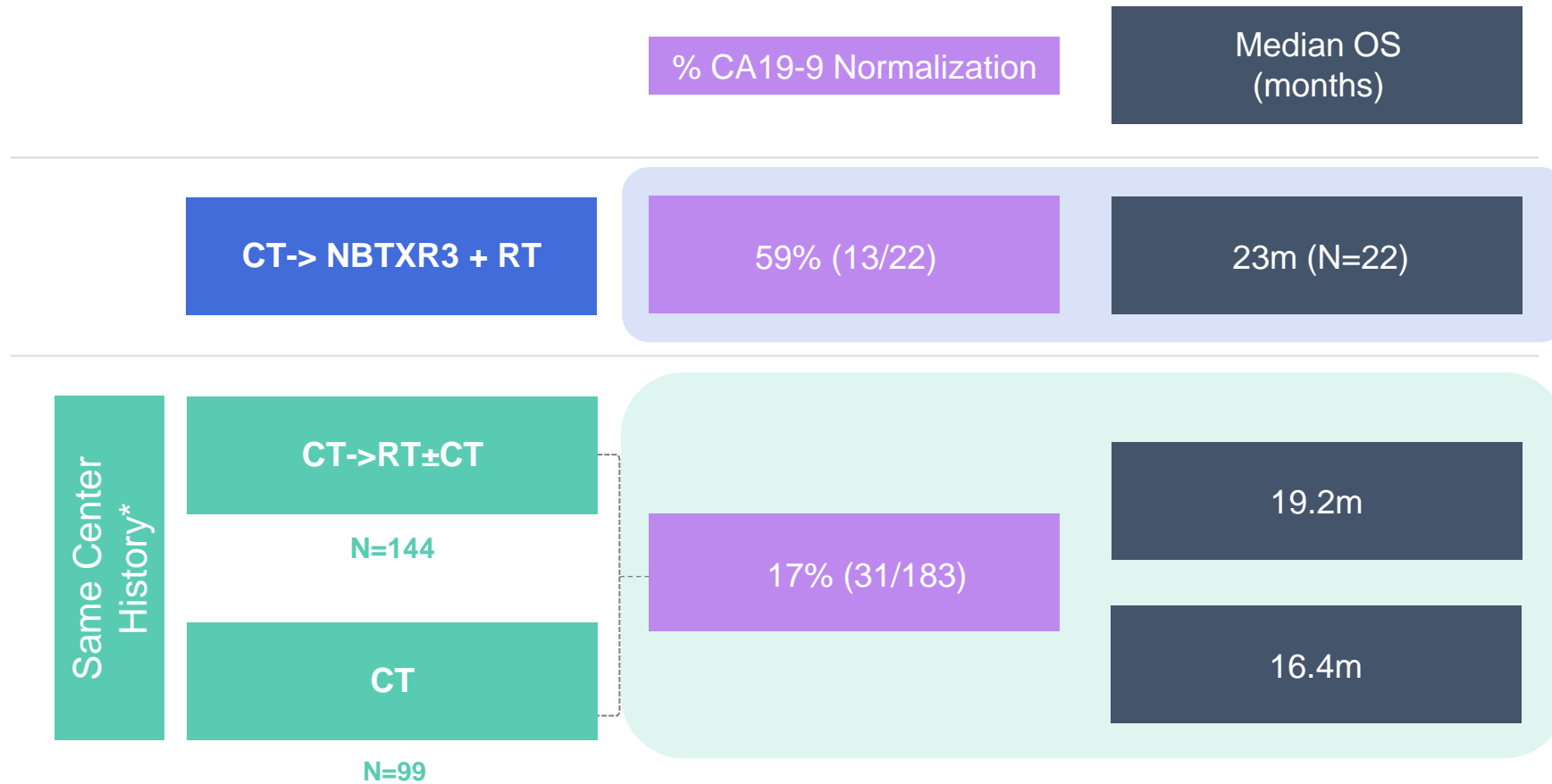
17%



17% of patients / Normalized CA19-9\*

# Comparison With Historical Control From Same Center

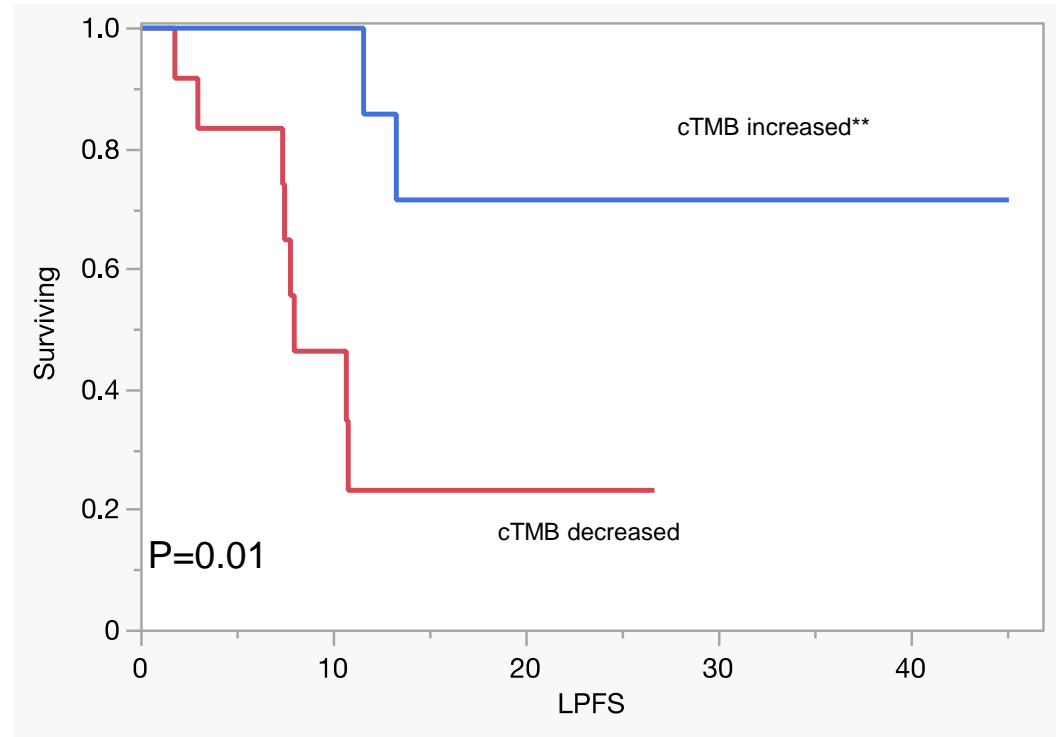
NBTXR3 allows for an increased normalization of CA19-9 which is associated with improved OS



\*patients treated between 2015-2019

# cTMB Could Be a Potential Correlative Biomarker of LPFS

40% of patients (8/20) had increased cTMB\*\*



Patients with increased cTMB had improved LPFS

# Local Control with NBTXR3+RT could Potentially Mediate an Immune Response in a Cold Tumor Like Pancreatic Cancer

01

cTMB is a potential prognostic biomarker associated with improved survival and better prognosis for the patients

02

Pancreatic cancer is a cold tumor with low TMB at baseline and Immune Resistant

03

40% of patients had increased cTMB post-NBTXR3 associated with improved local PFS



Local control with R3+RT could potentially mediate an immune response ; we continue to explore this hypothesis and use this biomarker in further studies

# Conclusion & Next Steps for NBTXR3+RT in Pancreatic Cancer

Oncologic outcomes are encouraging and warrant further investigation in a Phase 2 trial

## Key Data Highlights

**NBTXR3 activated by moderate dose RT is safe** for LAPC and BRPC with a RP2D of 42% of GTV

A **mOS of 23 mOS** has been observed in the 22 patients treated

An **association was seen** between:

- Survival and **CA19-9**
- Local control and **cTMB**

This furthers the **potential to incorporate cTMB and CA19-9 as correlative biomarkers**

Overall, the oncologic outcomes are encouraging and **warrant further investigation in a Phase 2 trial**

## Next Steps

A **new cohort is underway at MDA** with standard of care chemo / induction followed by radiation + capecitabine or 5-FU + R3

End of recruitment expected within the next 12 months

**First patient in the new cohort has been injected** and recruitment is ongoing

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Exploration ongoing for next pancreatic cancer trial



Thank you

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