**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 5, 2023**

**Protara Therapeutics, Inc.**
**(Exact name of registrant as specified in its charter)**

| Delaware | 001-36694 | 20-4580525 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File No.) | (IRS Employer Identification No.) |

| 345 Park Avenue South<br>Third Floor<br>New York, NY | 10010 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

**Registrant's telephone number, including area code: (646) 844-0337**

**N/A**
**(Former name or former address, if changed since last report.)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.001 per share | TARA | The Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01. Other Events.**

On January 5, 2023, the Company made available a Corporate Presentation on the Investor Relations page of the Company's website, which will be used at investor and other meetings. A copy of the Corporate Presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company does not undertake to update this presentation.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Protara Therapeutics, Inc. Corporate Presentation, January 2023 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROTARA THERAPEUTICS, INC.

Date: January 5, 2023

By: /s/ Jesse Shefferman
Jesse Shefferman
*Chief Executive Officer*

Exhibit 99.1

PROTARA
THERAPEUTICS

# CORPORATE PRESENTATION

January 2023

# FORWARD LOOKING STATEMENTS

Statements contained in this press release regarding matters that are not historical facts are "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Protara may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “designed,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words or expressions referencing future events, conditions or circumstances that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such forward-looking statements include but are not limited to, statements regarding Protara’s intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: Protara's business strategy, including its development plans for its product candidates and plans regarding the timing or outcome of existing or future clinical trials; statements related to expectations regarding interactions with the FDA, Protara's financial footing; statements regarding the anticipated safety or efficacy of Protara’s product candidates; and Protara's outlook for the remainder of the year. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that contribute to the uncertain nature of the forward-looking statements include: risks that Protara's financial guidance may not be as expected, as well as risks and uncertainties associated with: Protara’s development programs, including the initiation and completion of non-clinical studies and clinical trials and the timing of required filings with the FDA and other regulatory agencies; the impact of the COVID-19 pandemic on Protara’s business and the global economy as well as the impact on Protara's contract research organizations, study sites or other clinical partners; general market conditions; changes in the competitive landscape; changes in Protara's strategic and commercial plans; Protara's ability to obtain sufficient financing to fund its strategic plans and commercialization efforts; having to use cash in ways or on timing other than expected; the impact of market volatility on cash reserves; the loss of key members of management; the impact of general U.S. and foreign, economic, industry, market, regulatory or political conditions; and the risks and uncertainties associated with Protara’s business and financial condition in general, including the risks and uncertainties described more fully under the caption “Risk Factors” and elsewhere in Protara's filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Protara undertakes no obligation to update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise, except as required by law.

# ADVANCING TRANSFORMATIVE THERAPIES FOR PEOPLE WITH CANCER AND RARE DISEASES

## LEAD PROGRAM: TARA-002 IN NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC) AND LYMPHATIC MALFORMATIONS (LMS)

*Cell-based immunopotentiator based on originator therapy OK-432, which is approved in multiple oncology indications and LMs in Japan*

- NMIBC: *Phase 1 clinical trial of TARA-002 in adults with high-grade NMIBC - Phase 1a read out expected 1H 2023; preclinical work for I-O combos ongoing*
- LMs: *Phase 2 clinical trial of TARA-002 expected to initiate in 2023; FDA granted Rare Pediatric Disease Designation*

## MID-STAGE DEVELOPMENT PROGRAM PROVIDES DIVERSIFICATION & ADDITIONAL GROWTH POTENTIAL

*IV Choline in intestinal failure associated liver disease (IFALD)*

- IFALD: *Completed End of Phase 2 dialogue with FDA and aligned on Phase 3 clinical trial design*

Applying modern scientific advancements to established mechanisms

~25 team members who prioritize creativity, diverse perspectives and tenacity

Solid balance sheet with cash runway into 2H 2024 as of September 30, 2022

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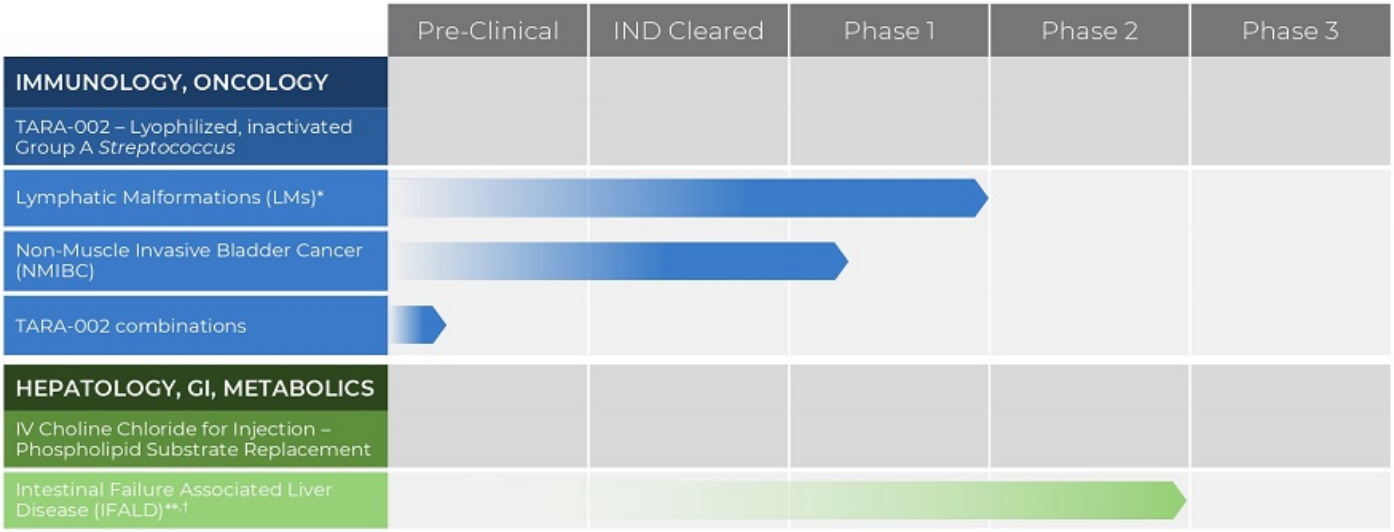
# PIPELINE ADDRESSES MULTIPLE INDICATIONS WITH HIGH UNMET NEED



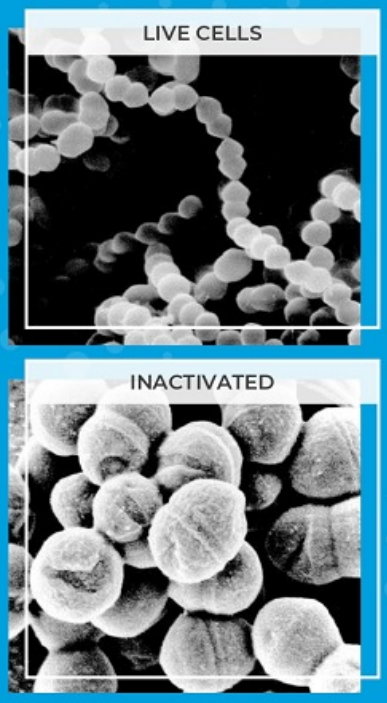

*TARA-002 Granted Rare Pediatric Disease Designation for the treatment of LMs.
**Granted Orphan Drug and Fast Track Designations by the U.S. FDA
† Phase 1 PK study to be conducted in addition to Phase 3 study

# 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 worldwide rights ex-Japan & Taiwan for TARA-002/OK-432




PROTARA THERAPEUTICS

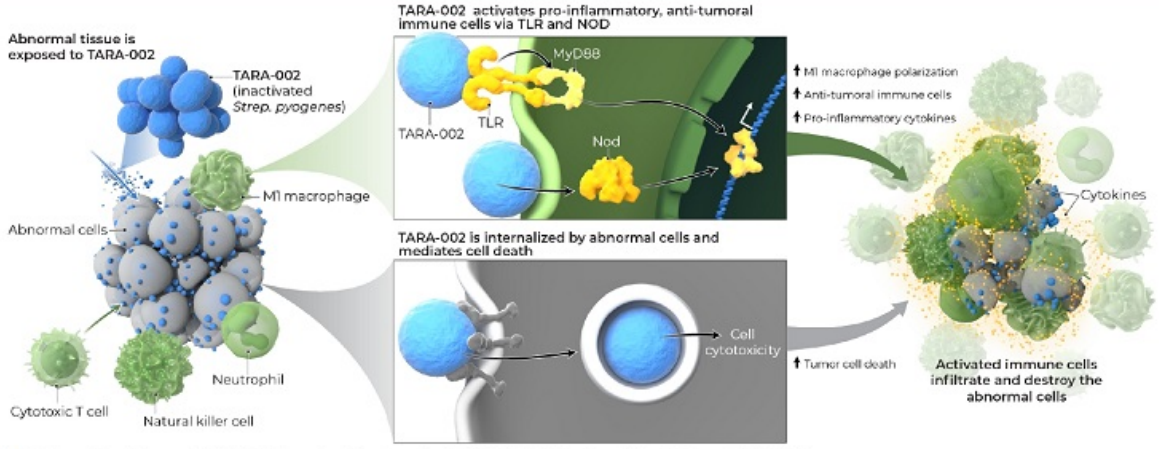
1. Marketed in Japan and Taiwan as Picibanil®.
Note: Manufacturing modifications reflect manufacturing to U.S. cGMP standards

# 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




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

# TARA-002

Non-Muscle Invasive Bladder Cancer (NMIBC)

# TARA-002 IN NMIBC: PROFILE SUPPORTS POTENTIAL

## CELL-BASED IMMUNOPOTENTIATOR WITH NOTABLE PATIENT EXPERIENCE

### Proven Anti-Cancer MOA

- Elicits Th1 type response inducing multiple cytokines to produce an anti-tumor effect
- Mechanistically similar to the current SOC, Bacille Calmette-Guérin (BCG)
- Potential to work well in combination with other NMIBC therapeutics

### Manufacturing Advantages

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

### Modality Familiar with Physicians

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

### Promising Existing Clinical Data

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

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1. Market Research Conducted by Protara Therapeutics |
Note: OK-432 is not approved for NMIBC

# TARA-002 IN NMIBC: CLINICAL EVIDENCE FROM PREDECESSOR THERAPY OK-432 PROVIDES STRONG RATIONALE FOR DEVELOPMENT 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

| OK-432 Study | Dose Regimen | Total Pts/ OK-432 Pts | OK-432 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 TNFα ($p<0.05$ 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. |

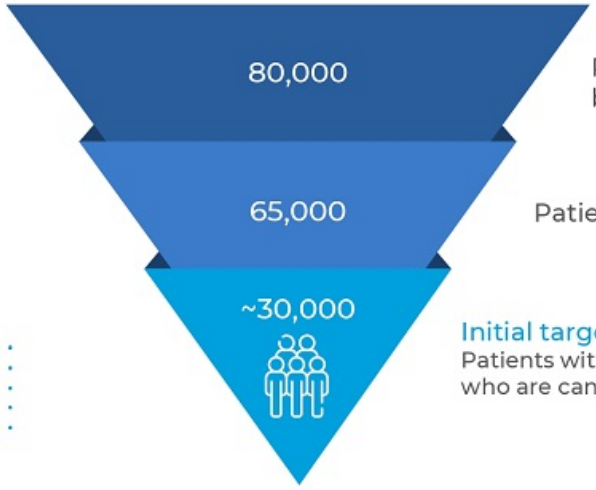
Fujita K, et al. Cancer. 1987; 59: 2027-2030 | Fujita K, et al. Cancer Detection and Prevention. 1988; 11: 397-403 | Sun X, et al. China Journal of Medicine. 2004; 14: 49-54 | Liu, Z.H, et al. Oncology Letters. 2017;13:4818-4824. | Fujioka et al. Acta Urol. Japan. 1989; 35: 253-257

# 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]

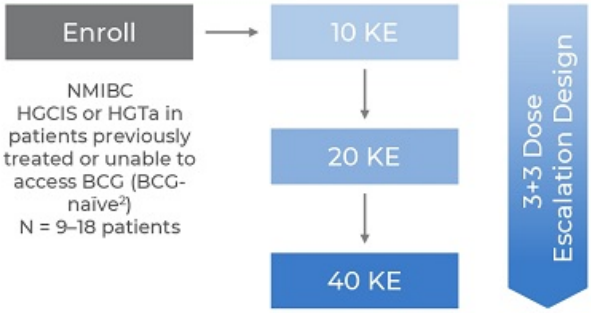
**Initial target patient population:**
Patients with high grade NMIBC who are candidates for immunotherapy[1-3]

1. National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2021. | 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 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]




- 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]


*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.

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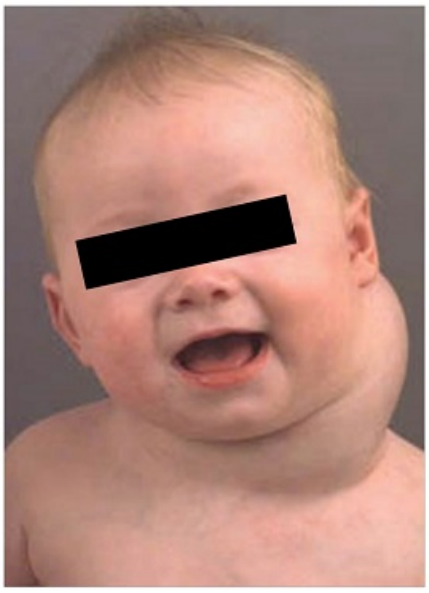
# TARA-002

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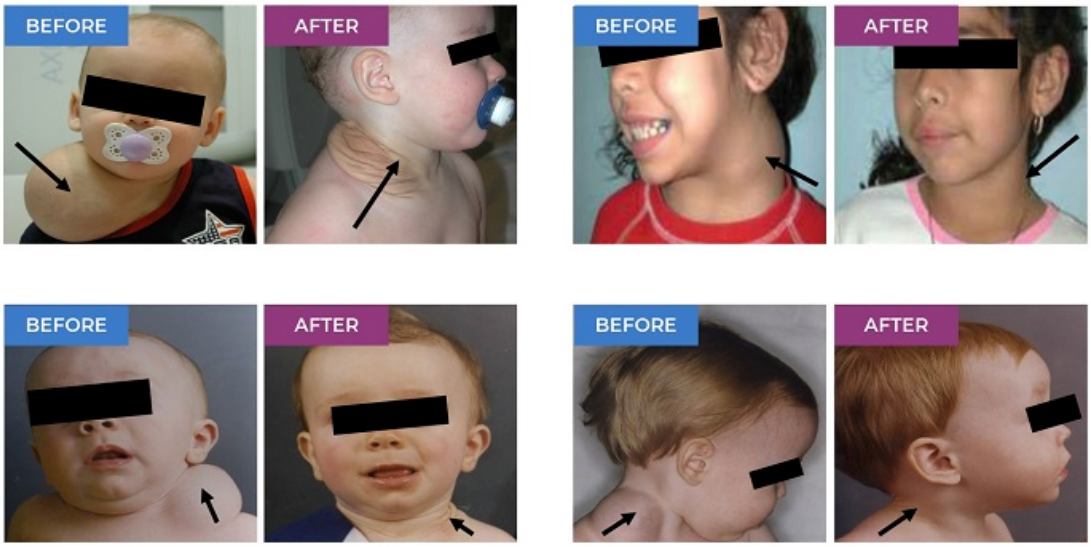
1. Brouillard P, et al. J Clin Invest. 2014;124:898-904. | 2. Internal company estimates | 3. Ha J, et al. Curr Ped Rev. 2014;10:238-248.

# TARA-002 IN LMs: CLEAR EVIDENCE OF BIOLOGIC ACTIVITY OBSERVED WITH PREDECESSOR THERAPY OK-432




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

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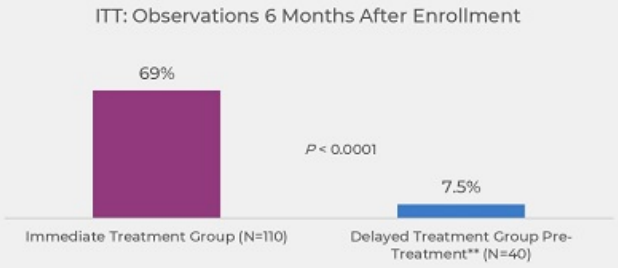
Protara Therapeutics data on file

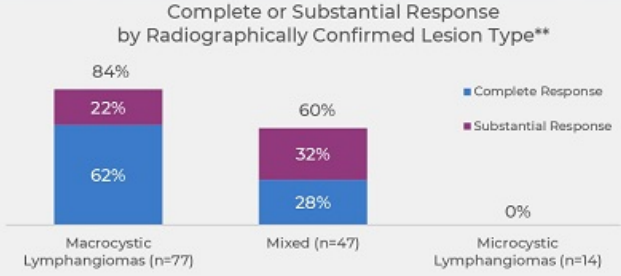
# TARA-002 IN LMs: ROBUST RESULTS OF COMPLETED CLINICAL TRIAL[1] IN U.S. OBSERVED WITH PREDECESSOR THERAPY OK-432

## 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.

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# TARA-002 IN LMs: COMPELLING SAFETY RECORD OF PREDECESSOR THERAPY OK-432

## 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 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 tracheostomy tube obstruction

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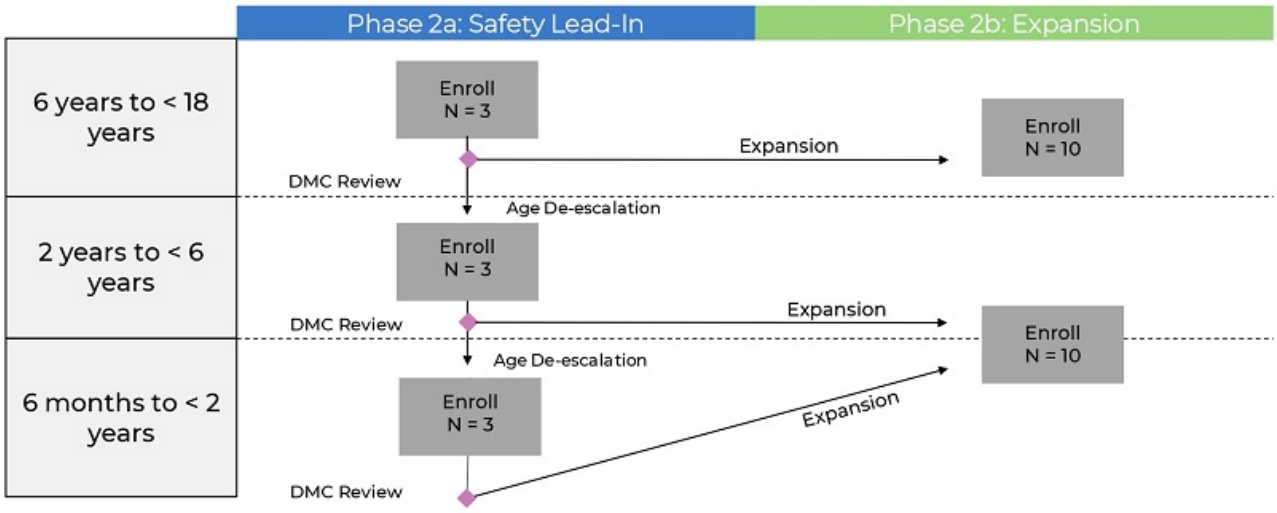
*Results based on retrospective analysis of source verified data that included the full dataset of subjects enrolled in randomized study between January 1998 and August 2005, including data in the published study (Smith et al. 2009) which included subjects enrolled between January 1998 and November 2004.

# TARA-002 IN LMS: PHASE 2 TRIAL DESIGN

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



# IV CHOLINE CHLORIDE

Intestinal Failure Associated Liver Disease (IFALD)

# IV CHOLINE IN IFALD: LATE-STAGE OPPORTUNITY FOR AN UNMET MEDICAL NEED

## HIGH UNMET NEED AMONG PATIENTS

- 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]

## INTELLECTUAL PROPERTY RECENTLY SECURED

- Patent and Trademark Office issued to the Company a patent claiming a sterile aqueous choline salt composition with a term expiring in 2041

## 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 clinical trial to complete registrational package

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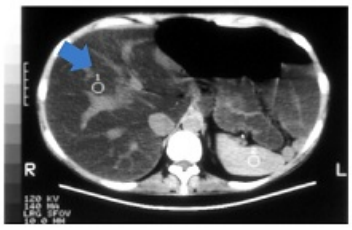
1. Buchman A, et al. JPEN. 2001;5:260-268.
IFALD, intestinal failure associated liver disease; IV, intravenous; PK, pharmacokinetic; PN, parenteral nutrition.

# IV CHOLINE IN IFALD: PHASE 2 TRIAL RESULTS

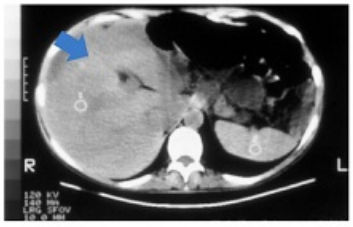
Improvement in Steatosis and Cholestasis

## CLINICALLY MEANINGFUL IMPROVEMENT IN STEATOSIS

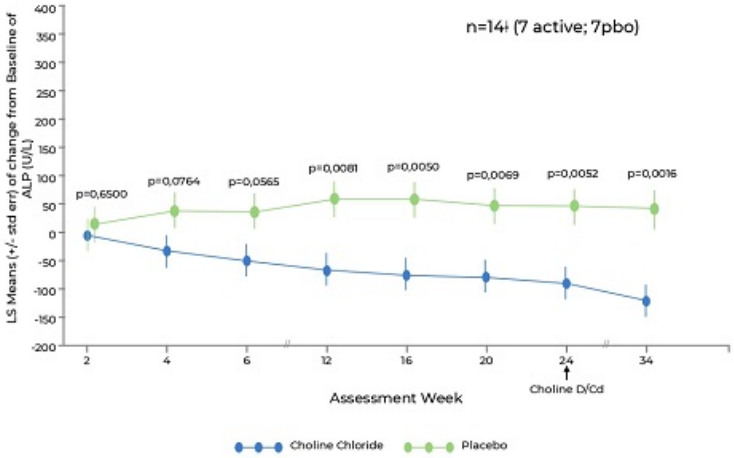
At Baseline




After 24 Weeks




## CHOLESTASIS IMPROVEMENT: ALL PATIENTS*[1]




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

1. Protara Therapeutics re-analysis of patient CRFs, data on file

# SUMMARY

# 2023: FOCUSED EXECUTION DESIGNED TO POSITION PROTARA FOR LONG-TERM GROWTH

Complete Phase 1a Portion of NMIBC Clinical Trial and Initiate Phase 1b

Initiate Phase 2 Clinical Trial in LMs

Complete Prospective Prevalence Study to Refine Development Pathway for IV Choline

Disciplined Approach to Investment

**STRONG BALANCE SHEET:**
$107M of cash, cash equivalents and investments as of September 30, 2022 expected to fund operations into 2H 2024

**19.3M COMMON SHARE EQUIVALENTS:**
11.3M Common + 8.0M Preferred on as converted basis as of September 30, 2022

PROTARA THERAPEUTICS

# APPENDIX

# NMIBC REPRESENTS THE MOST COMMON FORM OF BLADDER CANCER

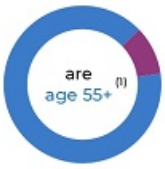
## Bladder Cancer in the U.S.

6th

most prevalent cancer in the U.S.[1]

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

9 in 10




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

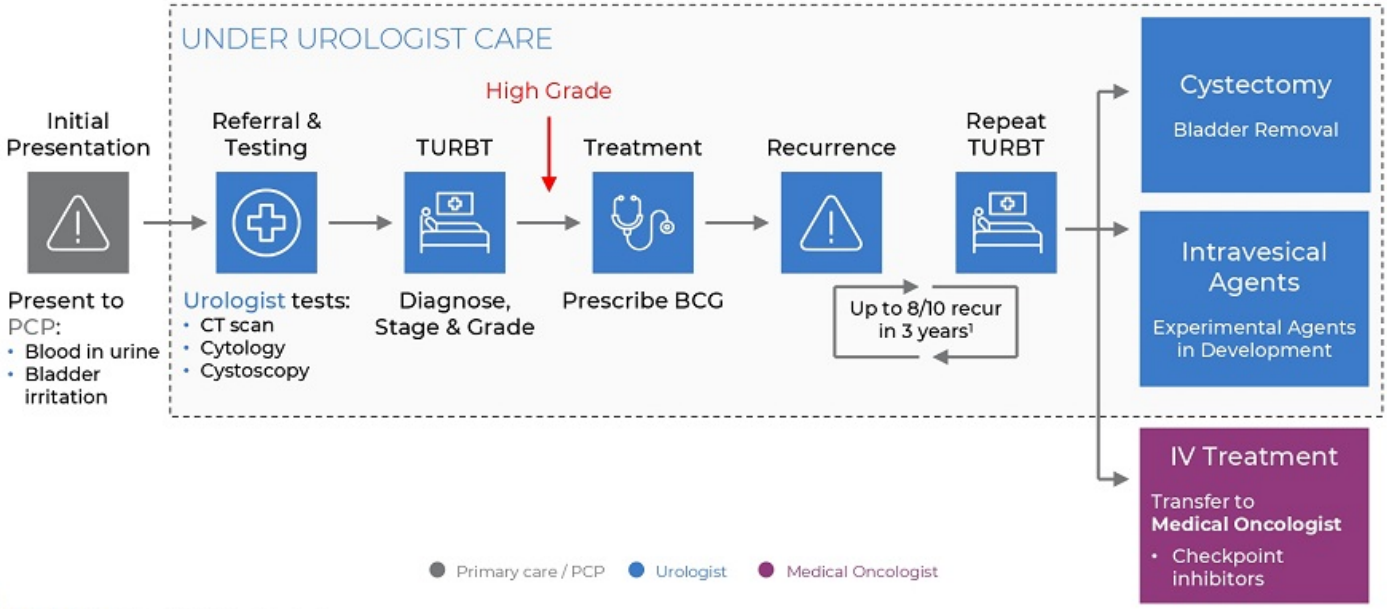
NMIBC makes up ~80% of all bladder cancer with ~65,000 diagnosed per year in the U.S.[4]

NMIBC patients are treated by a urologist

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

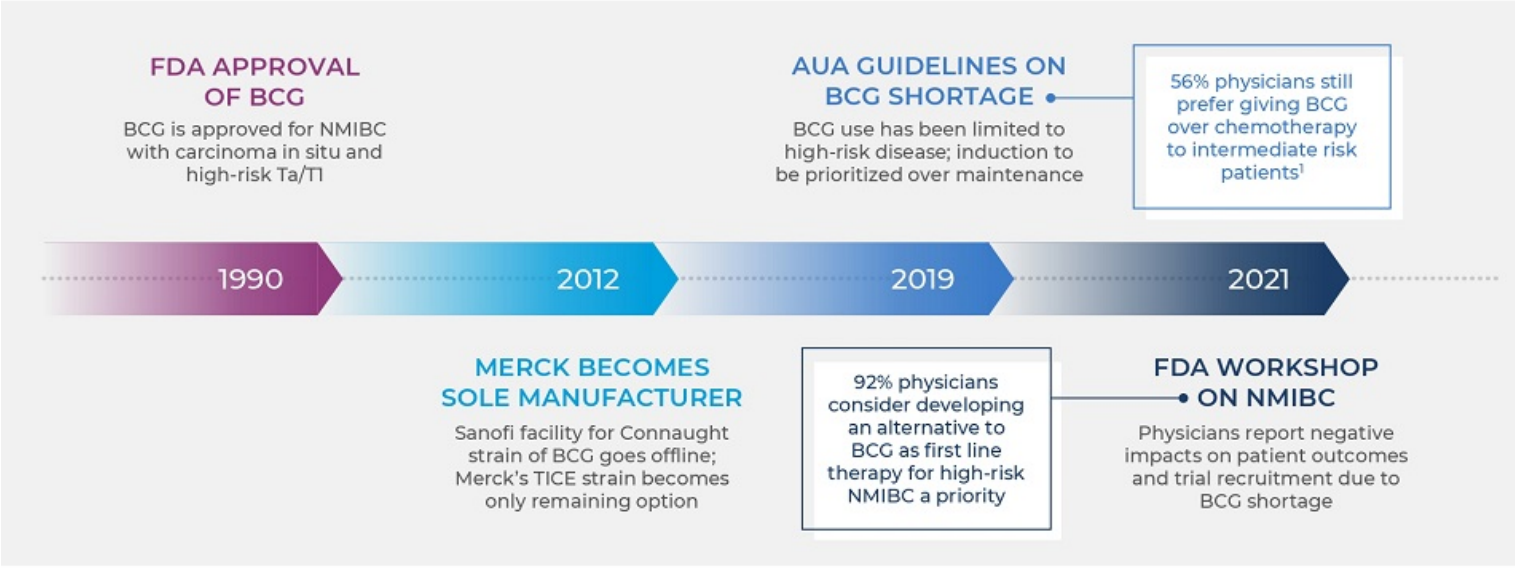
1. National Cancer Institute. SEER Bladder Cancer – Stat Facts. Accessed February 5, 2021. | 2. Saginala, K. et al. Med Sci. 2020. | 3. Campbell Walsh 11th edition, Elsevier. | 4. Anastasiadis et al. Therapeutic Advances in Urology. 2012. | 5. Ourfali, S. et. al. European urology focus. 2019.

# CURRENT STANDARD OF CARE HIGHLIGHTS HIGH UNMET NEED FOR PATIENTS




1. Campbell Walsh 11th edition, Elsevier.

# ONGOING BCG SHORTAGE PRESENTS OPPORTUNITY FOR ALTERNATIVE TREATMENT OPTIONS






1 FDA workshop on BCG shortage (2021)

# 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 | • Measure 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**.<br>• **~28%** of all patients had persistent ALP elevations greater than 1.5 times the ULN at **36 months**.<br>• 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.<br>• 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 |