PROTARA THERAPEUTICS

Corporate Presentation

November 2021

Forward Looking Statements

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Modernizing and Expediting Development of De-Risked Assets

Lead programs: TARA-002 in Non-Muscle Invasive Bladder Cancer (NMIBC) and Lymphatic Malformations (LMs)

- Cell-based immunopotentiator
- NMIBC: Promising existing clinical data in patients and a proven MOA generally similar to current standard of care; Planning to initiate Phase 1 clinical trial by year end
- LMs: Current standard of care in Japan; completed Phase 2 study in the U.S. with additional clinical study planned; FDA granted Rare Pediatric Disease Designation

Other mid-stage development programs provide diversification and additional growth potential

- IV Choline in intestinal failure associated liver disease (IFALD): Completed retrospective study evaluating the prevalence of IFALD in patients dependent on parenteral nutrition
- Completed End Of Phase 2 dialogue with FDA and aligned on Phase 3 design

Company well funded through anticipated key milestones

- $138M of cash, cash equivalents and marketable debt securities as of September 30, 2021

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Pipeline Addresses Multiple Indications With High Unmet Need

	IND Cleared	Phase 1	Phase 2	Phase 3
IMMUNOLOGY, ONCOLOGY				
TARA-002 – Lyophilized, inactivated Group A *Streptococcus*				
Lymphatic Malformations (LMs)*				
Non-Muscle Invasive Bladder Cancer (NMIBC)				
HEPATOLOGY, GI, METABOLICS				
IV Choline Chloride for Injection – Phospholipid Substrate Replacement				
Intestinal Failure Associated Liver Disease (IFALD)**,†				
OTHER				
Vonapanitase – Recombinant Human Type 1 Elastase *(phase 1 studies completed in fistula patency and PAD)*				

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*TARA-002 Granted Rare Pediatric Disease Designation for the treatment of LMs. OK-432 Granted Orphan Drug Designation by the U.S. FDA for the treatment of LMs, which we believe is applicable under established comparability.
**Granted Orphan Drug and Fast Track Designations by the U.S. FDA
† Phase 1 PK study to be conducted prior to commencing Phase 3

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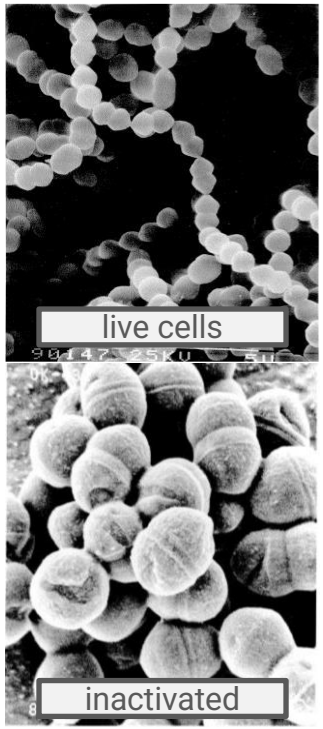
TARA-002

LYOPHILIZED, INACTIVATED GROUP A *STREPTOCOCCUS PYOGENES*

TARA-002: Cell-Based Immunopotentiator with Significant Potential

- 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 GMP conditions from the same Master Cell Bank as originator therapy OK-432[1], which is approved for LMs and a number of oncology indications in Japan
- OK-432 has been studied in many different types of cancer and there are close to 2,000 separate publications for OK-432 listed in PubMed
- Protara has successfully demonstrated GMP-scale manufacturing comparability between TARA-002 and OK-432, allowing the extensive data generated by OK-432 to help support TARA-002*
- Protara has worldwide rights ex-Japan & Taiwan for TARA-002/OK-432



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*Confirmed by FDA Office of Tissues and Advanced Therapies (OTAT) Division as part of NMIBC IND

(1) Marketed in Japan and Taiwan as Picibanil®.

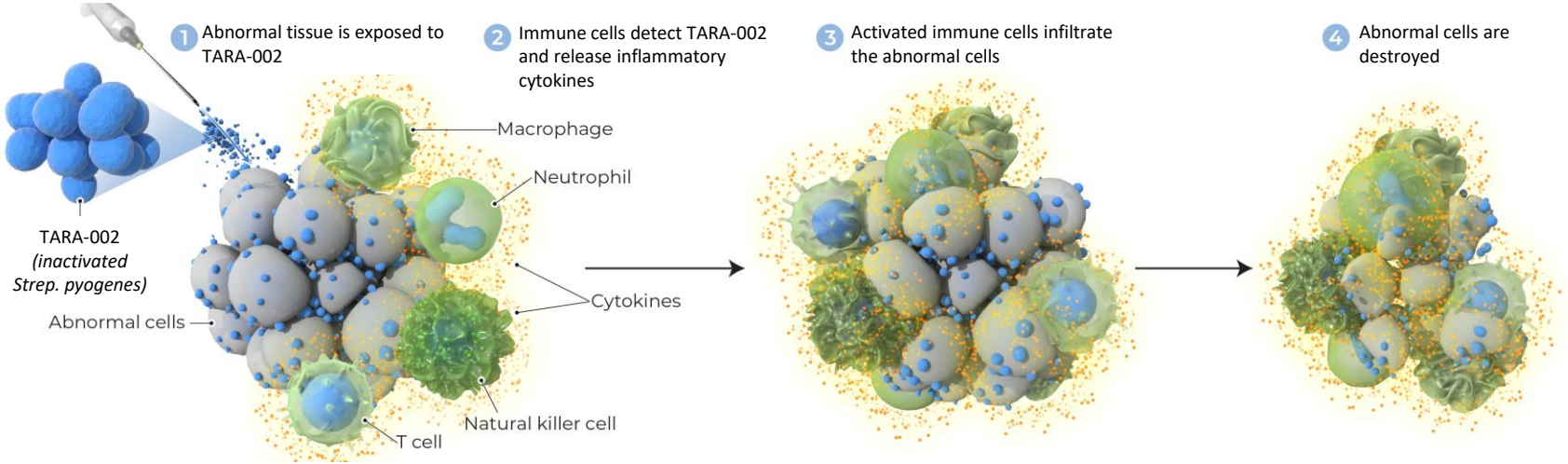
Note: Manufacturing modifications reflect manufacturing to U.S. cGMP standards

TARA-002: Mechanism of Anti-Tumor / Anti-Cystic Activity

Th1 Like Anti-Tumor Cytokine Response

Multi-Cytokine Inducer[1][2][3]

IL-2 IL-6 IL-8 IL-10 IL-12 GM-CSF G-CSF TNF-α IFN-γ



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(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.

OK-432: Human Efficacy Data in Multiple Indications

OK-432 has been approved (ex-US) or studied in multiple indications

APPROVED INDICATIONS IN JAPAN[1]

- **Lymphangiomas (Lymphatic Malformations)**
- Gastric cancer combo with chemo (post-operative)
- Primary lung cancer combo with chemo
- Reduction of ascites in gastrointestinal cancer
- Reduction of pleural effusion in lung cancer
- Unresponsive head, neck & thyroid cancer

OK-432 CLINICAL RESEARCH CONDUCTED IN:

- **Non-Muscle Invasive Bladder Cancer**
- Ovarian cancer
- Malignant mesothelioma
- Pancreatic cancer
- Esophageal cancer
- Oral squamous cell cancer
- Hepatocellular cancer
- Ranula
- Thyroglossal cysts
- Pleurodesis
- Seroma
- Symptomatic lymphocele
- Auricular hematoma

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1. Full Prescribing Information. Chugai Pharmaceuticals. 2016

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TARA-002

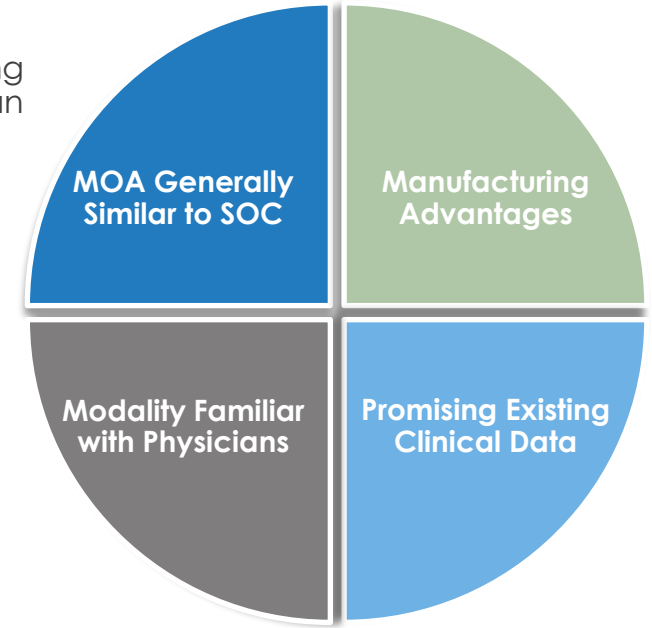
NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)

TARA-002 in NMIBC: Profile Supports Potential in NMIBC

Cell-Based Immunopotentiator with Notable Patient Experience

- Elicits Th1 type response inducing multiple cytokines to produce an anti-tumor effect
- Mechanistically similar to the current SOC, Bacille Calmette-Guérin (BCG)

- MOA with which urologists are familiar and have been using for decades
- Intravesical administration is preferred clinical approach among urologists[1]



- State-of-the-art U.S. manufacturing facility
- TARA-002 manufacturing process supported by 40 years of production history of OK-432

- ~150 NMIBC patients tested with OK-432 demonstrated promising results[2]
- Treatment generally well tolerated

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(1) Market Research Conducted by Protara Therapeutics
(2) Study references available by request
Note: OK-432 is not approved for NMIBC

Clinical Evidence of OK-432 Provides Strong Rationale for Development of TARA-002 in NMIBC

Data across multiple studies in ~150 NMIBC patients treated intravesically shows that OK-432:

- Was generally well-tolerated, with safety and tolerability observed across a range of doses
- Demonstrated treatment effect and lower rates of recurrence vs. control group, including in the randomized, controlled setting

Study	Dose Regimen	Total Pts/ OK-432 Pts	Efficacy Results
Fujita, 1987 Bladder Cancer	2 to 5 KE intratumoral, 5 KE intravesical instillation	78 / 37	In previously unresected tumors, 5 recurrences in OK-432 treated patients vs. 12 recurrences in the control arm ($p<0.05$) at 36 months. For patients with primary disease, OK-432 showed a benefit over control in multiple subgroups (multifocal, sessile, or high grade).
Fujita, 1988 Bladder Cancer	2 to 5 KE intratumoral, 5 KE intravesical instillation	36 /17	OK-432 reduced recurrence rates of disease (35% recurrence in OK-432 group compared to ~73% recurrence in surgery alone group); OK-432 caused lymphocyte infiltration into carcinomas (as evidenced by histology after resection).
Sun and Qiu, 2004 Bladder Cancer	3 KE intravesical instillation weekly for 6 weeks then monthly for 6 months	30 / 30	At a mean follow-up of 14 months, tumor recurrence was observed in 16.6% of patients, with no recurrence in 83.4% of patients. OK-432 stimulated secretion of IL-2 and TNFa ($p<0.05$ for both).
Liu et al., 2017 NMIBC	3 KE (in 30 ml) intravesical instillation	55 / 55	Overall, patients treated in the study had a recurrence rate of 34.5% and progression rate of 10.9%. Treatment with OK-432 was more effective when patients were negative for PD-L1 (16.7% recurrence rate, 4.2% progression rate), regardless of disease stage/grade.
Fujioka et al., 1989 NMIBC	5 KE (intravesical), 10 KE (intratumoral)	38 / 38	Tumors were eliminated endoscopically in 6 of 28 (21.4%) patients in which OK-432 was intravesically instilled [Stage Ta = 5 patients, Stage T1 = 1 patient; all patients Grade 1], and 3 of 10 (30%) patients with intratumoral OK-432 injection.

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Fujita K, et al. Cancer. 1987; 59: 2027-2030
Fujita K, et al. Cancer Detection and Prevention. 1988; 11: 397-403
Sun X, et al. China Journal of Medicine. 2004; 14: 49-54
Liu, Z.H, et al. Oncology Letters. 2017;13:4818-4824.
Fujioka et al. Acta Urol. Japan. 1989; 35: 253-257

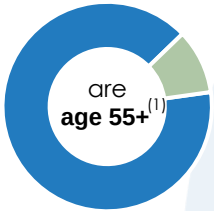
NMIBC Represents the Most Common Form of Bladder Cancer

Bladder Cancer in the US

6th *most prevalent cancer* in the U.S.[1]

4x more likely to be diagnosed in **men**[2]

9 in 10 are **age 55+**[1]



High rate of recurrence with 3-year rate estimated at up to **80%**[3]

NMIBC makes up **~80%** of all bladder cancer with **~65,000 diagnosed per year** in the U.S.[4]

NMIBC patients are treated by a **urologist**

Significant increase in **recurrence, progression** & an escalated number of patients needing **cystectomies**[5]

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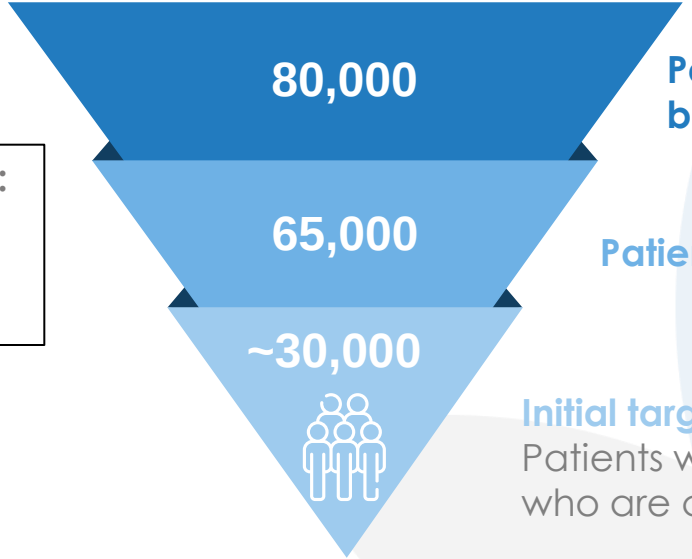
(1) National Cancer Institute. SEER Bladder Cancer – Stat Facts. Accessed February 5, 2021.
(2) Saginala, K. et al. Med Sci. 2020.
(3) Campbell Walsh 11th edition, Elsevier.
(4) Anastasiadis et al. Therapeutic Advances in Urology, 2012.
(5) Ourfali, S. et. al. European urology focus, 2019.

TARA-002 in NMIBC: Target Patient Population

NMIBC is categorized and treated based on risk stratification, determined by combination of tumor grade, stage, size, recurrence history and focality

Treatment goal is to prevent:
1. Progression
2. Cystectomy
3. Recurrence



Patients diagnosed with bladder cancer annually[1]

Patients with NMIBC[2]

Initial target patient population:
Patients with high grade NMIBC who are candidates for immunotherapy[1-3]

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1. National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2019. 2. Anastasiadis et al. Therapeutic Advances in Urology, 2012.
3. Market Research Conducted by Protara Therapeutics
NMIBC, non-muscle invasive bladder cancer.

TARA-002 in NMIBC: Phase 1a/1b Study Design

Phase 1 — Dose finding, open-label study evaluating intravesical TARA-002 in adults with high-grade NMIBC

Phase 1a: Dose Escalation[1]

Enroll → 10 KE → 20 KE → 40 KE

3+3 Dose Escalation Design

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]

Enroll → RP2D

NMIBC
HGCIS active disease[3]
N = 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

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[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.

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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 ≈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

FDA Granted Pediatric Rare Disease Designation

Majority of LMs present at birth (65-75%) or by age 3 (80-90%) during active lymphatic growth period[3]

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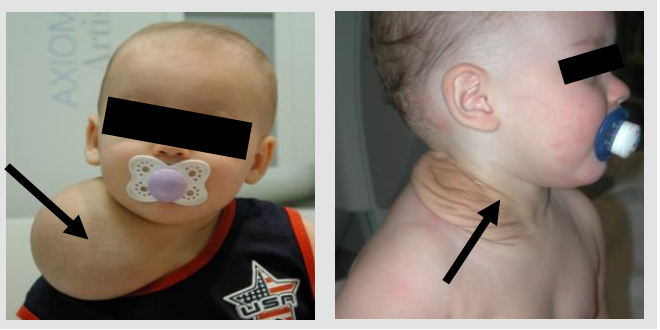
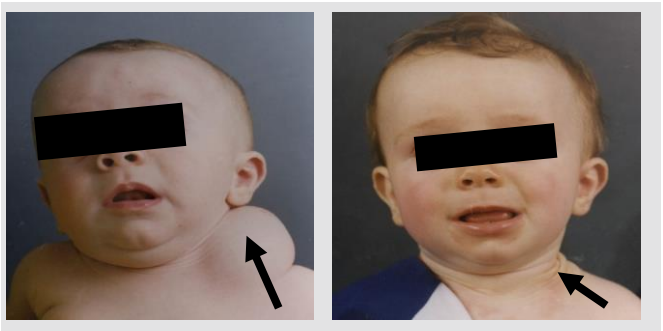
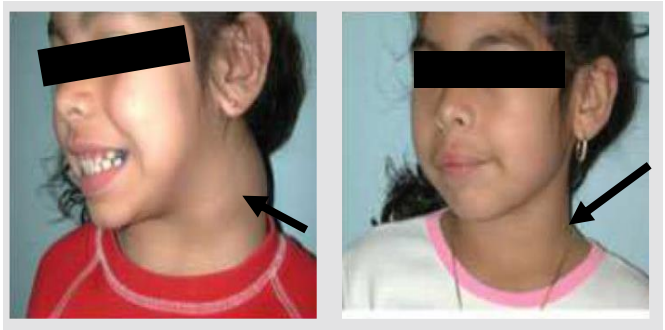
(1) Brouillard P, et al. J Clin Invest. 2014;124:898-904.
(2) Internal company estimates
(3) Ha J, et al. Curr Ped Rev. 2014;10:238-248.

OK-432 in LMs: Clear Evidence of Biologic Activity in Patients

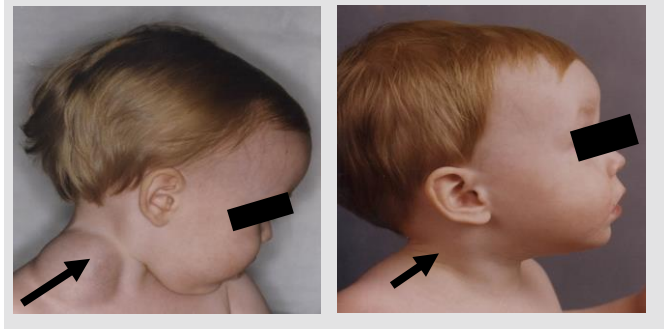


Before After





Before After

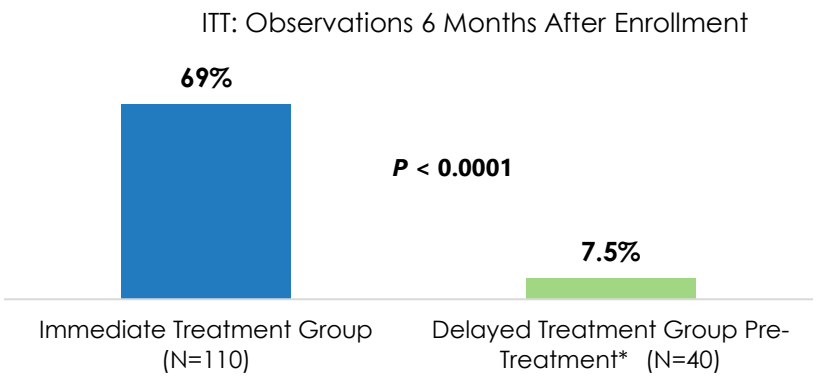


Completed Phase 2 study of OK-432 in U.S. provides evidence of treatment effect with support for strong safety profile

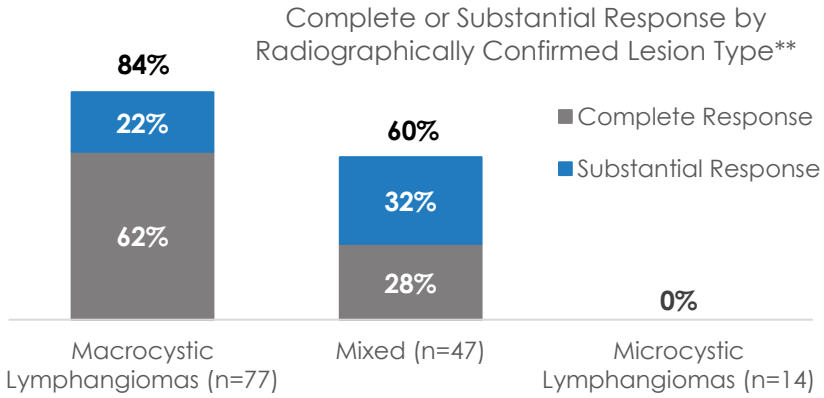
Protara Therapeutics data on file

OK-432 in LMs: Robust Results of Completed Phase 2 Study[1] in U.S.

69% CLINICAL SUCCESS‡ IN IMMEDIATE TREATMENT GROUP 6 MONTHS AFTER ENROLLMENT



84%* CLINICAL SUCCESS‡ IN PATIENTS WITH MACROCYSTIC LESION TYPES



- 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)

- 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 the P2 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.

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OK-432 in LMs: Compelling Safety Record

Safety Profile*

- Most common AEs with treatment were local injection site reactions, fever, fatigue, decreased appetite, with resolution within two weeks
- Treatment emergent SAEs **related** to OK-432: reported in 4.1% of patients, with the most severe events being airway obstruction and facial paralysis due to massive swelling post-injection that required tracheostomy and hospitalization. Both of these events were reported as resolved.
- One SAE **related** to OK-432 led to discontinuation: Proptosis of the eye
- One SAE **not related** to OK-432 led to death: Death due to tracheotomy tube obstruction

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*Results based on retrospective analysis of source verified data that included the full dataset of subjects enrolled in the P2 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.

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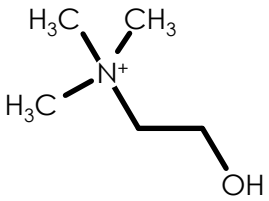
IV CHOLINE CHLORIDE

INTESTINAL FAILURE ASSOCIATED LIVER DISEASE (IFALD)

IV Choline in IFALD: Late-stage Opportunity for an Unmet Medical Need

An Essential Molecule in Several Metabolic Processes

Patients dependent on PN cannot absorb sufficient levels of choline. Data confirms that choline deficient diets results in steatosis and cholestasis.[1] There are currently no approved PN treatments that offer sufficient choline



Clinical History Supporting Choline Substrate Replacement in Patients with IFALD

A Phase 2 study demonstrated the clinical potential of choline substrate replacement therapy by reversing certain hallmark pathologies of IFALD[1]

Strong Market Opportunity with Potential to Expand Addressable Patients

Prevalence of patients on PN 79/million[2]; recent Medicare diagnosis data suggests ≈ 5,000 IFALD patients[3]

Clear Regulatory and Clinical Path Forward

Received Orphan Drug and Fast Track Designations from FDA. Positive End of Phase 2 meeting with FDA requesting Phase 1 PK study and Phase 3 trial to complete registrational package

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1. Buchman A, et al. *JPEN*. 2001;5:260-268. 2. Mundi M, et al. *ASEPN*. 2017;32:799-805. 3. Internal Protara market research.
IFALD, intestinal failure associated liver disease; IV, intravenous; PK, pharmacokinetic; PN, parenteral nutrition.

IV Choline in IFALD: Prevalence Study

Prevalence study to enhance understanding of the patient population

DESIGN	Retrospective, observational study of patients in both academic & community settings
POPULATION	Patients dependent on PN for 6 or more months
OBJECTIVE	• Understand the incidence of cholestasis, a hallmark pathology of IFALD in this patient population • Measuring serum alkaline phosphatase (ALP) levels greater than 1.5 times the upper limit of normal (ULN) as a key marker of cholestasis
RESULTS	• ~31% of all patients, irrespective of baseline levels, presented with ALP levels greater than 1.5 times the ULN at any given time during 6 to 36 months. • ~28% of all patients had persistent ALP elevations greater than 1.5 times the ULN at 36 months. • At baseline, ~23% of patients presented with ALP levels greater than 1.5 times the ULN with ~76% presenting with greater than 1.5 times the ULN at any given time during 6 to 36 months and ~59% with persistent ALP elevations greater than 1.5 times the ULN at 36 months. • While medical management demonstrated some improvement in ALP levels, it was not sufficient for managing ALP levels over the long term in patients on PN. • Results support further exploration in patient population to determine rates of choline deficiency & steatosis.
NEXT STEPS	Prospective observational study under way to further characterize the prevalence of choline deficiency, as well as cholestasis and steatosis, in ~300 patients dependent on PN

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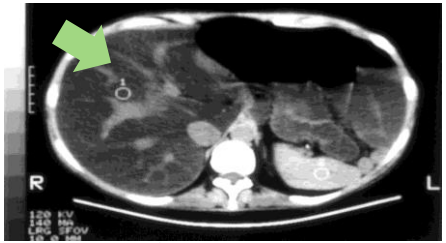
IV Choline in IFALD : Phase 2 Results

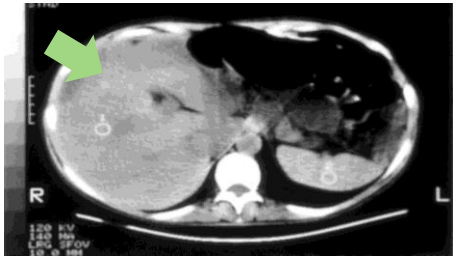
Improvement in Steatosis and Cholestasis

CLINICALLY MEANINGFUL IMPROVEMENT IN STEATOSIS

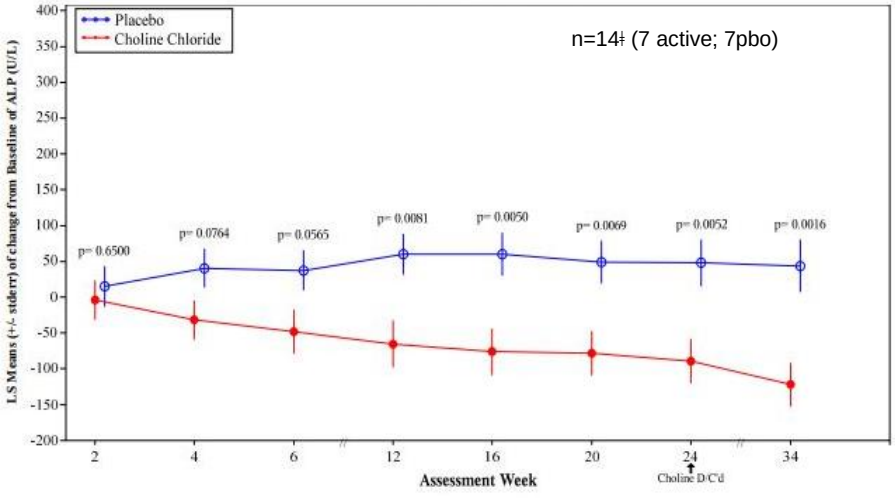
At Baseline



After 24 Weeks



CHOLESTASIS IMPROVEMENT: ALL PATIENTS*(1)



*Mixed model for repeated measurement (MMRM) method used
‡A placebo subject was excluded from all analyses due to likely IV contrast-induced imaging abnormalities, confirmed by independent radiologist

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(1) Protara Therapeutics re-analysis of patient CRF's, data on file

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Summary

Building Momentum in 2021

NMIBC: Significant Market Potential	☑ 2H'21: File IND with GMP scale confirmatory comparability data ● Year-End 2021: Initiate Phase 1 study
LMs: Rare Disease Opportunity	☑ 2H'21: Update IND with GMP scale confirmatory comparability data ● 2H'21: Engage FDA on design of additional clinical study
IV Choline: Late-Stage Pipeline Opportunity	☑ 2H'21: Complete retrospective prevalence study to better characterize the unmet need in IFALD
Solid Financial Position	• $138M of cash, cash equivalents and investments as of September 30, 2021 • 19.2M Common Share Equivalents:11.2M Common + 8.0M Preferred on as-converted basis as of September 30, 2021

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Corporate Presentation

November 2021

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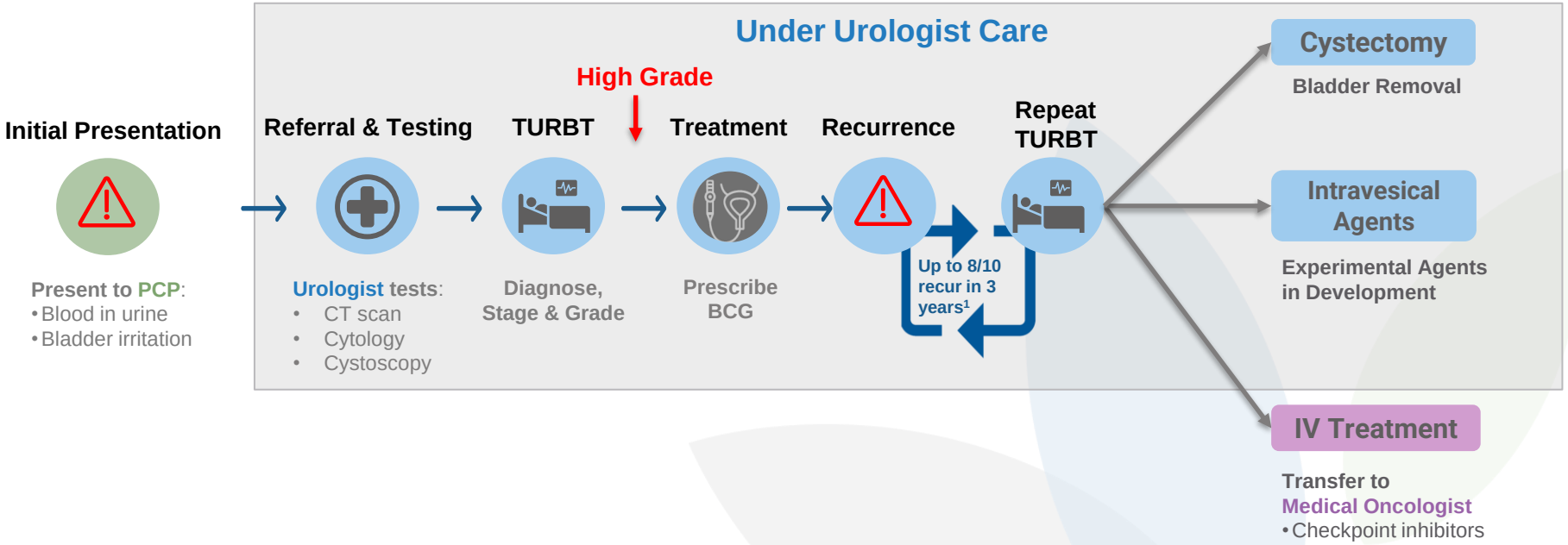
Appendix

Current Standard of Care Highlights High Unmet Need for Patients



(1) Campbell Walsh 11th edition, Elsevier.

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BCG Shortage Causes Significant Impact on Care

= BCG Shortage

2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020

- **2012:** BCG shortages begin after Sanofi lab is shut down due to mold infractions
- **2014:** Sanofi production of BCG resumes
- **2014:** Merck announces shortages of Tice strain of BCG
- **2016:** Sanofi announces discontinuation of TheraCys BCG; Merck becomes sole US provider of BCG
- **2017–2020:** US Urologists are continuing to ration BCG doses and adjust treatment decisions due to shortage
- **2019:** Merck announces anticipated BCG supply constraints despite expanding capacity
- **2020:** Merck announces plans to construct new facility to expand BCG manufacturing. Facility could take 5-6 years to construct.

Shortage has prompted major urological associations to issue guidance on patient management [1]

"…remain extremely concerned about this shortage and its effects on the care of bladder cancer patients…"

-Joint Statement on BCG Shortage, Feb 2019

American Urological Association | LUGPA Integrated Practices Comprehensive Care | AACU | Urology Care Foundation | SUO | BCAN

Dose rationing and resorting to less desirable treatment options are impacting patient care[2]

*"I see patients **every week** whose **treatment decisions are affected by the BCG shortage**…sometimes I just recommend moving patients more quickly to cystectomy because **we don't have any better options available.**"*

-Academic Hospital Urologist

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(1) AUA/SUO Joint Guideline: Published 2016; Amended 2020
(2) Market Research Conducted by Protara Therapeutics

IV Choline in IFALD: Informative Clinical History

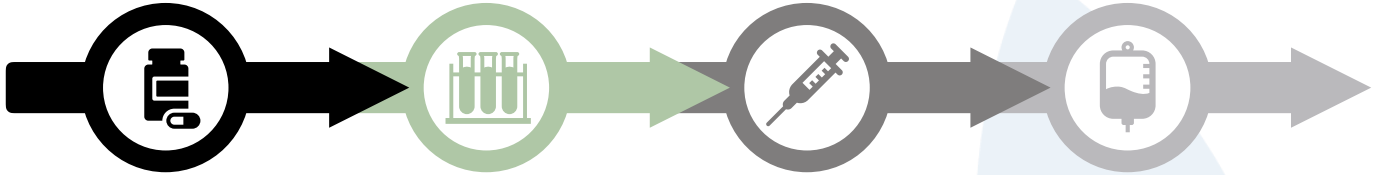
A significant body of supportive evidence across 4 studies

1994 - IV PK Study[2]
n=4 PN patients

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

2001 - IV Phase 2 RCT[4]
n=15 PN patients

2g dose confirmed, reversal of steatosis, improvement in cholestasis (reduction of ALP*)



1992 - Oral Lecithin Study[1]
n=15 PN patients

Lecithin did not achieve physiologic levels; however did reduce steatosis with moderate ALP* improvement

1995 - IV Pilot Study[3]
n=4 PN patients

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

PROTARA THERAPEUTICS

1) Buchman A, et al. Gastroenterology. 1992;102:1363-1370.
2) Buchman A, et al. Clin Pharmacol Ther. 1994;55:277-283.
3) Buchman A, et al. Hepatol. 1995;22:1399-1403.
4) Buchman A, et al. JPEN. 2001;5:260-268.

* ALP=Alkaline phosphatase

IV Choline in IFALD: Multi-Center Phase 2a POC Study

Randomized, Controlled Study Design & Objective

IV CHOLINE REPLACEMENT PROOF OF CONCEPT STUDY[1]	
Study Design	Randomized Double-blind Phase 2 Trial
Subjects	15 (9 per protocol)
Age	>16 years old
PN Requirement	Greater than 80% of all nutrient requirements supplied by PN
Randomization	1:1 Usual PN or PN + 2g IV choline/day
Duration of Treatment	24 Weeks
Visits	Weeks 2,4,6,12,16, 20, 24
Follow up	Week 34
Dose	2g Choline Chloride QD in PN solution

- The IV Choline Chloride replacement POC, randomized study did not have pre-specified endpoints
- The primary objective of the study was to determine if IV Choline Chloride substrate replacement would reverse hepatic steatosis and improve liver function in patients receiving long-term PN

PROTARA THERAPEUTICS

1. Buchman A, et al. *JPEN*. 2001;5:260-268.
IFALD, intestinal failure associated liver disease; IV, intravenous ; POC, proof of concept; PN, parenteral nutrition; QD, once a day.