



CORPORATE PRESENTATION

May 2024

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ENCOURAGING INTERIM NMIBC DATA; DE-RISKED RARE DISEASE PROGRAMS

TARA-002 in NMIBC

- **Encouraging**, pooled* **3-month interim** data in 16 CIS patients
- **Expecting enhanced CR Rates**
 - **MOA** and **non-clinical study** suggest **enhanced, durable** CRs following continued dosing
 - Planned **reinduction**, exploring **priming** and **higher dose**
 - Planned **anti-PD-1 combo** POC study
- **10-patient risk benefit** analyses from ADVANCED-2 trial **anticipated in 1H'24**
- **Unique characteristics** anticipated to drive significant adoption

IV Choline Chloride in Parenteral Nutrition

- **Aligned with FDA** on **single pivotal study** showing restoration of choline levels (already demonstrated in phase 2)
- **40K** addressable patient population, ODD and compound patent in U.S. (2041 exp.)

TARA-002 in LMs

- De-risked rare disease program with **PRV opportunity**
- Ph 2 trial ongoing

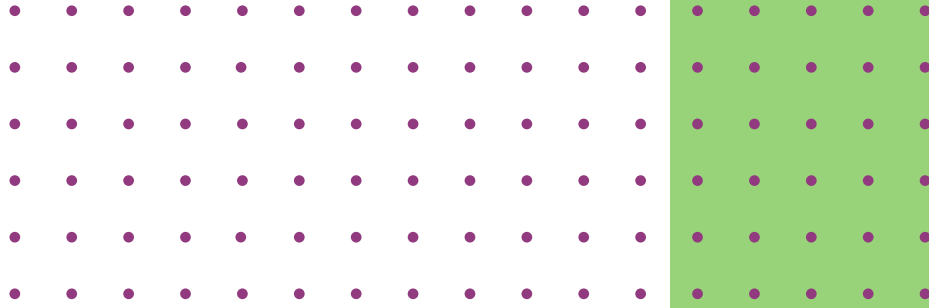
MULTIPLE VALUE CREATION OPPORTUNITIES ACROSS OUR PIPELINE

	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Current Status
ONCOLOGY						
TARA-002	NMIBC: CIS +/- Ta any BCG status	ADVANCED-1EXP				Encouraging POC activity data
	NMIBC: BCG-unresponsive CIS +/- Ta/T1	ADVANCED-2 (Cohort B)				Currently enrolling; Designed to be registrational
	NMIBC: BCG-naïve CIS +/- Ta/T1	ADVANCED-2 (Cohort A)				Currently enrolling POC Interim data across cohorts expected 2H'24
TARA-002 + Checkpoint inhibitor	NMIBC: CIS +/- Ta/T1					Initiate POC combo trial in Q4'24
RARE DISEASES						
IV CHOLINE	Choline for parenteral nutrition (PN) patients*	THRIVE-3				PK-based registrational study design confirmed by FDA
TARA-002	Lymphatic Malformations (LMs)**	STARBORN-1				Enrolling safety cohorts

*Granted Orphan Drug Designations by the U.S. FDA

**TARA-002 granted Rare Pediatric Disease designation by the FDA and orphan drug designation by the European Medicines Agency for the treatment of LMs.

PK=Pharmacokinetic



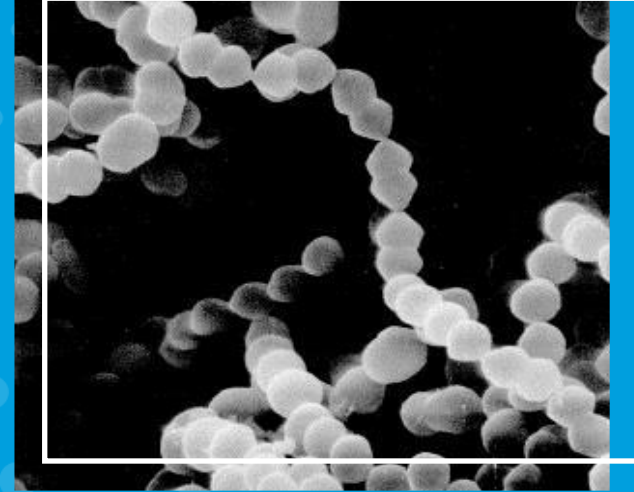
TARA-002

Lyophilized, Inactivated Group A *Streptococcus pyogenes*

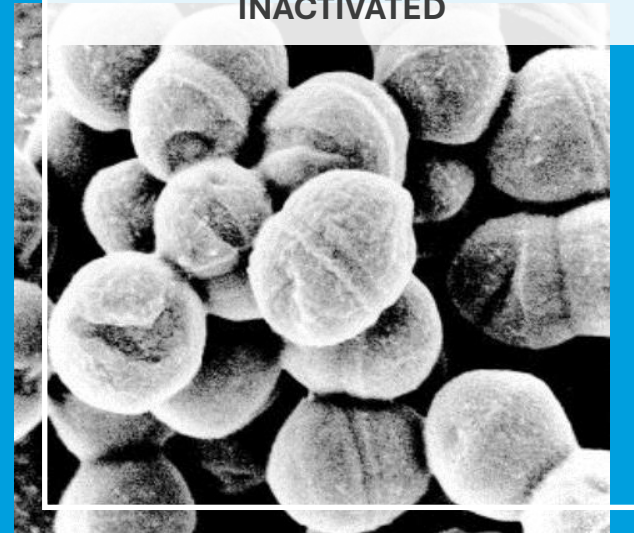
TARA-002: BROAD IMMUNOPOTENTIATOR WITH HISTORY OF ONCOLOGY USE IN JAPAN

- TARA-002 is an investigational, genetically distinct strain of *Streptococcus pyogenes* that is inactivated while retaining its immune-stimulating properties
- TARA-002 is manufactured under cGMP conditions from the same Master Cell Bank as originator therapy OK-432,⁽¹⁾ approved for LMs and a number of oncology indications in Japan
- There are close to 2,000 publications for OK-432 in Pubmed
- Protara has worldwide rights, excluding Japan & Taiwan, for TARA-002 / OK-432

LIVE CELLS



INACTIVATED



BROAD IMMUNOPOTENTIATION = POTENTIAL FOR DURABLE RESPONSE

Mechanism similar to BCG, unique to other agents in development

Activates Th1 Immune Cascade ⁽¹⁾⁽²⁾⁽³⁾

IL-1b

IL-6

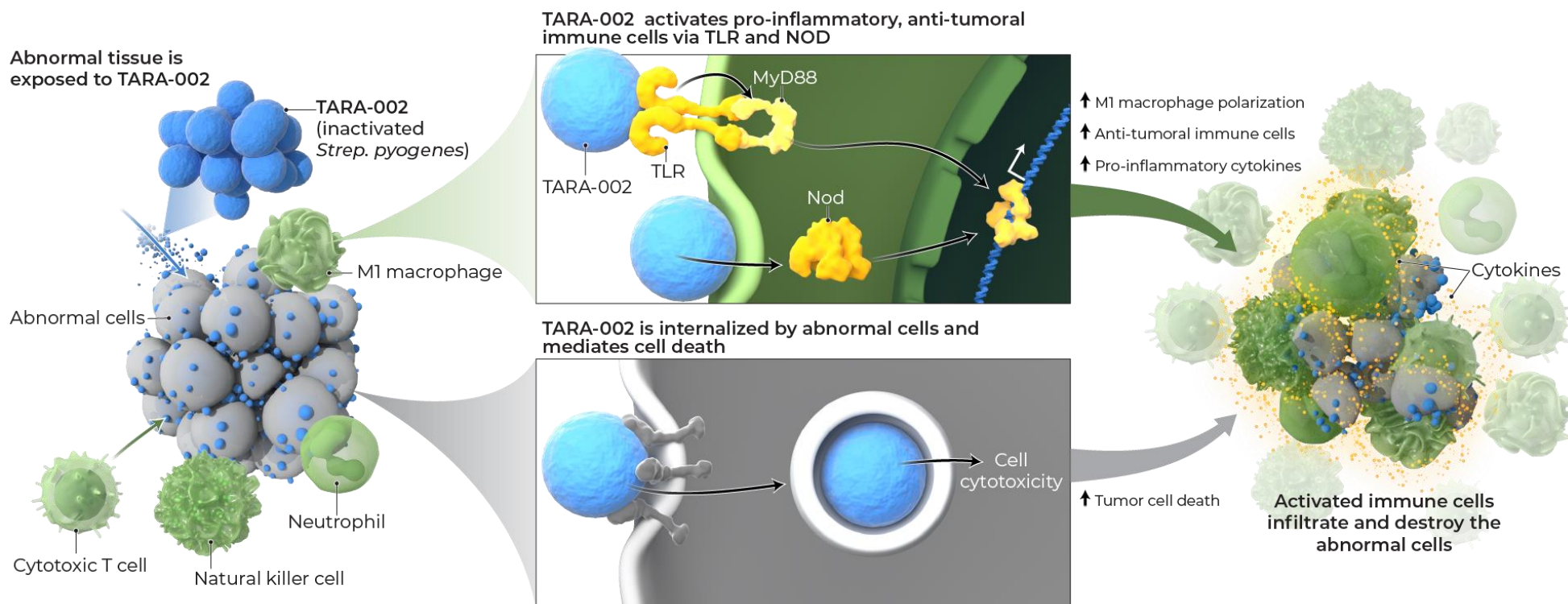
IL-12

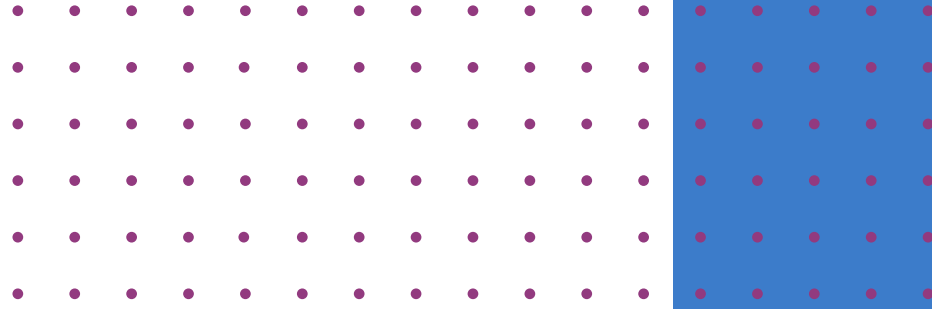
TNF-α

IFN-γ

GM-CSF

NK-Cells

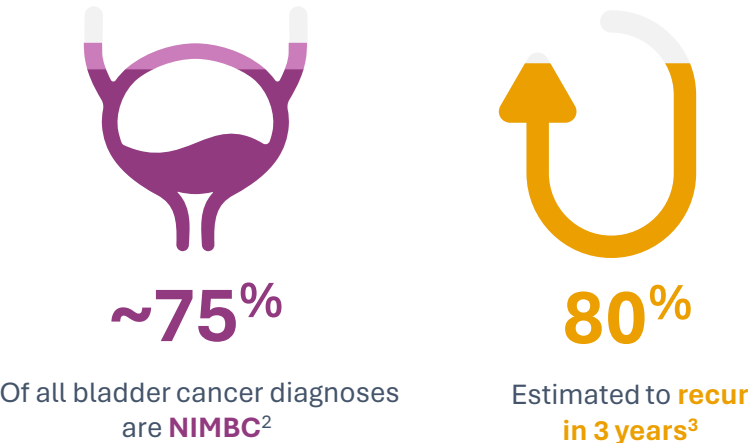
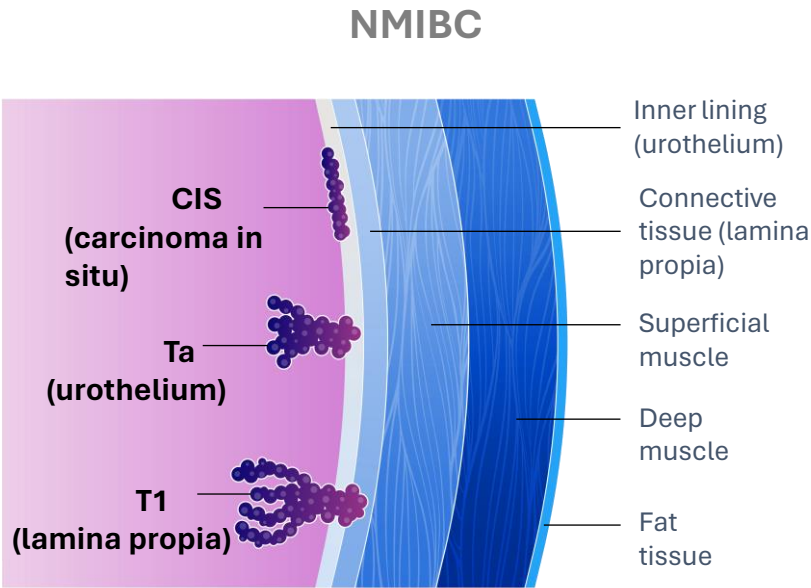
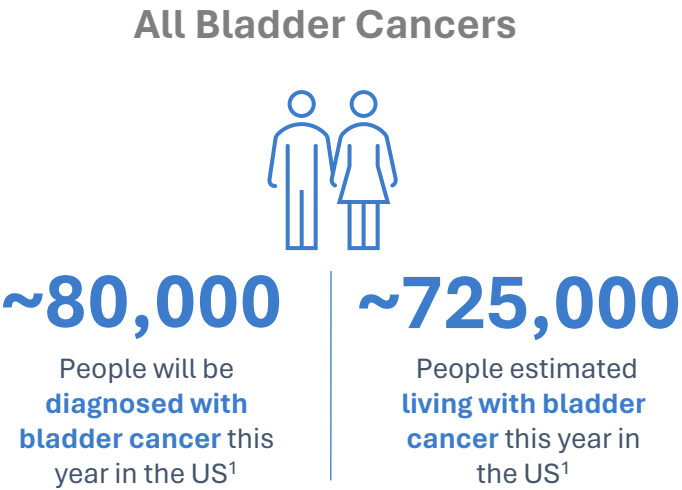




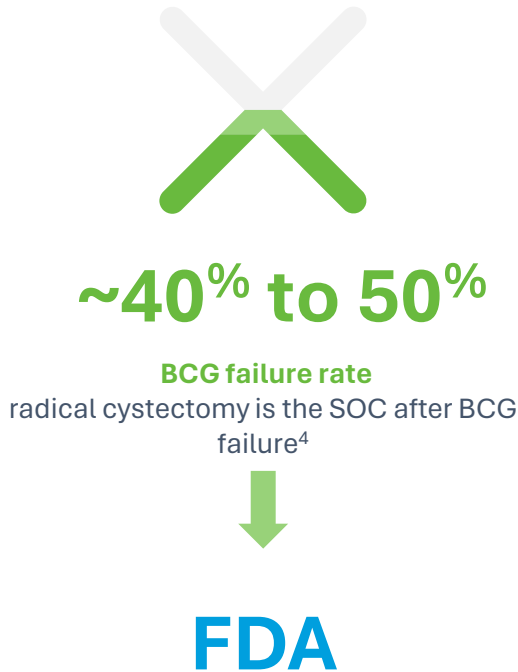
TARA-002

Non-Muscle Invasive Bladder Cancer

BLADDER CANCER: SIGNIFICANT UNMET NEED WITH LIMITED TREATMENT OPTIONS



BCG-UN; Significant unmet need

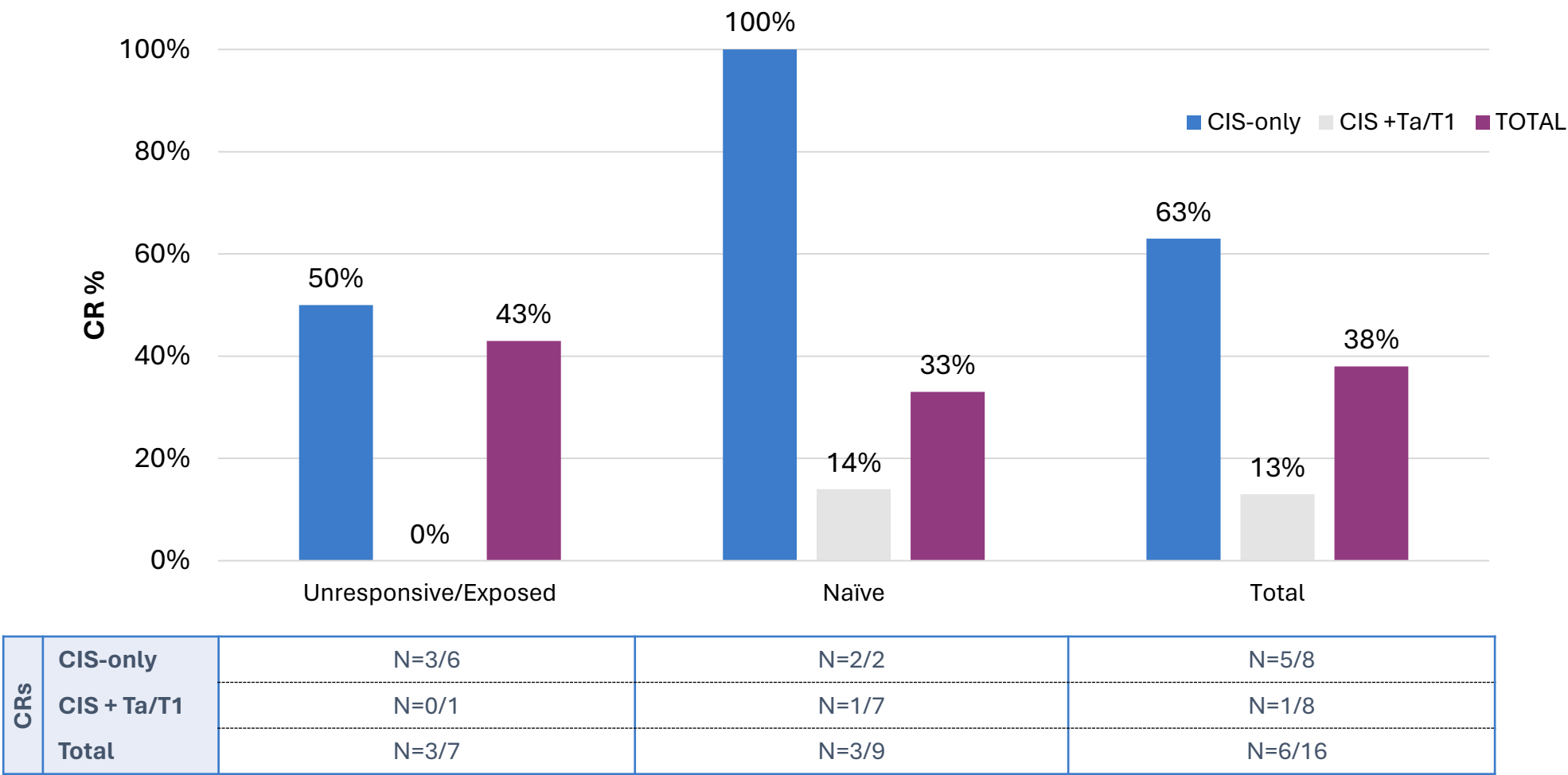


Currently approved therapies for **BCG-unresponsive NMIBC** were approved on the basis of **single arm trials**

1. National Cancer Institute. SEER Bladder Cancer – Stat Facts. Accessed April 25, 2023. | 2. Anastasiadis et al. Therapeutic Advances in Urology, 2012. | 3. Campbell Walsh 11th edition, Elsevier. | 4. J Gual Frau et al. Arch Esp Urol. 2016.

TARA-002 INTERIM 3-MONTH DATA DEMONSTRATES ENCOURAGING ACTIVITY

Pooled data from 3-month evaluable patients (N=16): Ph1a, Ph1b-EXP and Naïve Cohort from Ph2



*Patient contribution across trials: ADVANCED-1 Ph 1a = 3 patients - 1/3 CRs; ADVANCED-1 Ph 1b/EXP = 8 patients – 3/8 CRs; ADVANCED 2 Ph 2 naïve cohort = 5 patients – 2/5 CRs

Definition: CR = Complete response
Data cutoff 3/19/24

TARA-002 HAS FAVORABLE TOLERABILITY THAT WILL HELP SUPPORT ADOPTION

AEs reflect urinary tract instrumentation effects, such as bladder spasm, burning sensation and UTI
AEs consistent with known safety profile of an immune-potentiating drug, such as flu-like symptoms

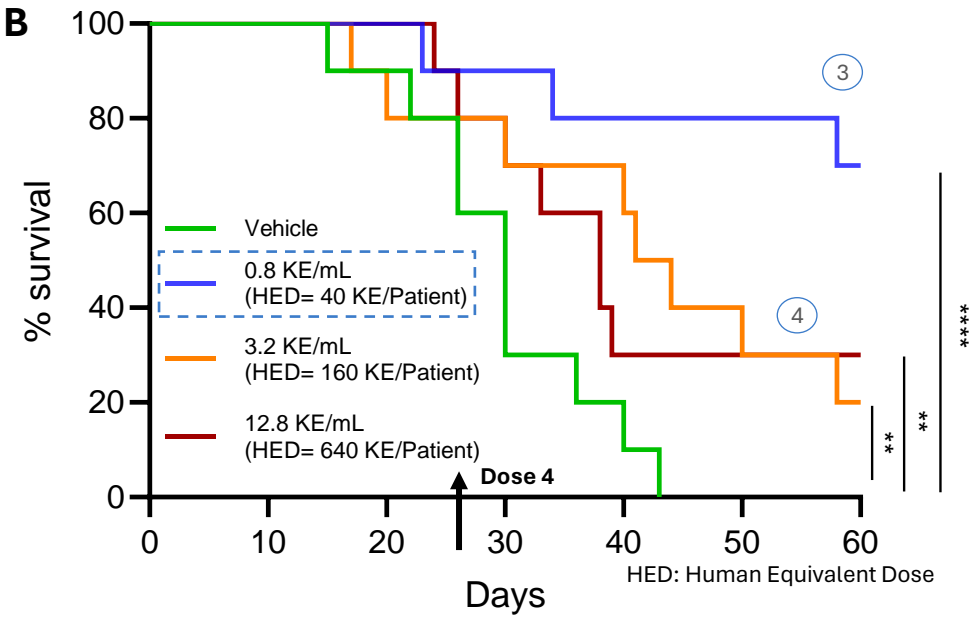
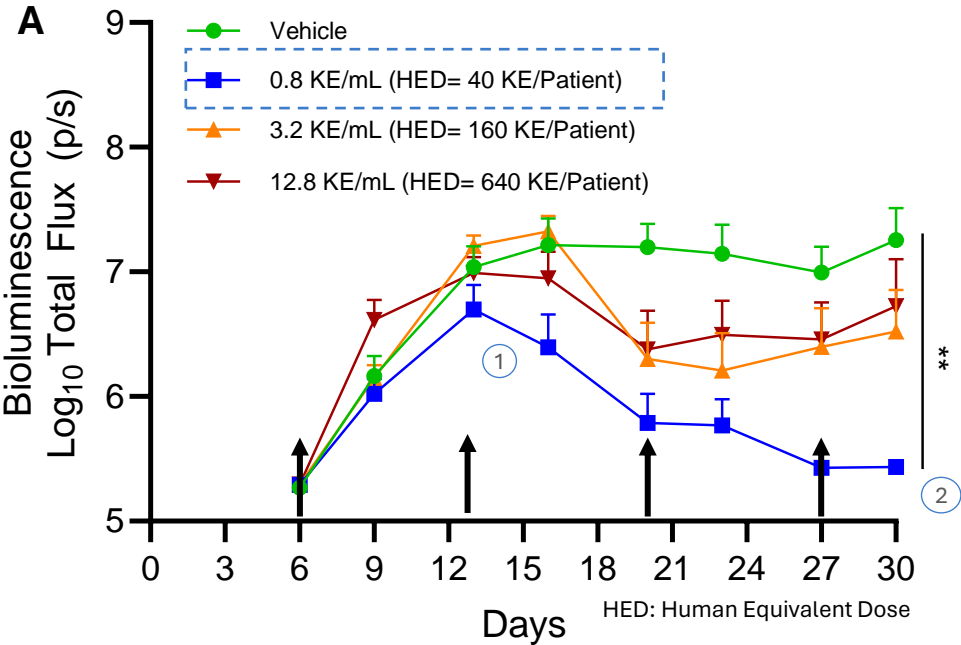
	Grade 1 Adverse Events (AEs) (mild)	Grade 2 AEs (moderate)	Grade 3 AEs (severe)	Grade 4 AEs (life-threatening)	Grade 5 AEs (result in death)
Total AEs for all dosing levels (16 CIS ± Ta/T1 and 6 HGTa)	132	22	4	-	-
Most commonly reported AEs (≥ 5%)	Bladder spasm (11%) Fatigue (9%) Micturition urgency (6%) Headache (5%) ALP low (5%) RBC count low (5%)	Bladder spasm (14%) Burning sensation (14%) UTI (14%) Cough (9%) Anorexia (5%) Anxiety (5%) Back pain (5%) Chills (5%) Dermatitis diaper (5%) Fatigue (5%) Hyperhidrosis (5%) Nausea (5%) Pyrexia (5%) Tinnitus (5%) Vomiting (5%)	<i>All Grade 3 AEs were deemed to be not treatment-related:</i> Hypoxia ¹ Creatinine increased ² Acute pyelonephritis ³ Sepsis ⁴	None	None

*Patient dosed across trials: ADVANCED-1 Ph 1a = 3 patients; ADVANCED-1 Ph 1b = 8 patients; ADVANCED-12 Ph2 naïve cohort = 5 patients

Data cutoff 3/19/24

1. Patient had hypoxia due to difficult extubation after TURBT and was resolved after treatment. Patient had ongoing asthma and COPD.
2. Patient had chronic pyelonephritis of right kidney (Stage 2 CKD). Not suspected to be caused by TARA-002 and resolved after management.
- 3 & 4. Patient had acute pyelonephritis and sepsis during screening period and was not enrolled into the study.

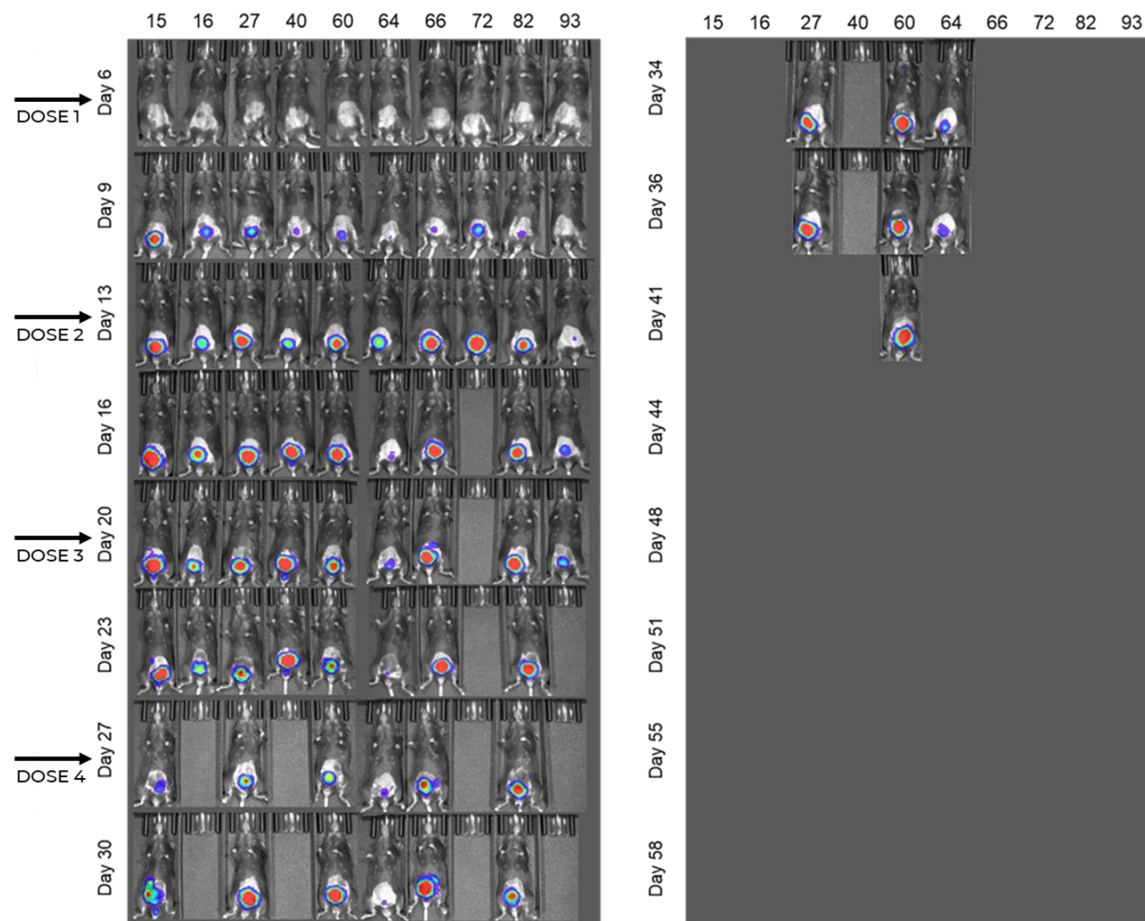
TARA-002 MOUSE MODEL SUGGESTS DURABLE EFFECT, SUPPORTS MODIFICATIONS



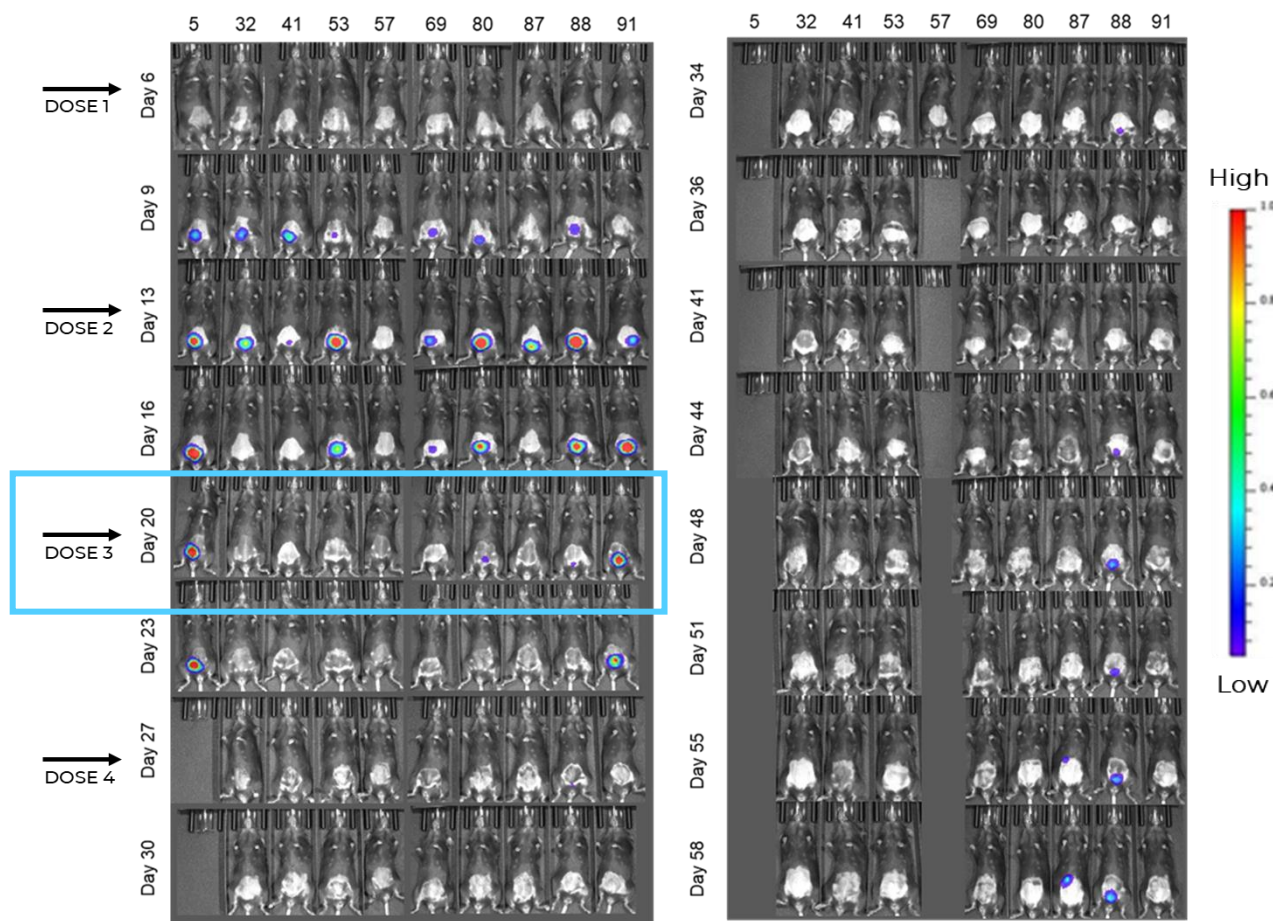
Luciferase-expressing MB49 bladder cancer cells were instilled in mouse bladder. Mice bearing orthotopic MB49 bladder tumors were treated intravesically with TARA-002. Tumor growth was evaluated by bioluminescence imaging.

DURABLE RESPONSES, SUSTAINED ACTIVITY FOLLOWING ONSET

Vehicle: 0.9% saline, Intravesical instillation



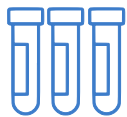
TARA-002, Intravesical instillation 40KE HED



Mouse #57 died of causes other than cancer, unrelated to drug

TARA-002 exhibited long-term anti-tumor effect in MB49 orthotopic mouse model. In vivo bioluminescence images of tumor development during and after intravesical instillation of vehicle and TARA-002.

PRIMING, REINDUCTION, AND MAINTENANCE EXPECTED TO ENHANCE TARA-002 RESPONSES



REINDUCTION

- **5/8 CIS+Ta/T1 Non-CRs** in our pooled data **had persistent CIS**, no papillary recurrence
- At 3 months, these patients were effectively CIS-only, our highest CRRs, and candidates for reinduction



MAINTENANCE

- MB49 Orthotopic model showed prolonged activity with repeat dosing
- BCG and VesAnktiva (incl. BCG) both show enhanced durability through maintenance



INCREASED DOSING

- 80KE dose already being studied in Ph 1a – may accelerate therapeutic onset



PRIMING

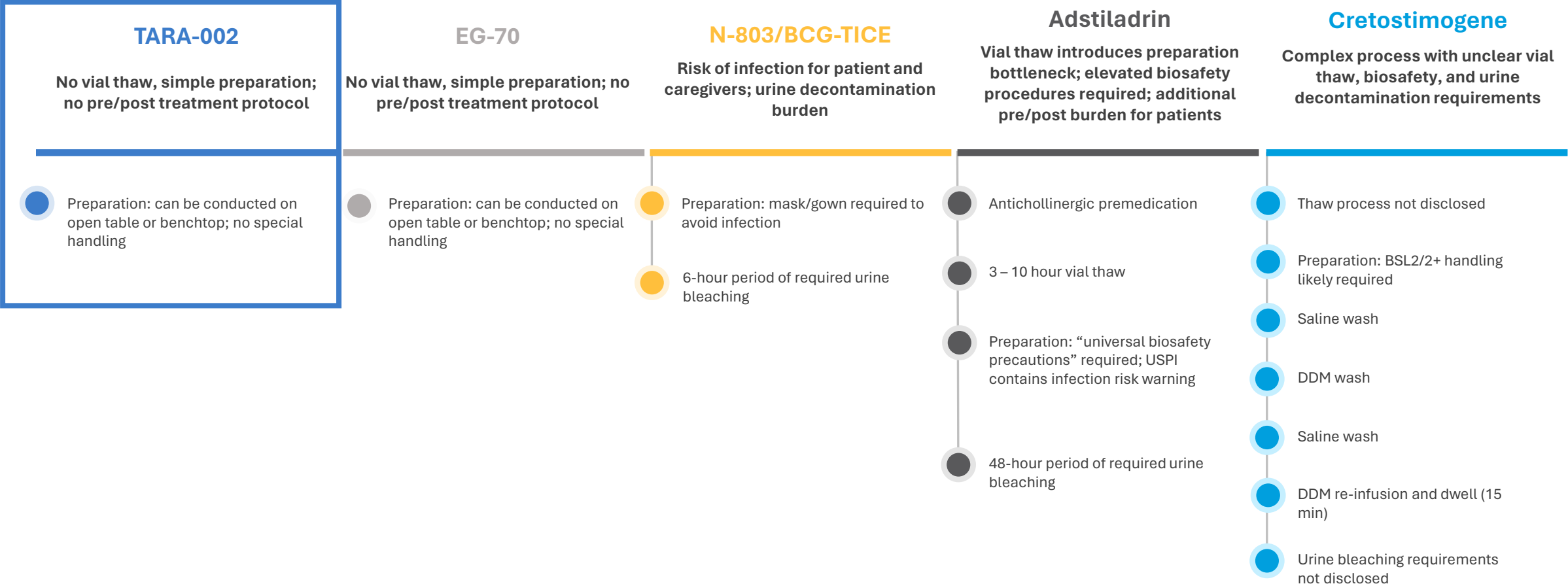
- Priming may shorten onset of activity
- Original BCG in NMIBC concept based on trained immunity from TB vaccination

Currently in
ADVANCED-2

Exploratory
Cohorts

TARA-002 ADMINISTRATION IS AMONG THE EASIEST OF NMIBC TREATMENTS

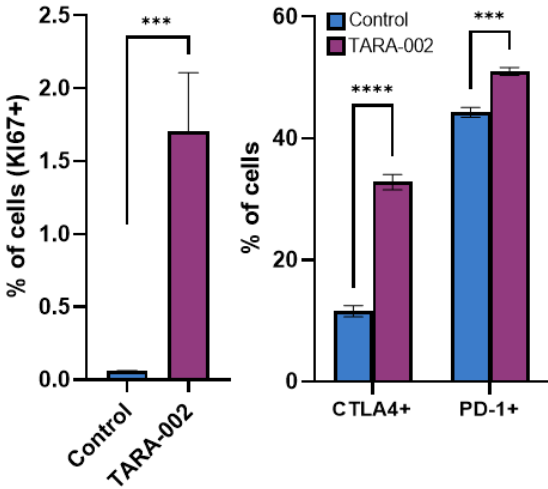
TARA-002 has reduced burden for physicians and patients



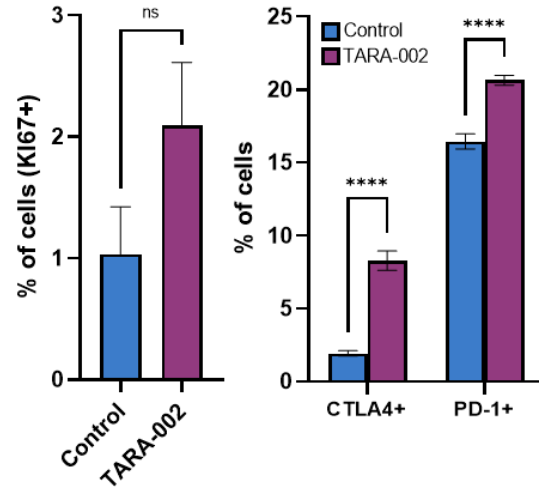
DEMONSTRATED SYNERGY WITH ANTI-PD1, PREVIEW OF PAPILLARY STRATEGY

In-Vitro Evidence of Immune-Activation

CD4 T cells



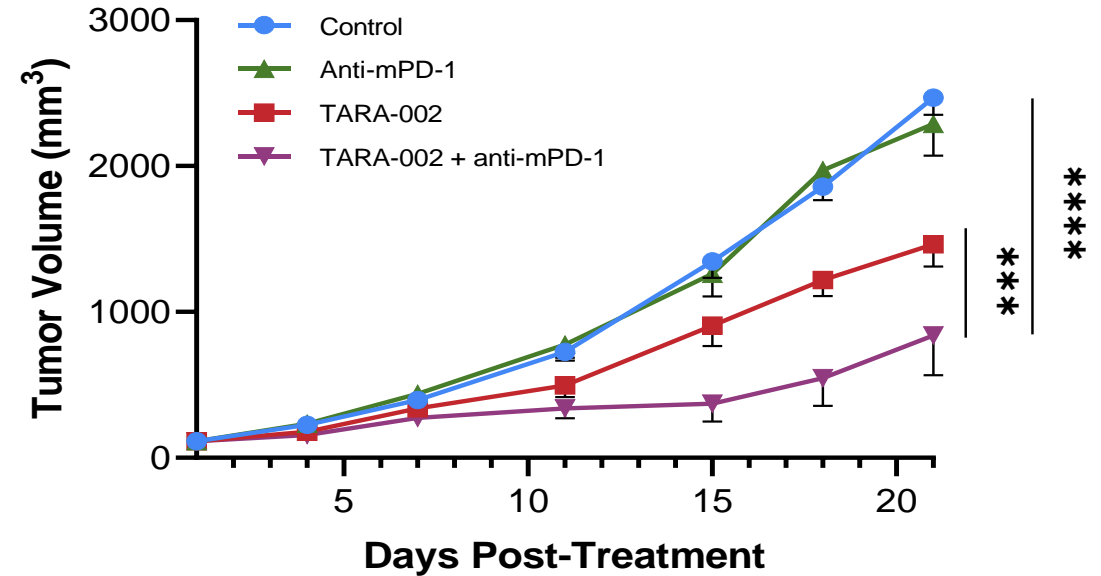
CD8+ T cells



T cells isolated from two healthy donors (n=2) were treated with 0.2 KE/ml TARA-002 for 72 hours. Then, T cells were analyzed by flow cytometry for KI67, CTLA4 and PD-1 quantification. Supernatants were collected for ELISA test

Mean ±SEM. Two-way ANOVA, post-hoc Sidak's test. *, P<0.05, ***, P<0.001, ****, P<0.0001

Murine study in non-immunoresponsive cancer model

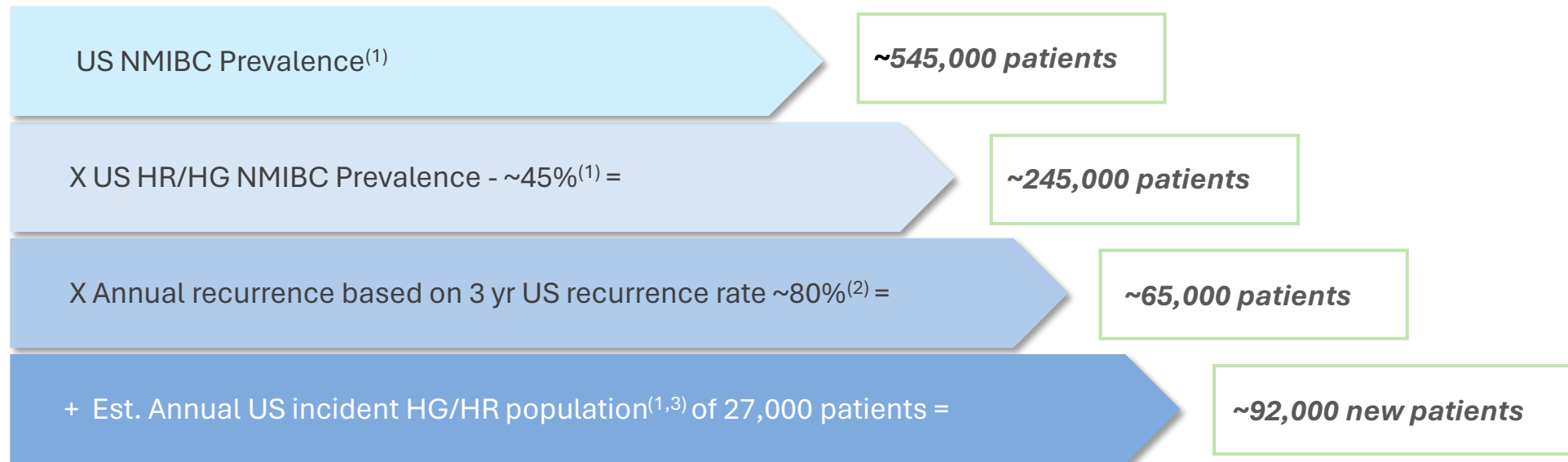


In an orthotopic mouse model of TNBC (using EMT6 cells) that is **unresponsive to anti-PD-1 monotherapy**, combination of an anti-PD-1 mAb and TARA-002 was more effective than either monotherapy.

FDA has cleared combo with pembrolizumab study, plan to initiate Ph2 in 2H'24

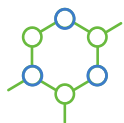
HIGH-RISK, HIGH GRADE NMIBC: A SIGNIFICANT ADDRESSABLE MARKET IN THE US

Even in highly competitive scenarios, the market is large enough to sustain multiple entrants



Over 90K HR/HG NMIBC annual patients, at branded therapeutics pricing = ~\$5bn-\$6bn addressable US market broad enough for a variety of modalities and mechanisms of action (MOAs) to succeed

TARA-002 HAS A DIFFERENTIATED PROFILE IN NMIBC WITH ENCOURAGING INTERIM DATA



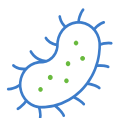
BROAD SPECTRUM IMMUNE ACTIVATION

- Broad immunopotential is known to drive durable response (e.g., BCG)



LOGISTIC PROFILE IDEAL FOR COMMUNITY SETTING

- No additional administration procedures or safety protocols required vs. other products



INACTIVATED BACTERIA

- Improves tolerability
- Allows for systemic administration



FAVORABLE REGULATORY PATH

- Single arm, open-label trial design in BCG-unresponsive NMIBC
- Mandatory 3-month biopsy with NO mandatory 6-or 12-month biopsy



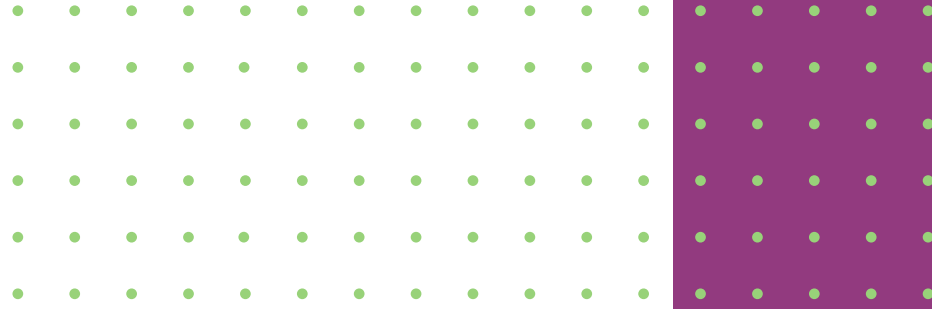
PROMISING PROFILE FOR COMBINATION THERAPY

- No overlapping toxicities with other treatments
- Pre-clinical studies underway



STATE-OF-THE-ART MANUFACTURING WITH RELIABLE SUPPLY

- Advanced, FDA-inspected manufacturing with 20mm vial capacity
- Reliable cGMP process; capable of commercial scale product manufacturing
- Significantly shorter doubling time (2hrs) vs. BCG (16hrs) means TARA-002 will not face any of the BCG supply issues

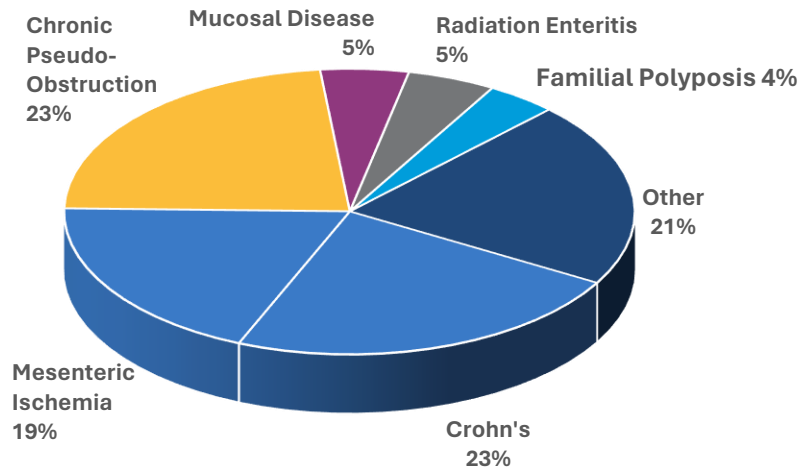


IV CHOLINE CHLORIDE

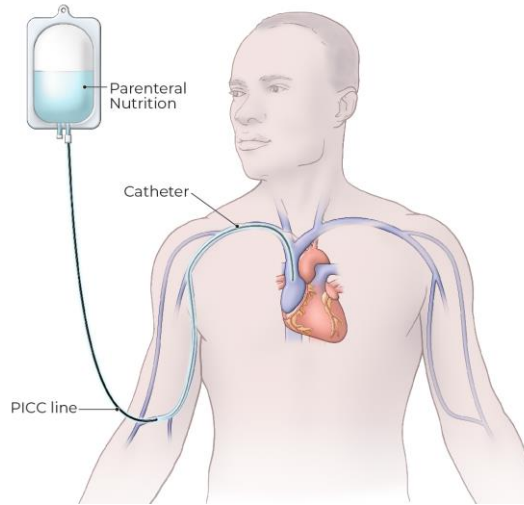
Phospholipid substrate replacement therapy for patients
dependent on parenteral nutrition (PN)

OVERVIEW OF PARENTERAL NUTRITION

Underlying Etiology⁽¹⁾

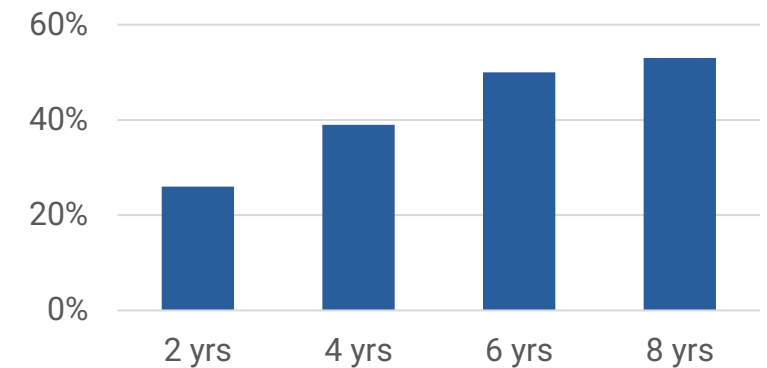


Over time, dependent on PN



Liver disease a well-known consequence of PN

Complicated Liver Disease in PN⁽²⁾



Patients are dependent on PN to meet their nutritional needs; cannot sufficiently create or absorb many important nutrients;
most notably Choline

Majority of nutrition is delivered via **central line** as a **sterile injectable drug** – only approved via NDA

~40,000 HPN patients in the US³

FDA HAS CLEARED THE WAY FOR PK/PD-BASED ENDPOINTS FOR OUR PIVOTAL STUDY



~80% of PN patients are choline deficient

- ~80% of PN-dependent patients are choline-deficient and have some degree of liver damage¹
 - Data confirm choline deficiency results in liver, bone, muscle and cognitive impairment.^{2,3}
-



Phase 2 study confirmed choline replacement restored normal levels

- Choline replacement is included in guidelines and recommendations by key PN professional associations
 - Independently conducted Phase 2 data demonstrated significant improvement in serum choline concentrations and a pronounced impact on steatosis³
-

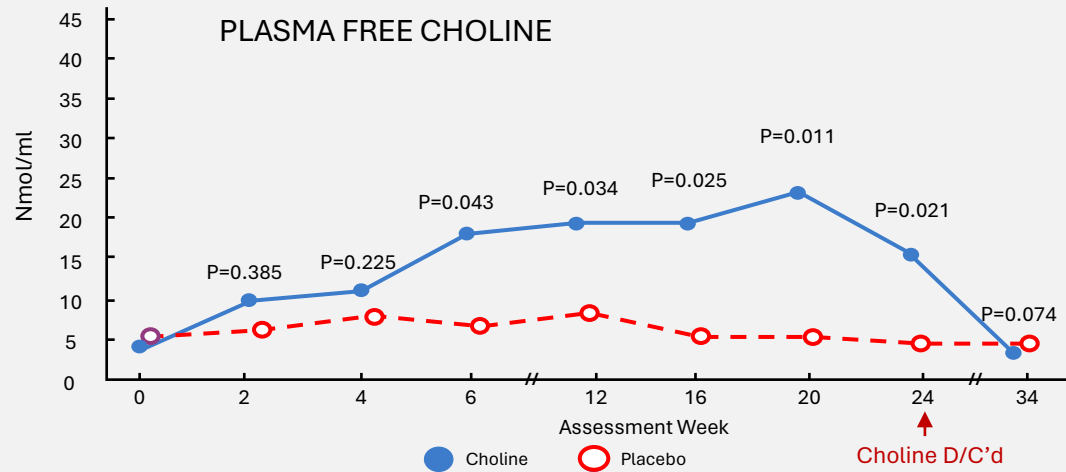


FDA has cleared the way for “source of choline” label with single study

- FDA granted a targeted label of “source of choline for parenteral nutrition patients who are, or may become, choline-deficient”
- Single study demonstrating an increase in choline levels required (already demonstrated in Ph 2 trial)
- 40K addressable patient population, no competitors and compound patent in U.S. to 2041

INDEPENDENT STUDIES DEMONSTRATE THAT TREATMENT WITH IV CHOLINE RAPIDLY RESTORES CHOLINE LEVELS AND IMPROVES STEATOSIS

PLASMA FREE CHOLINE LEVELS: ALL PATIENTS⁽¹⁾



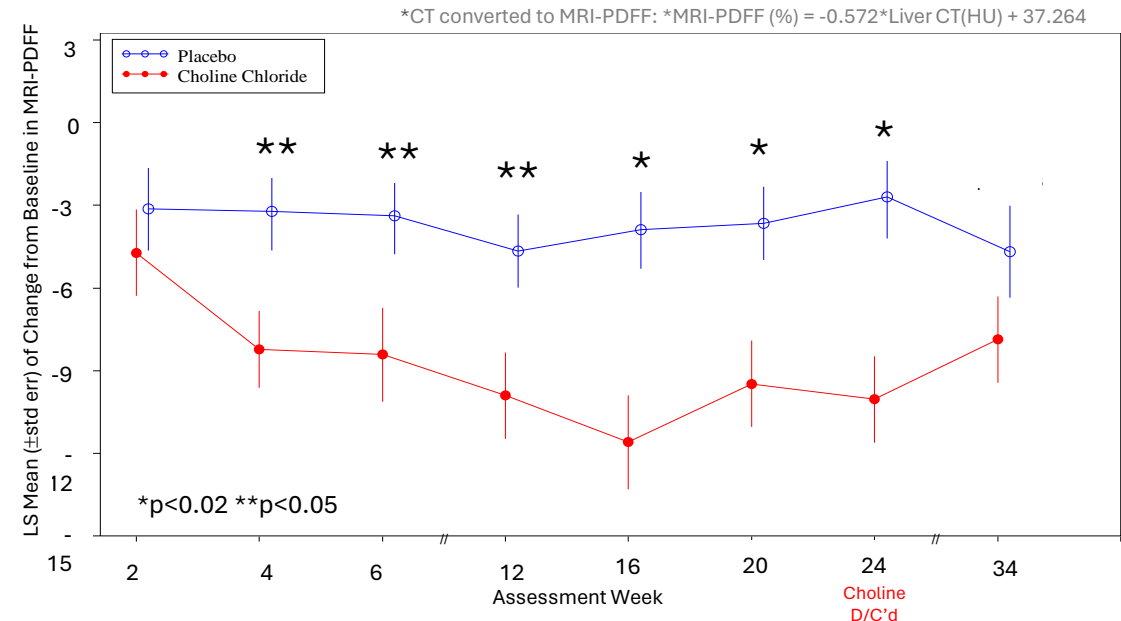
Choline supplementation was discontinued at week 24. Data are presented for all subjects up until time of withdrawal from the study.

Studies conducted by independent academic institution

1. Buchman et al. JPEN, 2002 - Protara Therapeutics re-analysis of patient CRFs, data on file.

Primary endpoint to replicate in registrational trial

CLINICALLY MEANINGFUL IMPROVEMENT IN STEATOSIS⁽¹⁾








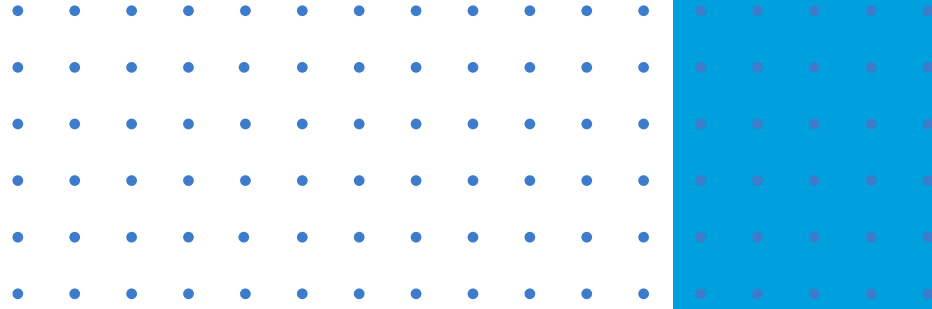
Significant differences in the LS mean change from baseline in MRI-PDFF observed in Choline group vs. placebo at Weeks 4 - 24, demonstrating a clinically meaningful and statistically significant reduction in steatosis (range 31%-54%)

Secondary endpoint to replicate in registrational trial to support clinical benefit

CHOLINE REPLACEMENT RECOMMENDED IN KEY PN GUIDELINES

Parenteral Nutrition Professional Societies' Position on Choline

 <p>Guidelines / Position Paper</p>	<p>ASPEN 2012 Position Paper (Vanek et al.)³:</p> <ul style="list-style-type: none">• Includes recommendations for Multivitamins & Multi-Trace Element PN Products• Recognises the impact of long-term choline deficiency on the development of steatosis and hepatocellular carcinoma• Recommends that a commercially available parenteral choline product, either as an individual product or incorporated into a multivitamin product, should be developed and routinely added to adult PN formulas at a dose of 550 mg per day  	<p>ESPEN Micronutrient Guideline 2022 (Berger et al.)⁴:</p> <ul style="list-style-type: none">• (Can/may) monitor choline in patients with abnormal liver function• (Can/may) consider treatment of HPN patients with abnormal liver function or proven deficiency with 550mg-2g/day choline• (Can/may) prescribe a dose of 400-550 mg choline via EN or PN per day has been suggested to support lipid metabolism  
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TARA-002

Lymphatic Malformations (LMs)



TARA-002 IN LMs



LYMPHATIC MALFORMATIONS

Rare, non-malignant lesions consisting of dilated, lymphatic fluid-filled sacs caused by abnormal development of the lymphatic endothelial system⁽¹⁾



EPIDEMIOLOGY

Epidemiology: incidence of lymphatic malformations is \approx 1,400-1,800 LM cases per year⁽²⁾



CURRENT TREATMENT OPTIONS

Current treatment options include surgical excision with high complication (33%) and recurrence (55%) rates⁽³⁾ as well as off-label use of sclerosants



POTENTIAL PRV UPON APPROVAL (**POTENTIALLY \$75MM-\$100MM NON-DILUTIVE CAPITAL**)

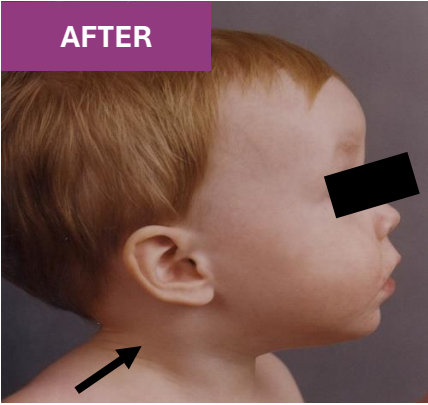
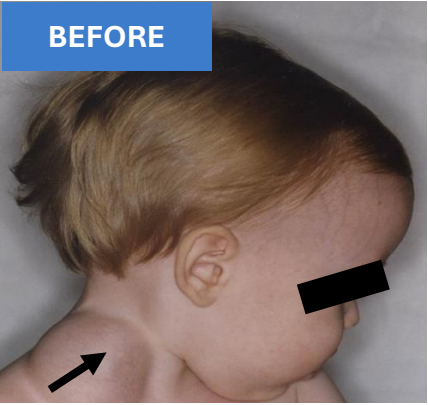
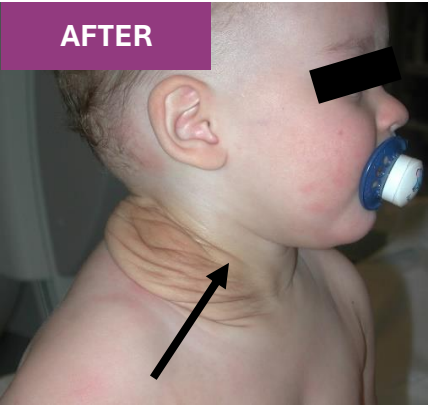
Granted RPDD in 2021



NEXT STEPS

Complete enrollment of first safety cohort and commence efficacy expansion cohort in Ph 2 STARBORN-1 trial by end-2024

CLEAR EVIDENCE OF BIOLOGIC ACTIVITY OBSERVED WITH OK-432*



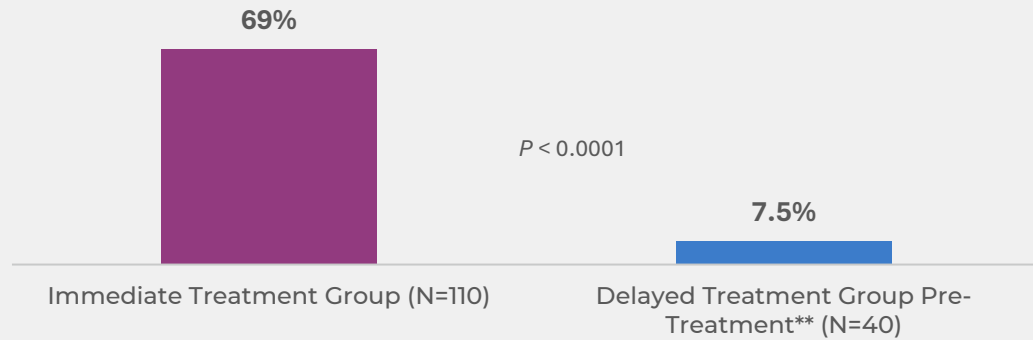
Completed clinical study of OK-432 (TARA-002 predecessor therapy) in U.S. suggests effectiveness with strong support for safety profile

*TARA-002 is developed from the same master cell bank as OK-432

ROBUST CLINICAL RESULTS IN LARGE, ACADEMIC STUDY OF OK-432

69% CLINICAL SUCCESS[†] IN IMMEDIATE TREATMENT GROUP 6 MONTHS AFTER ENROLLMENT

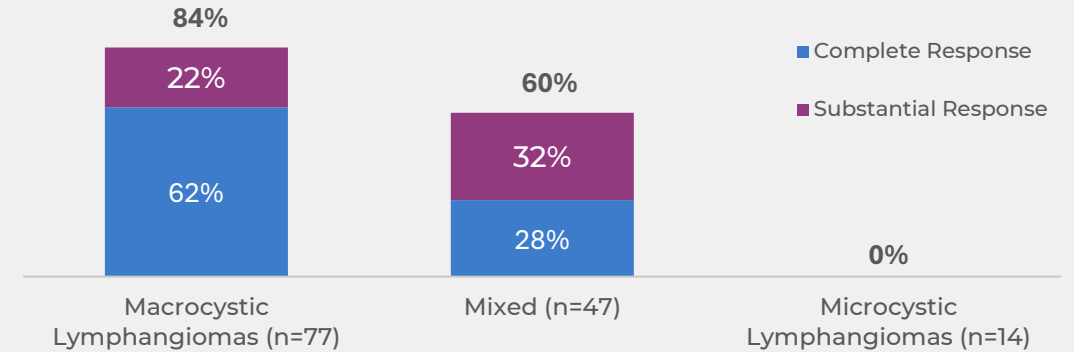
ITT: Observations 6 Months After Enrollment



- During this same period, 7.5% of patients in the delayed treatment group experienced spontaneous regression of LM
- Treatment: 1-4 injections at 8-week intervals max of 0.2mg/session (2KE)

84%* CLINICAL SUCCESS[†] IN PATIENTS WITH MACROCYSTIC LESION TYPES

Complete or Substantial Response by Radiographically Confirmed Lesion Type**



- Patients with radiographically confirmed macrocystic lesions had the greatest chance for clinical success
- In those patients with mixed lesions, clinical success was still achieved

[†] Clinical Success was defined as complete or substantial response.

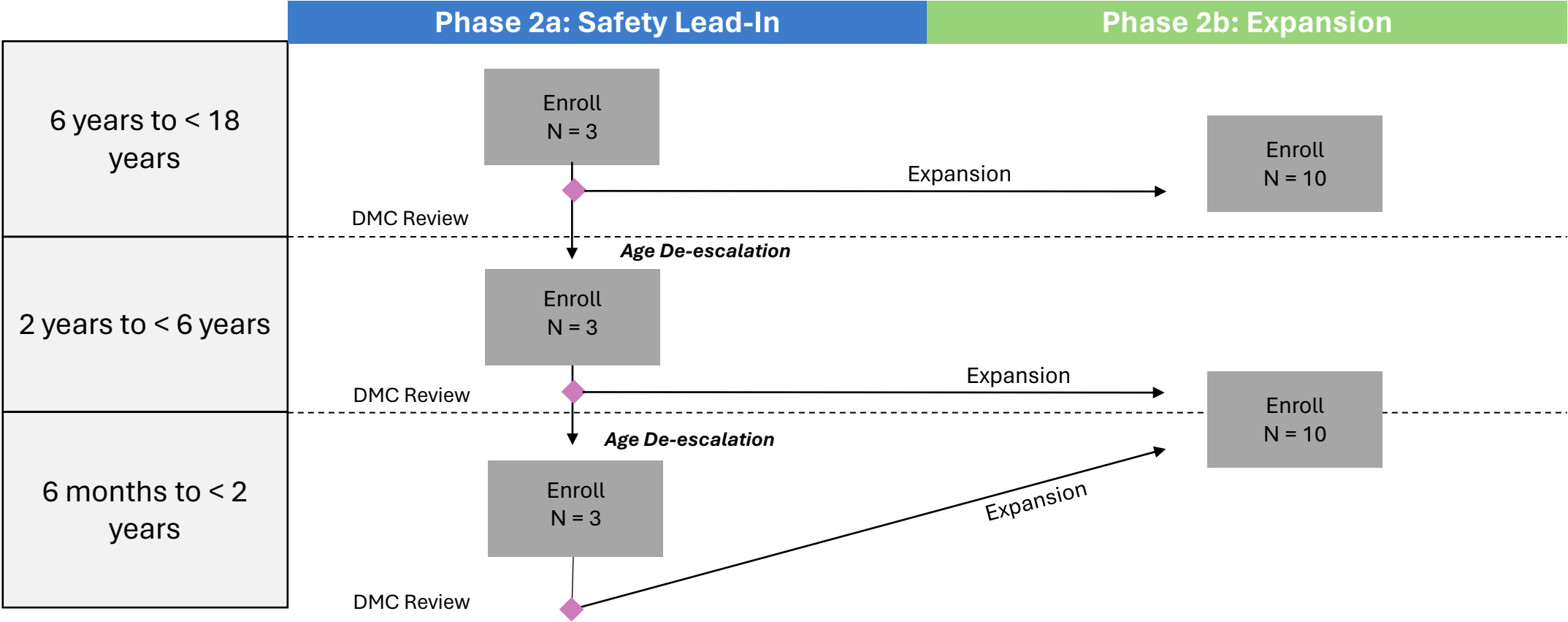
*Reflects data prior to dosing with OK-432. After dosing, the clinical success rate was 66%, which was not statistically different from the Immediate Treatment Group.

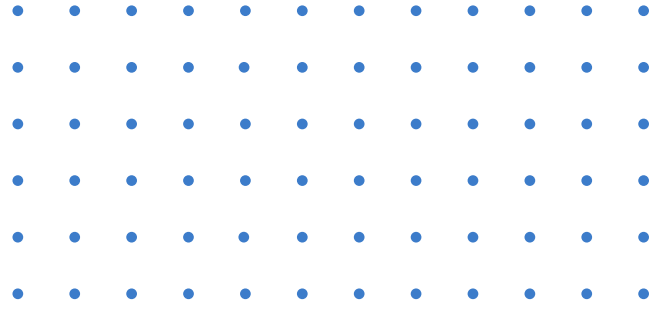
**Results were analyzed by lesion type across all treatment groups

1. Results based on retrospective analysis of source verified data that included the full dataset of subjects enrolled in randomized study between January 1998 and August 2005, including data in the published study (Smith et al. 2009) which included subjects enrolled between January 1998 and November 2004.

TARA-002 IN LMS: PHASE 2 STARBORN-1 TRIAL UNDERWAY

Single Arm Open-Label Safety and Efficacy Study of TARA-002 in Pediatric Patients with Macrocytic and Mixed-cystic LMs (N=29)





SUMMARY

MULTIPLE NEAR-TERM CATALYSTS

	1H'24	2H'24	1H'25	2H'25
NMIBC: BCG-Naïve POC	<div></div> Current pooled preliminary 3-month data from ADVANCED-1a, 1b and ADVANCED-2	<div></div> 10 patient risk benefit Begin 80KE and systemic priming exploration	<div></div> 80KE data	<div></div> Systemic Priming data
NMIBC: BCG-Unresponsive registrational*			<div></div> 25 patient futility analysis	<div></div> Complete enrollment of registrational* trial
Combination Study with checkpoint inhibitor in BCG-experienced		<div></div> Initiate Ph 2 POC combo		<div></div> Results of Ph 2 POC combo trial Initiate Ph 3 trial
IV Choline	<div></div> Announce PK-based pivotal study design			
LMs Ph 2			<div></div> Interim data	<div></div> Interim data on first efficacy cohort

BALANCE SHEET:
 \$55M of cash, cash equivalents and investments as of March 31, 2024;
 Cash runway into 2026 (with \$45M gross proceeds from April 2024 private placement)

COMMON SHARE EQUIVALENTS:**
 11.4M Common + 8.0M Preferred on as converted basis as of March 31, 2024
 20.6M Common + 8.0M Preferred + 1.7M Pre-funded warrants (reflects April 2024 private placement)

*Designed to be registrational aligned with FDA guidance on NMIBC clinical trials **Does not include 10.8M common warrants issued with the April 2024 private placement exercisable at a \$5.25 per share at the earlier of April 10, 2027 or 90 days after public announcement of a minimum 42% six-month CR rate from at least 25 BCG-Unresponsive patients in the ADVANCED-2 clinical trial.

APPENDIX



TARA-002 IN NMIBC: DEMOGRAPHICS AND DISEASE CHARACTERISTICS FROM POOLED 3-MONTH EVALUABLE PATIENTS

Median age, years [range]	73	[56-90]
Sex, number		
Men	13	81%
Women	3	19%
Race/Ethnicity		
White	16	100%
Black	-	
Asian	-	
Other	-	
Hispanic or Latino	1	6%
Non-Hispanic or non-Latino	15	94%
Baseline ECOG		
1	5	31%
2	10	63%
3	1	6%

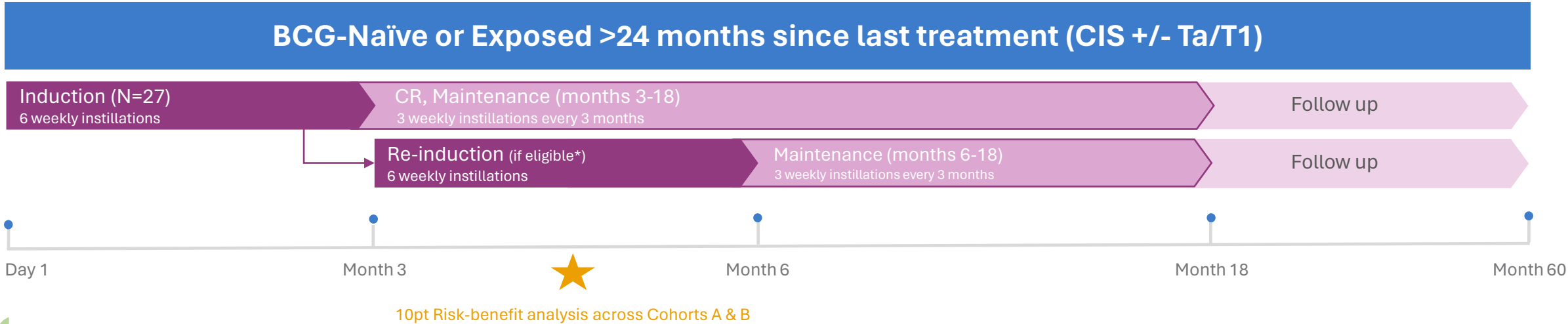
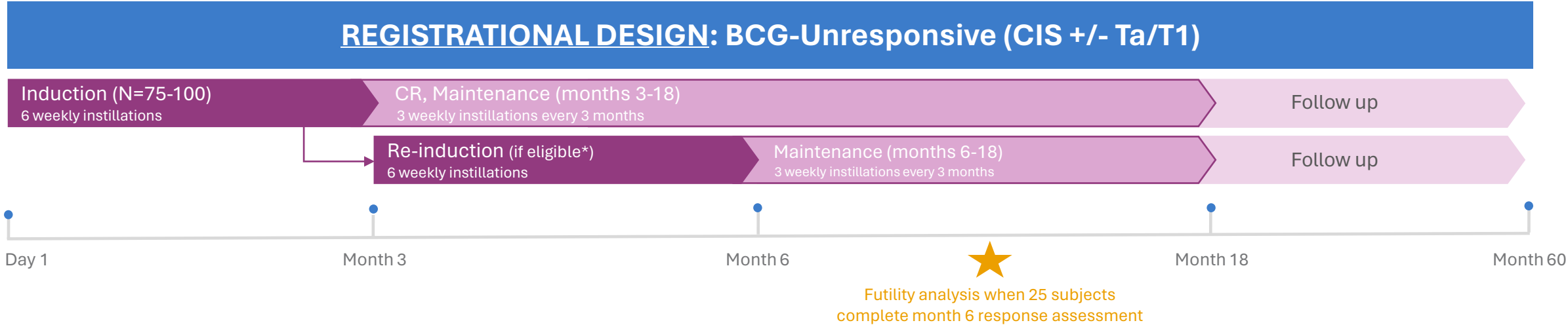
Data cutoff 3/19/24

Median number of prior BCG doses	n	%
Subjects with ≥ 12 prior BCG doses	3	19%
Subjects with < 12 prior BCG doses	13	81%
Type of prior non-BCG treatments		
Gem	1	
Gem/Doce	3	
Mitomycin	2	
Pembrolizumab	1	
Other	1	
Number of prior TURBT		
Subjects with > 3 TURBTs	2	12%
Subjects with ≤ 3 TURBTs	14	88%
BCG Status		
BCG naïve	9	57%
BCG unresponsive	5	12%
BCG exposed	2	31%
Disease type		
CIS only	8	50%
CIS + Ta	5	32%
CIS + T1	3	18%

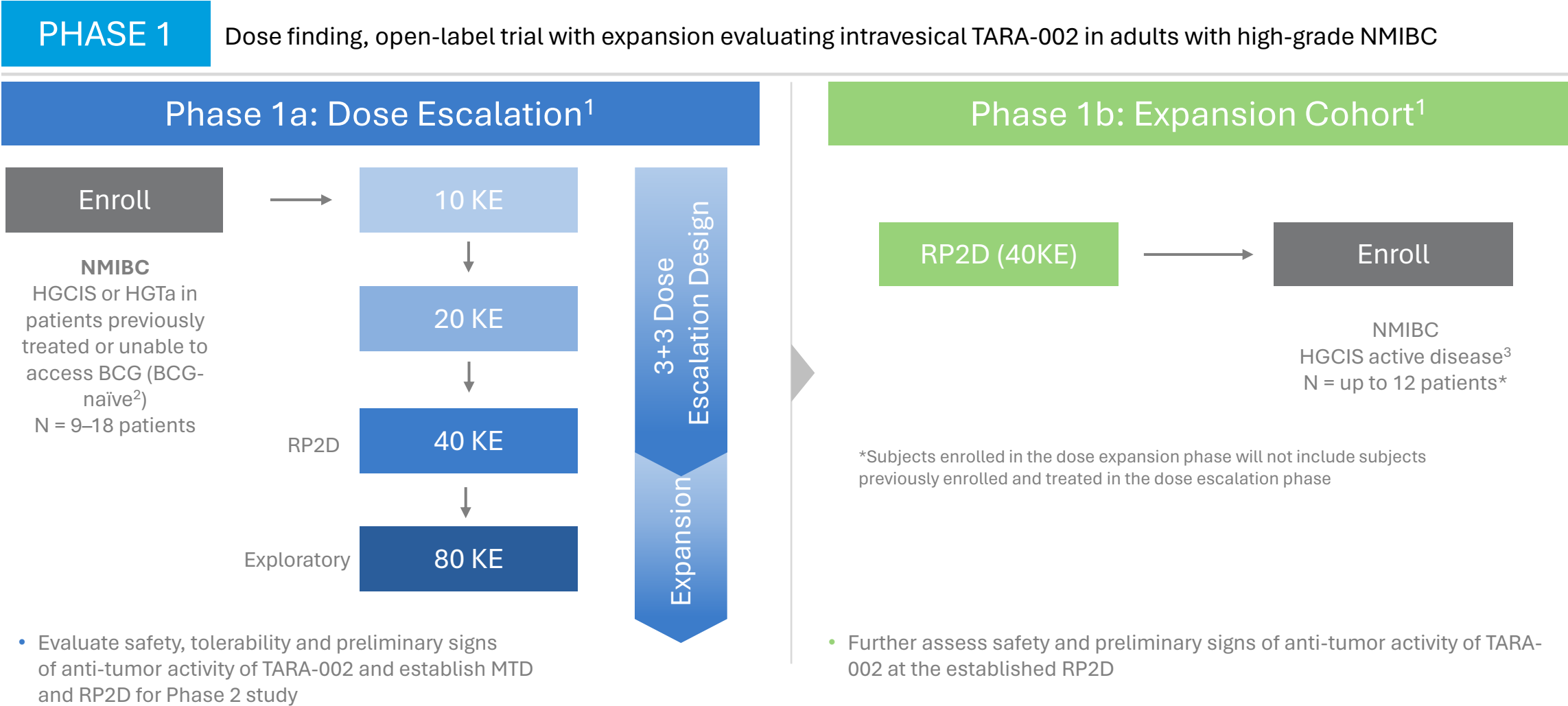
*Patient contribution across trials: ADVANCED-1 Ph 1a = 3 patients; ADVANCED-1 Ph 1b = 8 patients; ADVANCED-12 Ph2 naïve cohort = 5 patients

TARA-002 IN NMIBC: ADVANCED-2 TRIAL DESIGN

Primary endpoint of high-grade complete response (CR) at any time at 6mos; Key secondary of 12-month DOR



TARA-002 IN NMIBC: PHASE 1 CLINICAL TRIAL DESIGN



TARA-002: MANUFACTURING IS A POTENTIAL COMPETITIVE ADVANTAGE

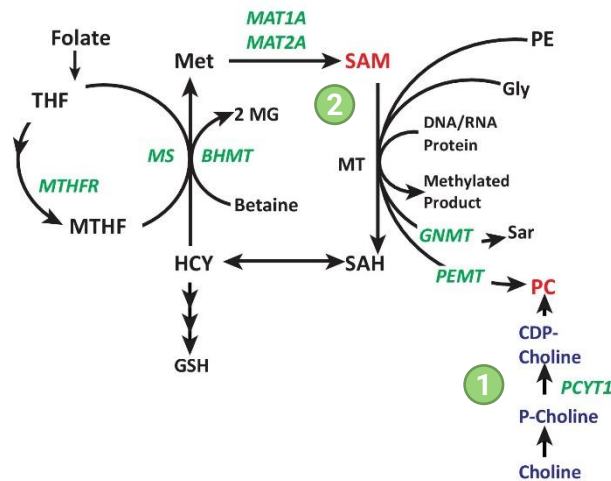


- ✓ 20 million vial/year capacity with ability to 5x supply as needed
- ✓ 47 successful batches run to date, 15 at commercial scale
- ✓ Capable of manufacturing cGMP commercial product in preparation of Chugai partial change application completion; anticipated for end-2024
- ✓ Completed FDA inspection without Form 483s
- ✓ Two-week batch completion time vs. 3 months for BCG
- ✓ We believe our manufacturing process is a competitive advantage

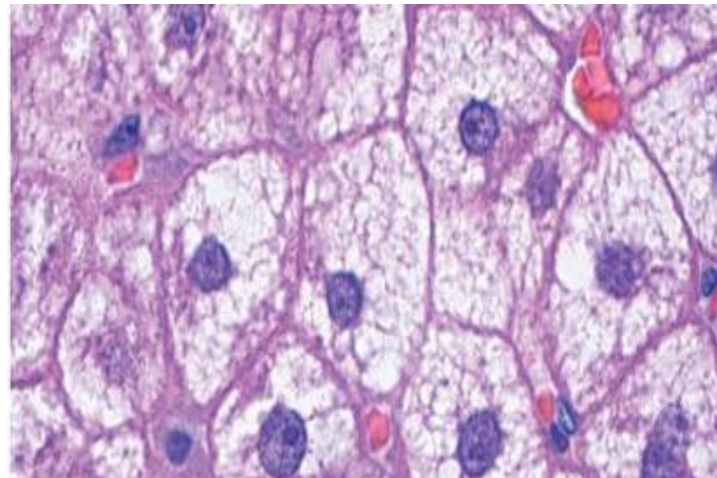
CHOLINE DEFICIENCY RESULTS IN HEPATOBILIARY PATHOPHYSIOLOGY

Diminished Choline = Insufficient phosphatidylcholine (PC), resulting in hepatobiliary injury

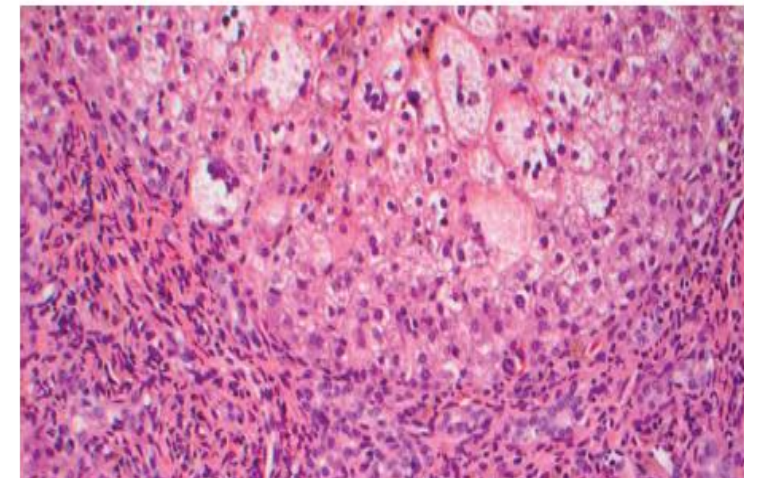
Affected Pathways



Steatosis



Cholestasis



- PC is the most ubiquitous phospholipid in the body

- Throughout the body, PC is synthesized almost exclusively through exogenous choline consumption (Kennedy pathway)
- Intra-hepatically, the PEMT pathway can provide 30% of the liver's needs⁽¹⁾

- PC is the primary lipid of the VLDL particle surface monolayer. Low PC levels inhibit VLDL packaging and secretion. Without sufficient VLDL – fats rapidly accumulate in hepatocytes⁽²⁾

- PC comprises ~ 40% of bile's organic matter⁽³⁾. Insufficient PC in bile increases free bile salts, restricting bile flow and damaging biliary epithelium⁽⁴⁾⁽⁵⁾

IV CHOLINE: SUPPORTIVE EVIDENCE ACROSS 4 INDEPENDENTLY CONDUCTED CLINICAL STUDIES

