PROTARA
THERAPEUTICS

CORPORATE PRESENTATION

November 2024

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PROTARA THERAPEUTICS

DE-RISKED PIPELINE

- Applying modern scientific advancements to established mechanisms for attractive markets

TARA-002 IN NMIBC

- Encouraging, pooled 3-month interim data in 16 CIS patients
- Interim data from ADVANCED-2 trial anticipated in Q4’24
- Unique product characteristics anticipated to drive significant adoption
- Non-clinical work for priming and combination therapy ongoing

IV CHOLINE IN PS PATIENTS

- Plan to initiate pivotal PK trial in Q1’25
- FDA granted Orphan Drug Designation and Fast Track Designation

TARA-002 IN LMs

- Dosing pediatric LMs patients in Phase 2 STARTBORN-1 trial
- FDA granted Rare Pediatric Disease Designation

Non-muscle invasive bladder cancer (NMIBC); Lymphatic malformations (LMs); Parenteral Nutrition (PN) Carcinoma in situ (CIS); Bacillus Calmette-Guerin (BCG); Immuno-oncology (I-O)

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 Q4'24*
TARA-002 Combination	NMIBC: CIS+/- Ta/T1					*Assessing best possible combination*
RARE DISEASES						
IV CHOLINE	Choline for parenteral support (PS) patients*	**THRIVE-3**				*PK-based registrational study to initiate in Q1'25*
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; POC=Proof of Concept

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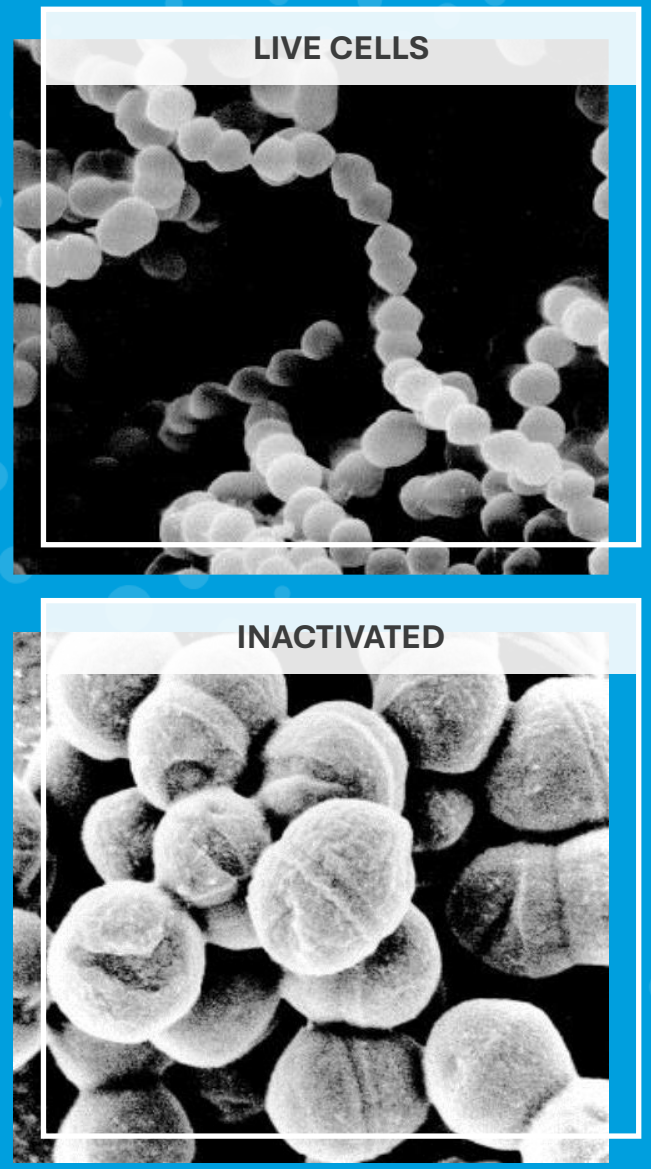
TARA-002

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



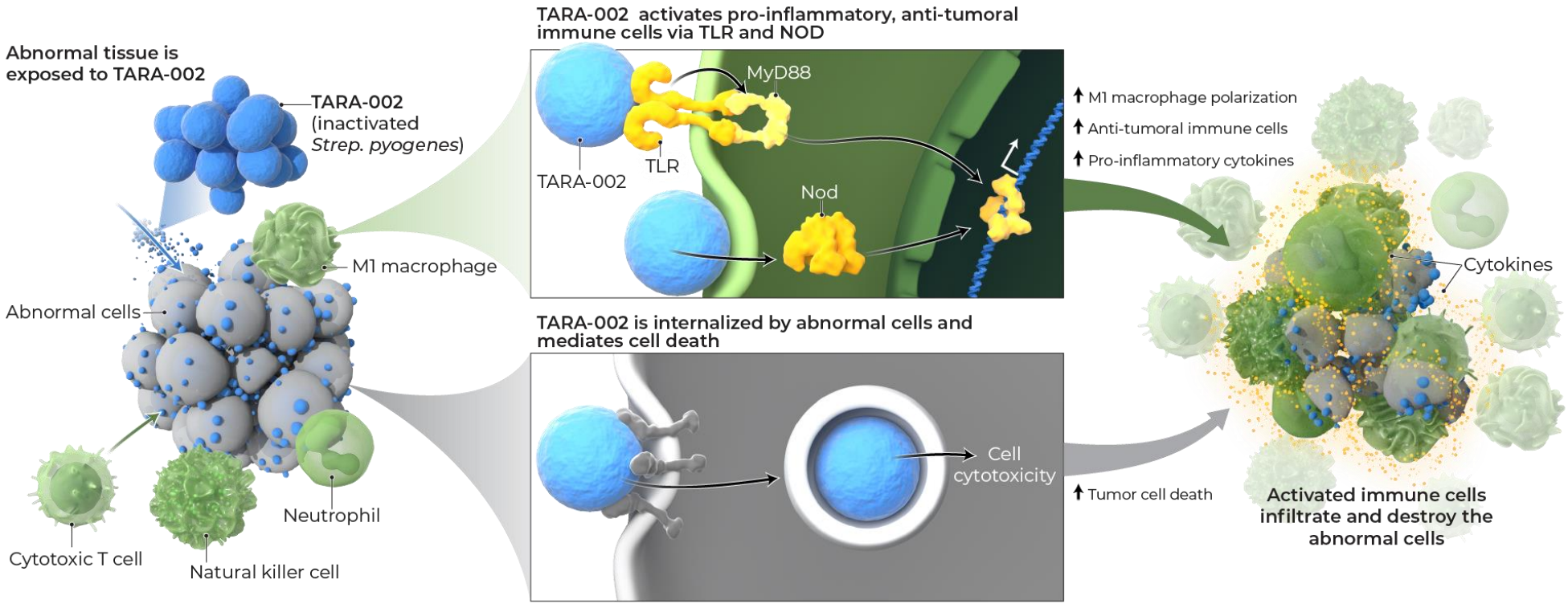
1. Marketed in Japan as Picibanil®.

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



1. Fujimoto T., et al. J Immunol. 1997: 5619. | 2. Ryoma Y, et al. Anticancer Res. 2004; 3295-3298. | 3. Zhao H, et al. Microbiol. Immunol. 1994; 183-190.

TARA-002

Non-Muscle Invasive Bladder Cancer

BLADDER CANCER: SIGNIFICANT UNMET NEED WITH LIMITED TREATMENT OPTIONS

All Bladder Cancers

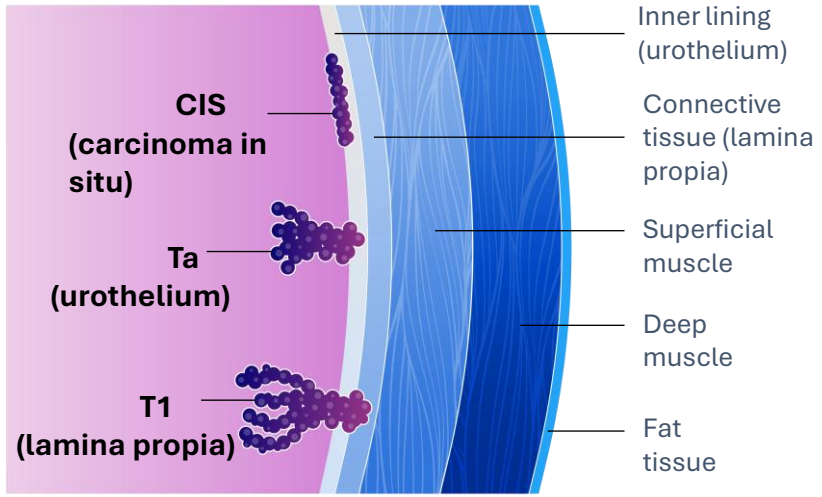
~80,000

People will be **diagnosed with bladder cancer** this year in the US[1]

~725,000

People estimated **living with bladder cancer** this year in the US[1]

NMIBC



~75%

Of all bladder cancer diagnoses are **NIMBC**[2]

80%

Estimated to **recur in 3 years**[3]

BCG-UN; Significant unmet need

~40% to 50%

BCG failure rate
radical cystectomy is the SOC after BCG failure[4]

FDA

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.

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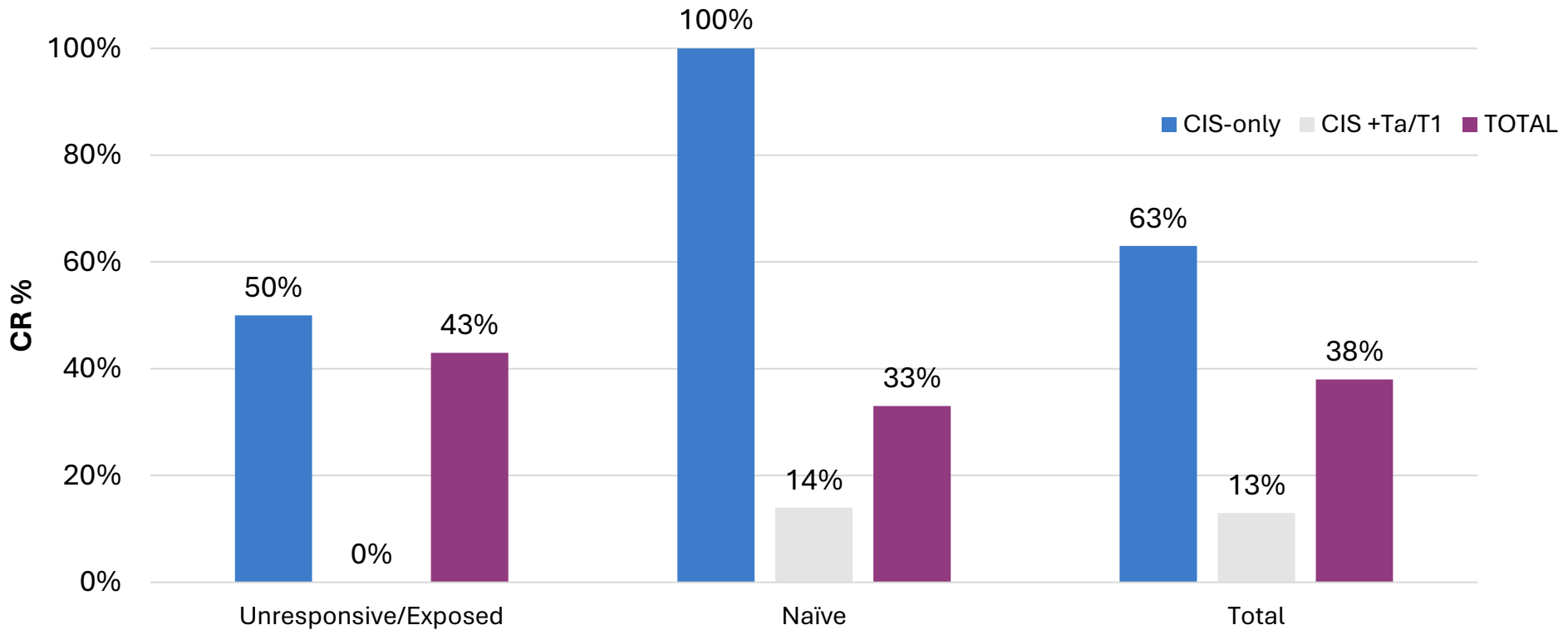
TARA-002 INTERIM 3-MONTH DATA DEMONSTRATES ENCOURAGING ACTIVITY

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



CRs	**CIS-only**	N=3/6	N=2/2	N=5/8
	CIS + Ta/T1	N=0/1	N=1/7	N=1/8
	Total	N=3/7	N=3/9	N=6/16

*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%)	***All Grade 3 AEs were deemed to be not treatment-related:*** 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 extabation 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.

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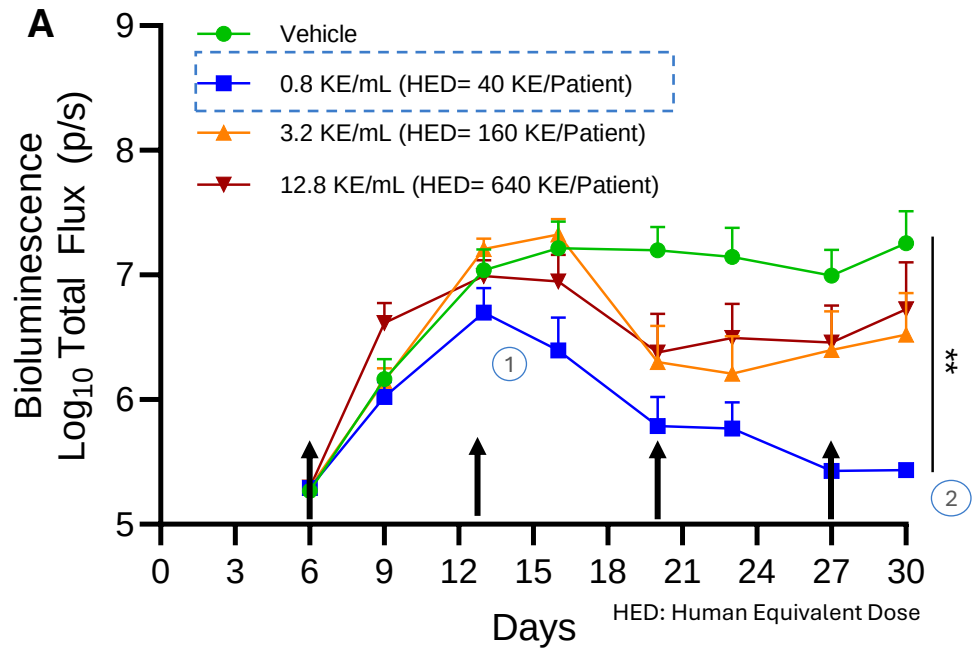
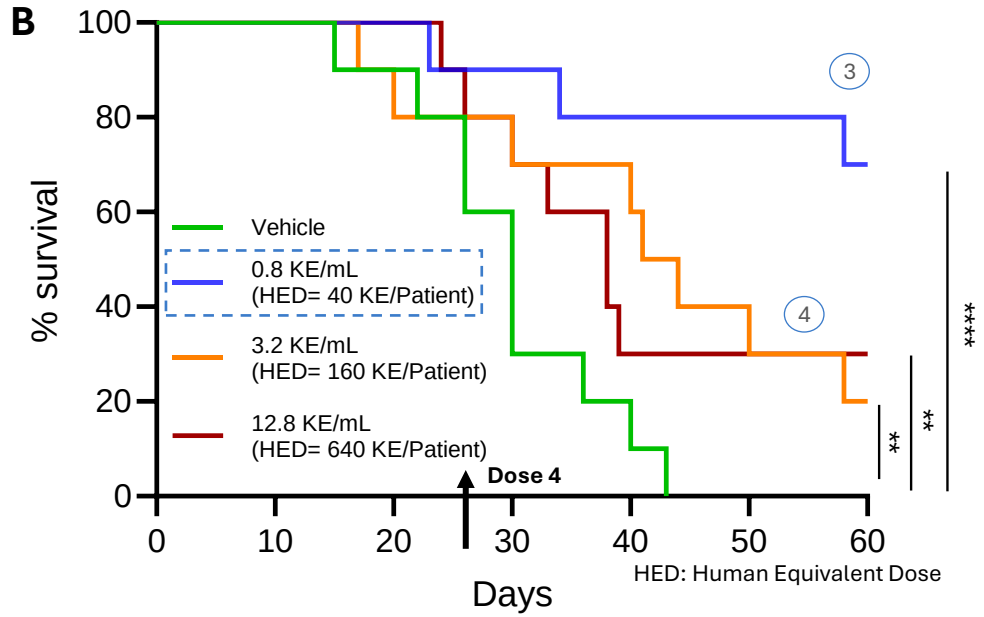
Definitions: AEs=Adverse events; UTI=urinary tract infection; ALP=Alkaline phosphatase; RBCs=red blood cells

TARA-002 MOUSE MODEL SUGGESTS DURABLE EFFECT, SUPPORTS MODIFICATIONS





1. Evidence of delayed onset to peak therapeutic effect – onset at dose 2
2. Sustained activity following onset
3. Evidence of durable effect – 80% survival and 60% DFS at day 60
4. Apparent 4x clearance to immune exhausting dose

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.

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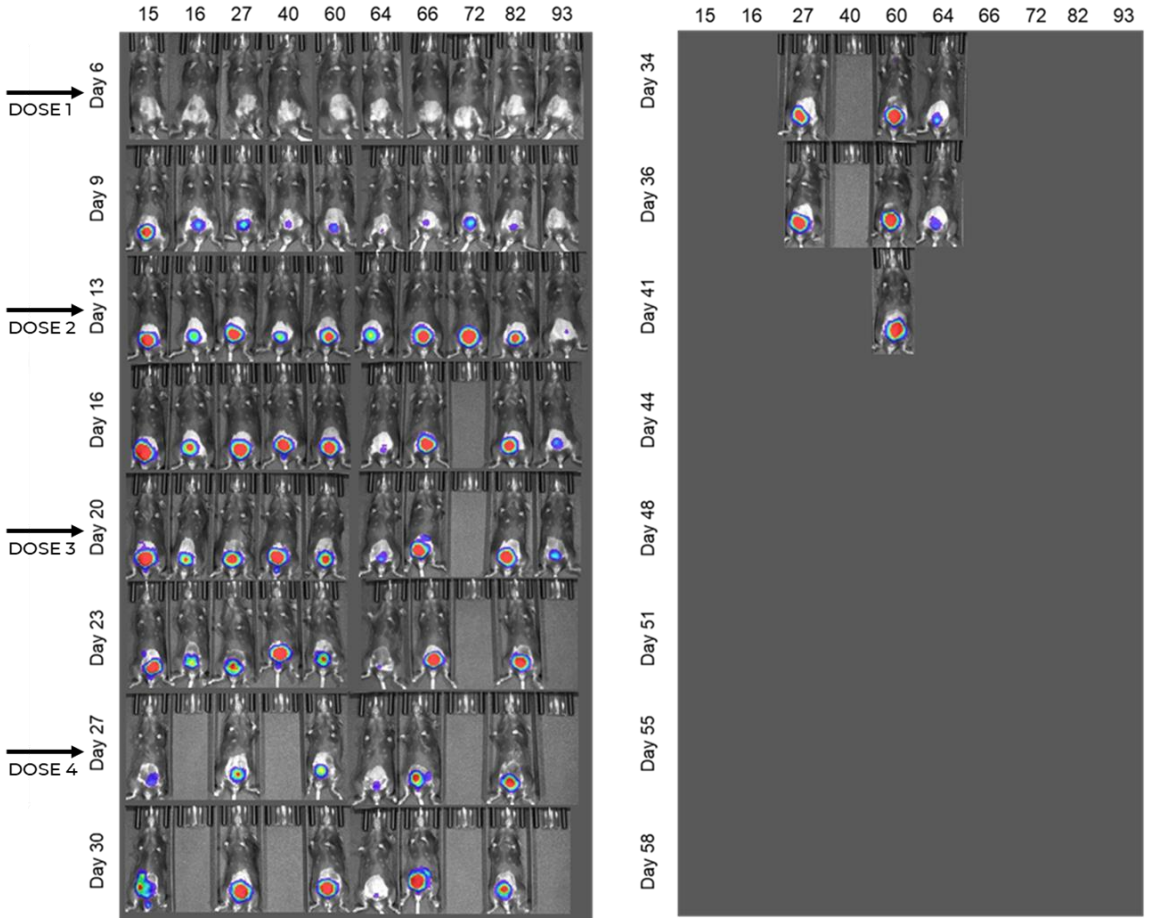
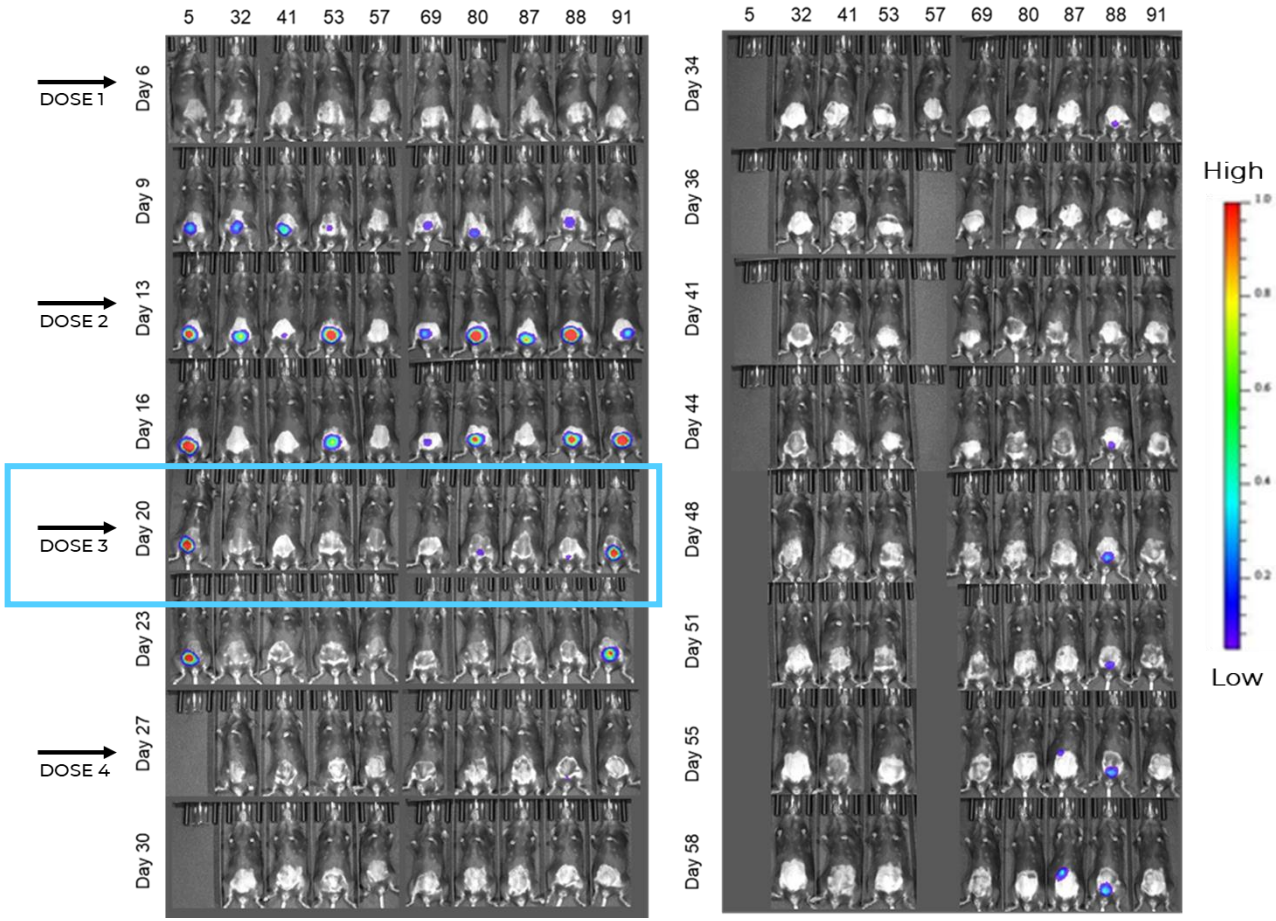
Kaplan Meyer survival curve. Mantel-Cox Test, Bonferroni correction . *, P<0.05; **, P<0.01; ***, P<0.001

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.

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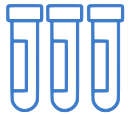
PRIMING, REINDUCTION, AND MAINTENANCE EXPECTED TO ENHANCE TARA-002 RESPONSES



REINDUCTION

- Reinduction using immune therapies has demonstrated 30% to 50%+ salvage[1,2]
- Reinduction with BCG is included in AUA treatment guidelines for NMIBC[3]

MAINTENANCE

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

PRIMING

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

Currently in ADVANCED-2

Exploratory Cohort

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1. Chamie, et al. NEJM. 2022DOI: 10.1056/EVIDoa2200167 | 2. Uchio EM, Lamm DL, Shore ND, et al.. J Clin Oncol. 2022;40(6) TPS598-TPS598. doi: 10.1200/JCO.2022.40.6 | 3. AUA Guidelines: https://www.auanet.org/guidelines-and-quality/guidelines/bladder-cancer-non-muscle-invasive-guideline

TARA-002 ADMINISTRATION IS AMONG THE EASIEST OF NMIBC TREATMENTS APPROVED AND IN DEVELOPMENT

TARA-002 has reduced burden for physicians and patients

TARA-002

No vial thaw, simple preparation; no pre/post treatment protocol

- Preparation: can be conducted on open table or benchtop; no special handling

EG-70

No vial thaw, simple preparation; no pre/post treatment protocol

- Preparation: can be conducted on open table or benchtop; no special handling

N-803/BCG-TICE

Risk of infection for patient and caregivers; urine decontamination burden

- Preparation: mask/gown required to avoid infection
- 6-hour period of required urine bleaching

Adstiladrin

Vial thaw introduces preparation bottleneck; elevated biosafety procedures required; additional pre/post burden for patients

- Anticholinergic premedication
- 3 – 10 hour vial thaw
- Preparation: “universal biosafety precautions” required; USPI contains infection risk warning
- 48-hour period of required urine bleaching

Cretostimogene

Complex process with unclear vial thaw, biosafety, and urine decontamination requirements

- Thaw process not disclosed
- Preparation: BSL2/2+ handling likely required
- Saline wash
- DDM wash
- Saline wash
- DDM re-infusion and dwell (15 min)
- Urine bleaching requirements not disclosed

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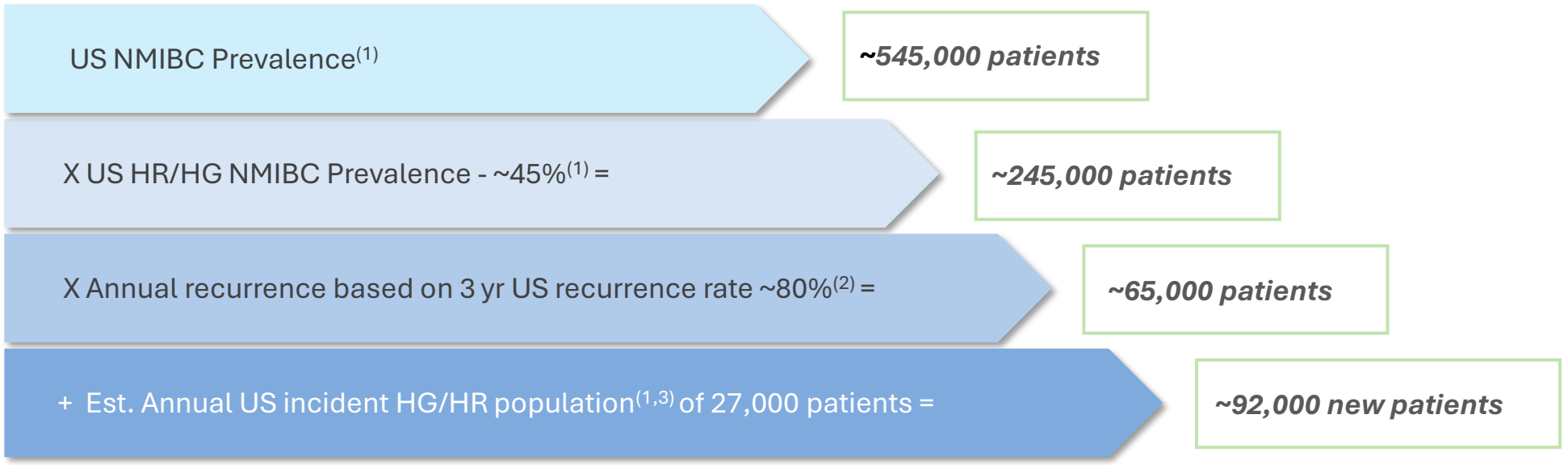
Definitions: USPI – U.S. prescribing information; DDM - dodecyl maltoside;
Data derived from product SOPIs and clinical trial publications

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

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1. SEER Bladder Cancer Facts, estimated from 2020 figures. 2. Campbell Walsh 11th edition, Elsevier.
3. Yu, et al: j European Urology; Volume 61, Issue 6, June 2012, Pages 1239-1244

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

BROAD SPECTRUM IMMUNE ACTIVATION

- Broad immunopotentiation 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

- Currently marketed products in BCG-unresponsive NMIBC approved on basis of a single arm, open-label trial
- Current trial design includes 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 PROCESS

- 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

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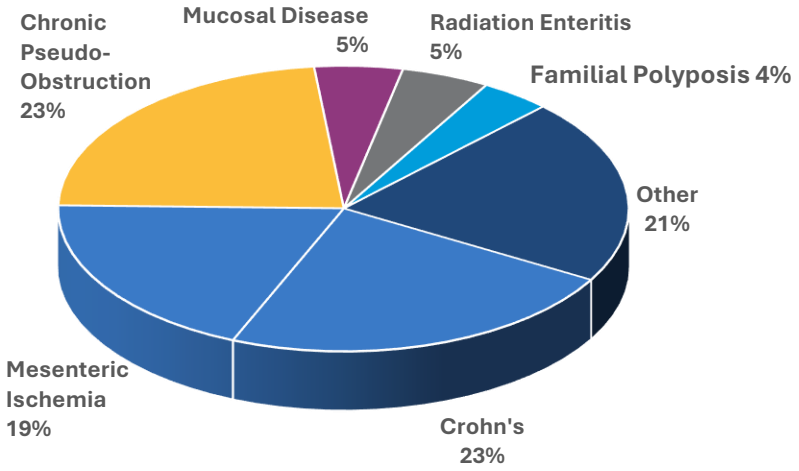
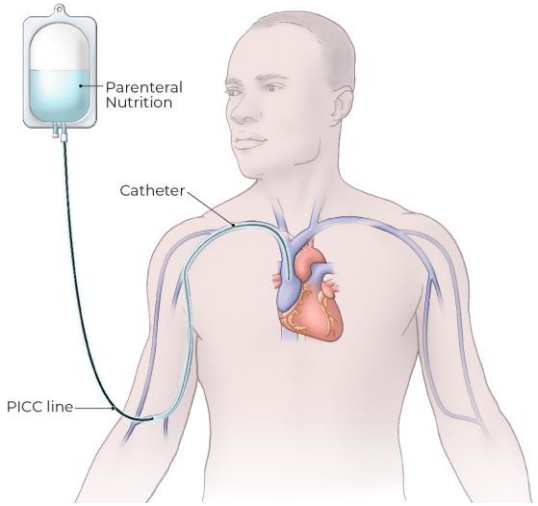
IV CHOLINE CHLORIDE

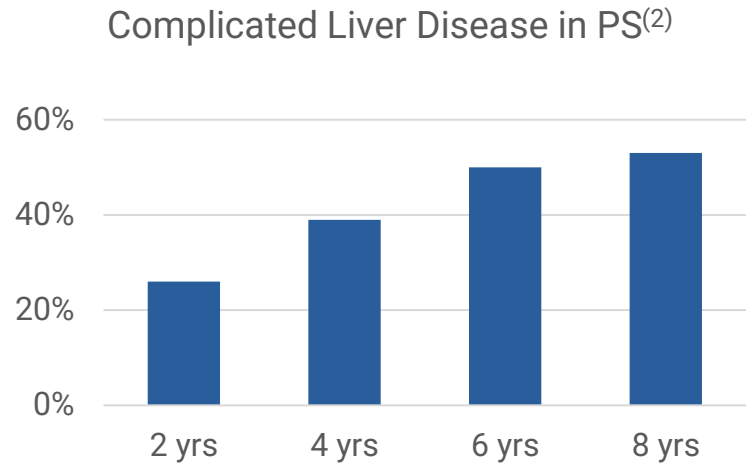
Phospholipid substrate replacement therapy for patients dependent on parenteral support (PS)

OVERVIEW OF PARENTERAL SUPPORT

Underlying Etiology[1] → **Over time, dependent on PS** → **Liver disease a well-known consequence of PS**







Patients are dependent on PS 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

No currently available PS formulations contain choline

1. Sasdelli et al. J Clin Nutr.2018;1:8. | 2. Cavicchi et al. Ann Intern Med. 2000;132:525-532
HPN=Home parenteral nutrition; NDA=New Drug Application

SIGNIFICANT UNMET NEED

~30,000[1] PS patients in the U.S. and the majority are choline deficient

- 78% of PS-dependent patients are choline-deficient and of those 63% have some degree of liver damage[2]
- Data confirm choline deficiency results in liver, bone, muscle and cognitive impairment[3,4]

Phase 2 study confirmed choline replacement restored normal levels

- Independently conducted Phase 2 data demonstrated significant improvement in serum choline concentrations and a pronounced impact on steatosis[4]
- Choline replacement is included in guidelines and recommendations by key PS professional associations

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

- FDA granted a targeted indication of “source of choline for PS patients who are, or may become, choline-deficient”
- Single study demonstrating an increase in choline levels required (already demonstrated in Ph 2 trial)
- Both a compound patent and a method of treatment patent in U.S. to 2041

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1. Data on file | 2. THRIVE-1: A Multi-Center, Cross-Sectional, Observational Study to Assess the Prevalence of Choline Deficiency in Patients Dependent on Parenteral Nutrition. ESPEN. 2024 | 3. Chawla R, et al. Am J Clin Nutr. 1986 42:577-584. | 3. Zeisel S, et al. Neurology. 1980 30:1226-1229. | 4. Buchman et al. JPEN, 2002 - Protara Therapeutics re-analysis of patient CRFs, data on file.
Definitions: IV, intravenous; PN, parenteral nutrition.

CHOLINE REPLACEMENT RECOMMENDED IN KEY PS GUIDELINES

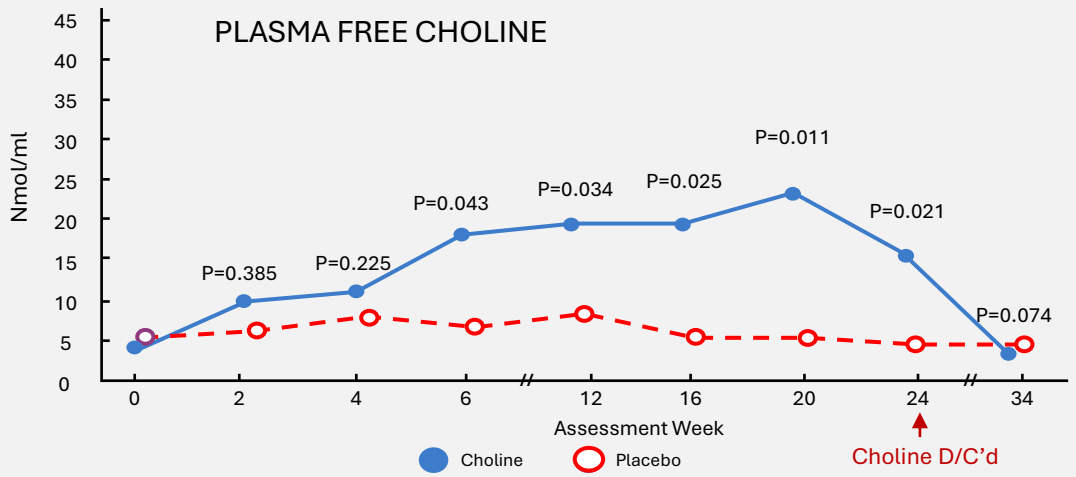
Parenteral Support Professional Societies' Position on Choline

Guidelines / Position Paper	ASPEN 2012 Position Paper (Vanek et al.)[3]:	ESPEN Micronutrient Guideline 2022 (Berger et al.)[4]:
	• Includes recommendations for Multivitamins & Multi-Trace Elements • 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 parenteral formulas** at a dose of 550 mg per day	• **(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

Sources: 1. ASPEN PN Guidelines 2. ESPEN Guideline 3. Vanek et al. 2012. 4. Berger et al. 2022 . Abbreviations: IV = intravenous; (H)PN = (home) parenteral nutrition; EN = enteral nutrition.

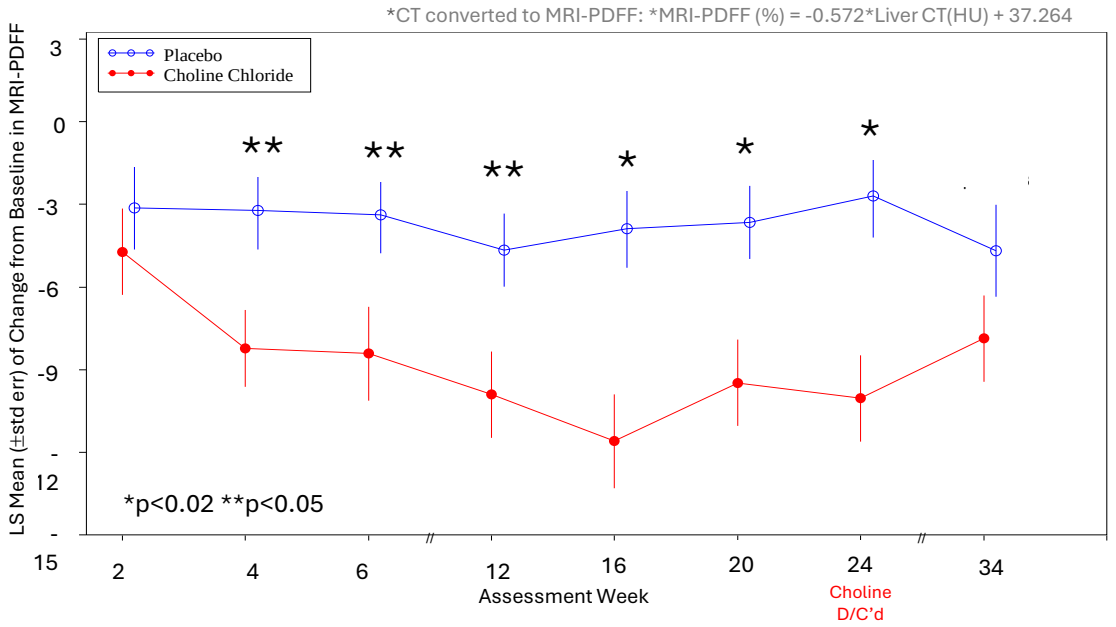
INDEPENDENT STUDIES DEMONSTRATE THAT TREATMENT WITH IV CHOLINE RAPIDLY RESTORES CHOLINE LEVELS AND IMPROVES STEATOSIS

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.

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%)

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

Secondary endpoint to replicate in registrational trial to support clinical benefit

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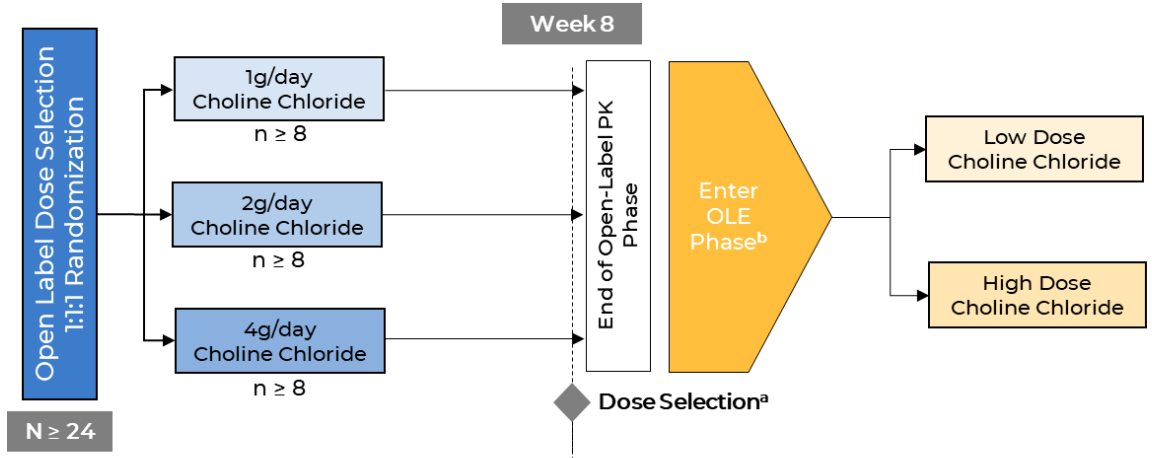
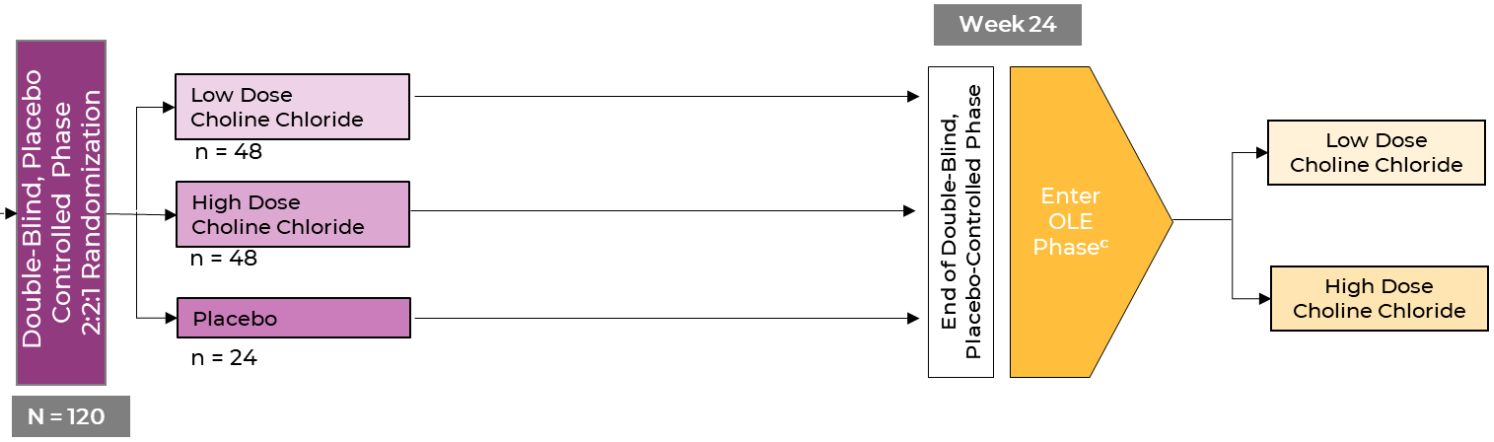
PIVOTAL TRIAL WITH PK-BASED ENDPOINTS TO INITIATE IN Q1’25

THRIVE-3 is a seamless Phase 2b/3 trial with dose confirmation followed by double-blinded, randomized, placebo-controlled trial to assess the safety and efficacy of IV Choline Chloride in adolescents and adults on long-term PS when oral or enteral nutrition is not possible, insufficient, or contraindicated (n=120)



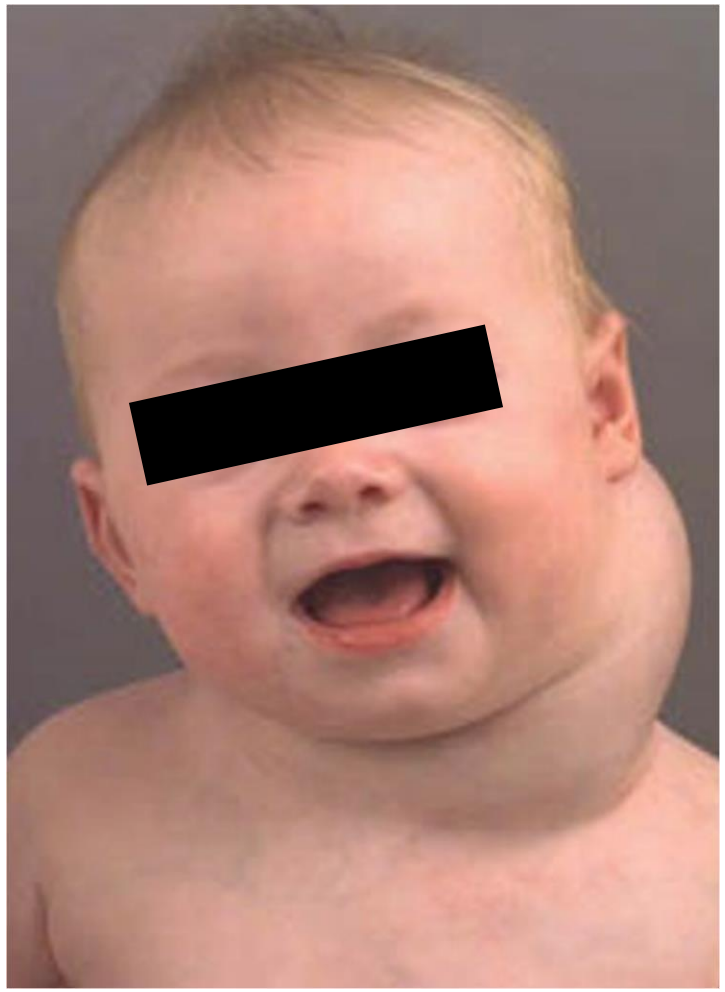
- Primary endpoint: Change in plasma choline concentration from baseline to Week 8
- Secondary endpoints: Steatosis and liver function tests



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: incidence of lymphatic malformations is ≈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

ONGOING PH 2 CLINICAL TRIAL

Ph 2 STARBORN-1 trial in pediatric LMs patients is ongoing

ADDITIONAL INDICATIONS

Historical literature and patient experience indicate that TARA-002 could have the potential to treat other maxillofacial cysts

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1. Brouillard P, et al. J Clin Invest. 2014;124:898-904. | 2. Internal company estimates | 3. Ha J, et al. Curr Ped Rev. 2014;10:238-248.

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

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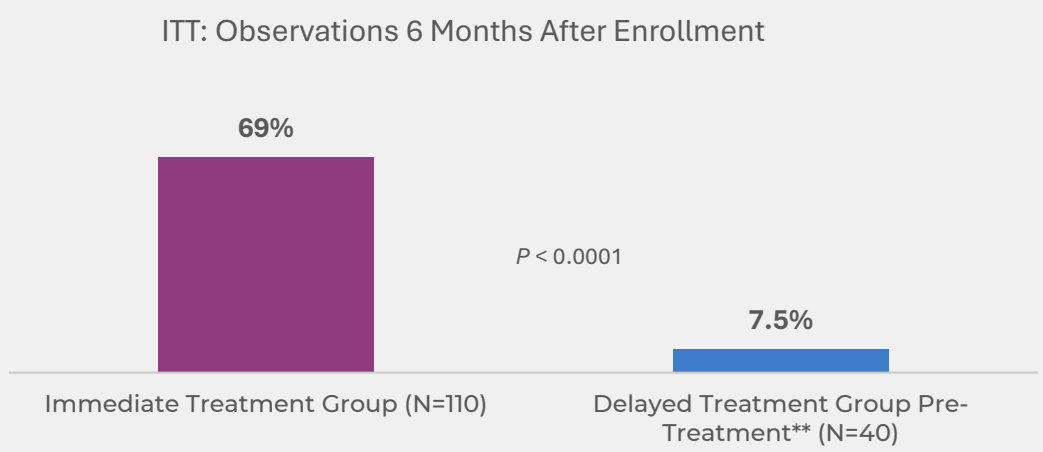
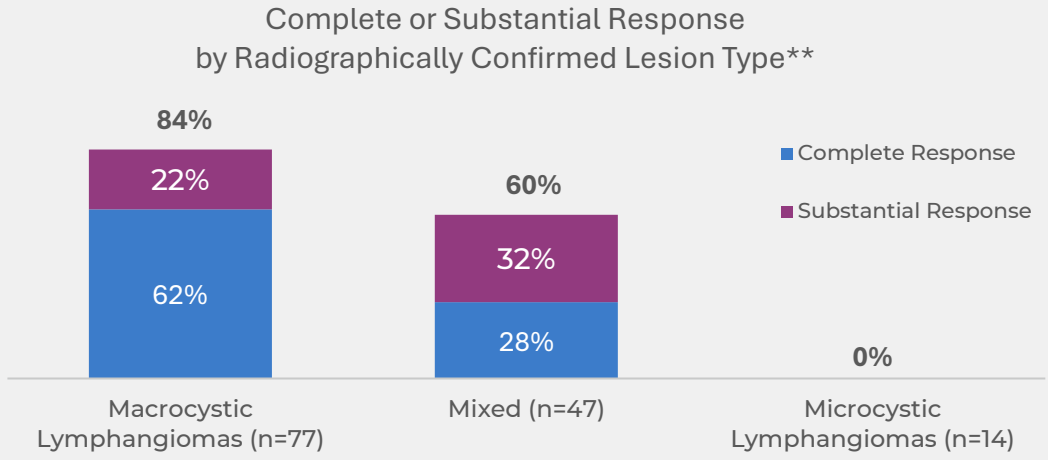
ROBUST CLINICAL RESULTS IN LARGE, ACADEMIC STUDY OF OK-432

69% CLINICAL SUCCESS‡ IN IMMEDIATE TREATMENT GROUP 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



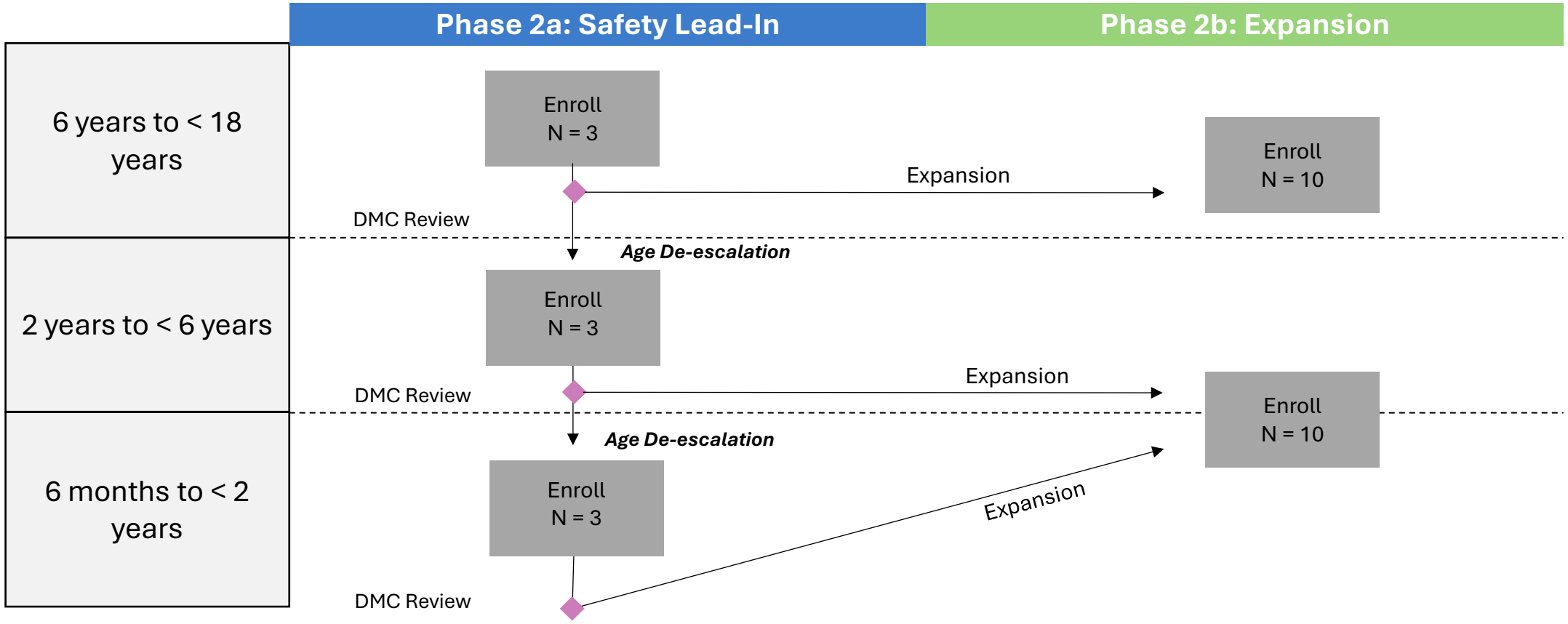
- Patients with radiographically confirmed macrocystic lesions had the greatest chance for clinical success
- In those patients with mixed lesions, clinical success was still achieved

‡ 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.

PROTARA THERAPEUTICS

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 Macrocystic and Mixed-cystic LMs (N=29)



SUMMARY

MULTIPLE NEAR-TERM CATALYSTS

2H'24	1H'25	2H'25
ADVANCED-2 interim data in 6-month evaluable patients	**Initiate combination trial** Ph 2 POC combo **Initiate THRIVE-3 registrational trial** **STARBORN-1 interim data**	**ADVANCED-2 BCG-Unresponsive Registrational*** futility analysis **Initial priming data** **THRIVE-3 interim data** **STARBORN-1 interim data**

MID-2025
ADVANCED-2 interim data in 12-month evaluable patients

NMIBC **IV Choline** **LMs**

BALANCE SHEET: $81.5M of cash, cash equivalents and investments as of September 30, 2024, with cash runway into 2026

COMMON SHARE EQUIVALENTS (30.3M):** 20.6M Common + 8.0M Preferred + 1.7M Pre-funded warrants on as converted basis as of September 30, 2024

*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 or 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.

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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%

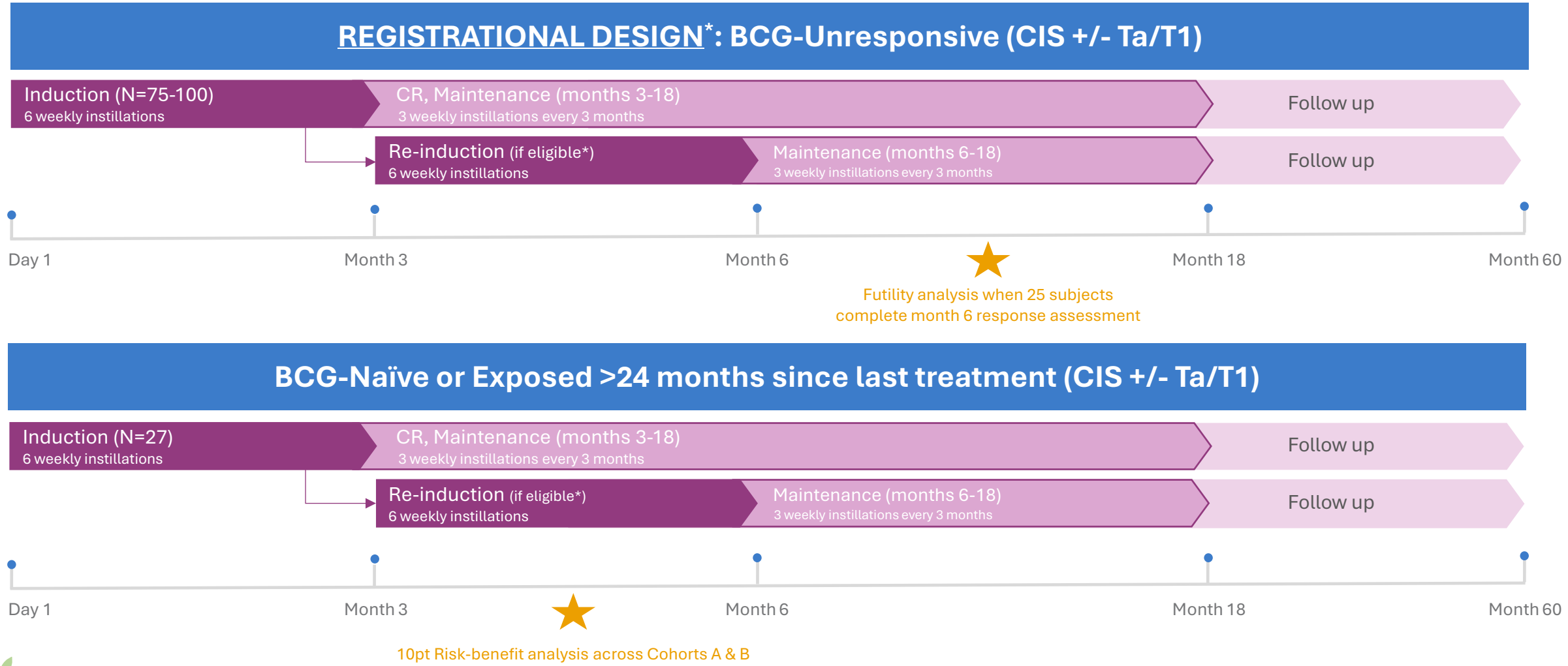
Data cutoff 3/19/24

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



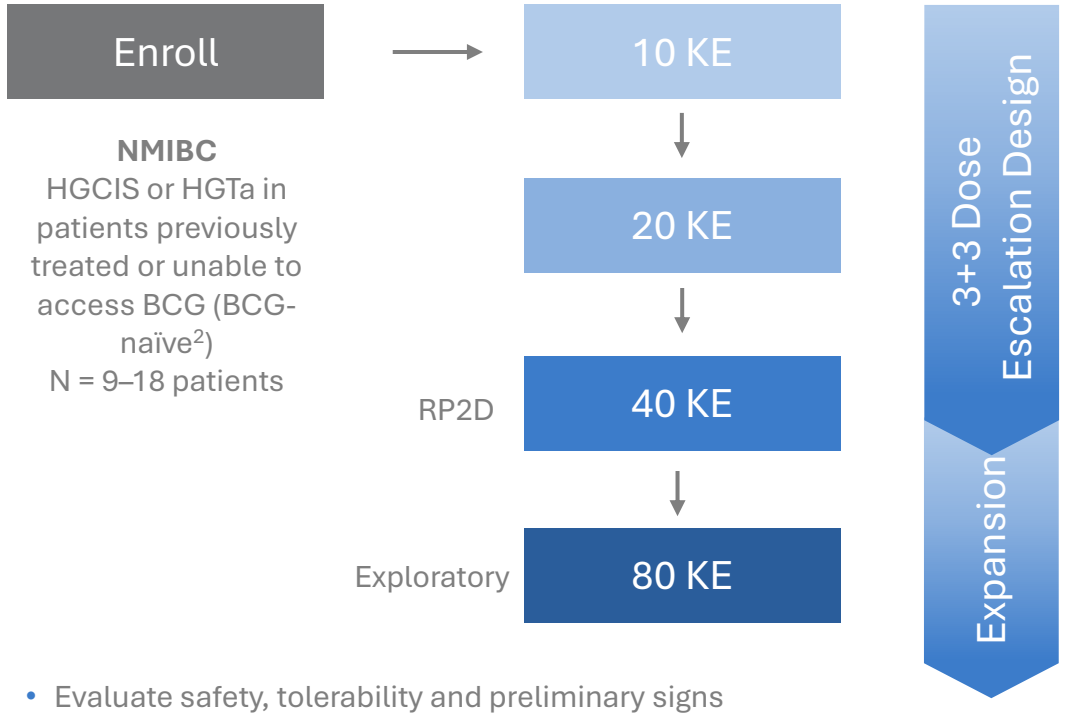
DOR = Duration of response

*Aligned with the FDA's 2018 BCG-Unresponsive Non-muscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industry

TARA-002 IN NMIBC: PHASE 1 CLINICAL TRIAL DESIGN

PHASE 1 Dose finding, open-label trial with expansion evaluating intravesical TARA-002 in adults with high-grade NMIBC

Phase 1a: Dose Escalation[1]



NMIBC
HGCIS or HGTa in patients previously treated or unable to access BCG (BCG-naïve[2])
N = 9–18 patients

- Evaluate safety, tolerability and preliminary signs of anti-tumor activity of TARA-002 and establish MTD and RP2D for Phase 2 study

Phase 1b: Expansion Cohort[1]

RP2D (40KE) → Enroll

NMIBC
HGCIS active disease[3]
N = up to 12 patients*

*Subjects enrolled in the dose expansion phase will not include subjects previously enrolled and treated in the dose escalation phase

- Further assess safety and preliminary signs of anti-tumor activity of TARA-002 at the established RP2D

1. Subjects will receive weekly intravesical doses of TARA-002 instillation for 6 weeks. | 2. Defined as not previously treated with or unable to access BCG. | 3. Defined as disease present at last cystoscopic evaluation during the dose expansion phase.
Definitions: BCG, bacillus Calmette-Guérin; HGCIS, high-grade carcinoma in situ; HGTa, high-grade Ta; KE, Klinische Einheit; MTD, maximum tolerated dose; RP2D, recommended phase 2 dose; TURBT, trans urethral resection of bladder tumor.

PROTARA THERAPEUTICS

TARA-002: MANUFACTURING IS A POTENTIAL COMPETITIVE ADVANTAGE

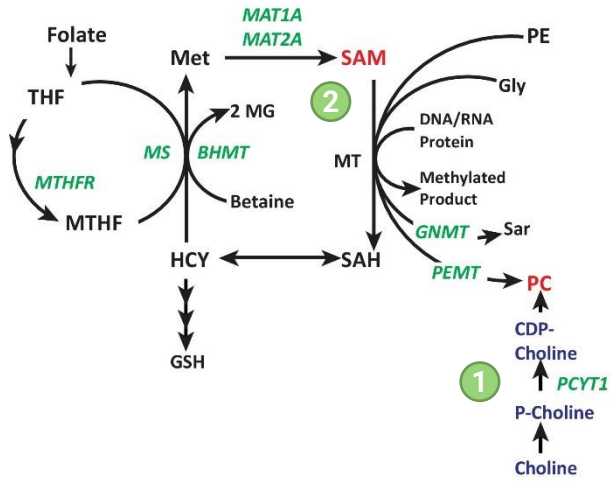
- ✓ 20 million vial/year capacity with ability to 5x supply as needed
- ✓ 47 successful batches run to date, 15 at commercial scale
- ✓ Capable of manufacturing cGMP commercial product in preparation of Chugai partial change application completion; anticipated for end-2024
- ✓ Completed FDA inspection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

PROTARA THERAPEUTICS

CHOLINE DEFICIENCY RESULTS IN HEPATOBILIARY PATHOPHYSIOLOGY

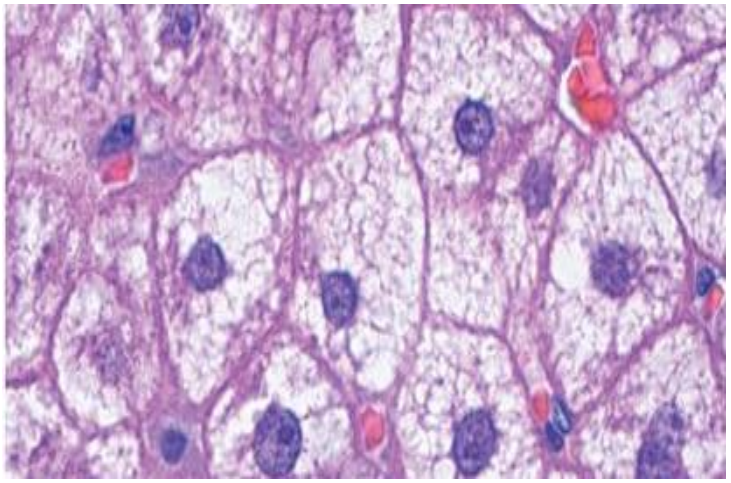
Diminished Choline = Insufficient phosphatidylcholine (PC), resulting in hepatobiliary injury

Affected Pathways



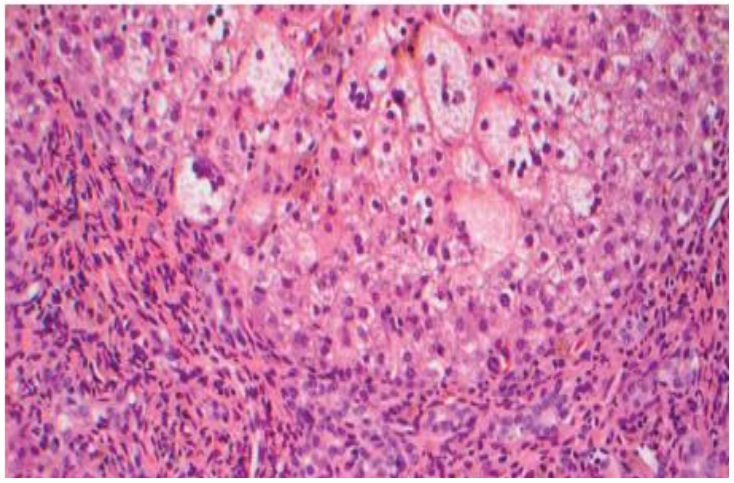
- PC is the most ubiquitous phospholipid in the body
  - 1 Throughout the body, PC is synthesized almost exclusively through exogenous choline consumption (Kennedy pathway)
  - 2 Intra-hepatically, the PEMT pathway can provide 30% of the liver's needs[1]

Steatosis



- PC is the primary lipid of the VLDL particle surface mono-layer. Low PC levels inhibit VLDL packaging and secretion. Without sufficient VLDL – fats rapidly accumulate in hepatocytes[2]

Cholestasis



- 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]

PROTARA THERAPEUTICS

IV CHOLINE: SUPPORTIVE EVIDENCE ACROSS 4 INDEPENDENTLY CONDUCTED CLINICAL STUDIES

1994 – Choline PK Study[1]
n=4 patients

1st continuous exposure to IV Choline, established safety and 2g dose

1995 - Choline Pilot Study[2]
n=4 patients

IV Choline replacement reversed steatosis, improved other measures of hepatobiliary injury

2001 - Choline Phase 2 RCT[3]
n=15 patients

2g dose confirmed, reversal of steatosis, improvement in cholestasis (reduction of Alkaline Phosphatase)

2023 – THRIVE-1[4]
n=88 patients
(non-interventional study)

78% of PN patients were choline deficient and of those 62% had liver dysfunction

1. Buchman A, et al. Clin Pharmacol Ther. 1994;55:277-283.. | 2. Buchman A, et al. Hepatol. 1995;22:1399-1403. | 3. Buchman A, et al. JPEN. 2001;5:260-268. | 4. Protara data on file