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): October 12, 2021

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 Third Floor 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 7.01. Regulation FD Disclosure.

On October 12, 2021, Protara Therapeutics, Inc. (the "Company") issued a press release entitled "Protara Therapeutics Announces FDA Clearance of Investigational New Drug Application for TARA-002 for the Treatment of Non-Muscle Invasive Bladder Cancer," a copy of which is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.1, is being furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall the information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01. Other Events.

On October 12, 2021, 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 99.2 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	Press Release dated October 12, 2021, issued by the Registrant.
99.2	Protara Therapeutics, Inc. Corporate Presentation, October 2021.
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: October 12, 2021

By: /s/ Blaine Davis
Blaine Davis
Chief Financial Officer

Exhibit 99.1

Protara Therapeutics Announces FDA Clearance of Investigational New Drug Application for TARA-002 for the Treatment of Non-Muscle Invasive Bladder Cancer

-- Company Plans to Initiate Phase 1 Study of TARA-002 by Year-End --

-- IND Application Included Submission of Confirmatory Large-Scale GMP Comparability Data --

New York, October 12, 2021 – Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage company developing transformative therapies for the treatment of cancer and rare diseases, today announced the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for TARA-002, an investigational cell-based therapy being developed for the treatment of non-muscle invasive bladder cancer (NMIBC). Protara expects to initiate a Phase 1 clinical trial of TARA-002 in adults with high-grade NMIBC by the end of 2021.

"We are thrilled to have reached this important milestone and look forward to quickly initiating our Phase 1 study in patients with NMIBC," said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. "There is an urgent need for new treatments for NMIBC. We are seeing significant increases in recurrence and disease progression, as well as an escalating number of patients requiring cystectomies. Supported by the strength of the existing clinical data in NMIBC for OK-432, the originator therapy for TARA-002, we believe this treatment represents a promising new option for NMIBC patients."

The Phase 1 dose-finding, open-label trial will evaluate TARA-002 in treatment-naïve and treatment-experienced NMIBC patients with high-grade carcinoma in situ (CIS) and high-grade papillary tumors (Ta). In the initial dose escalation phase of the trial, patients will receive six weekly intravesical doses of TARA-002. The primary objective of the trial is to evaluate the safety, tolerability and preliminary signs of anti-tumor activity of TARA-002, with the goal of establishing a maximum tolerated dose and recommended dose for a future Phase 2 clinical trial.

TARA-002 is manufactured from the same cell bank as OK-432, an approved therapy in Japan and Taiwan for multiple oncologic indications. In 2020, Protara successfully demonstrated initial manufacturing comparability between TARA-002 and OK-432. The confirmatory, GMP-scale comparability data for TARA-002 in relation to OK-432 have been completed and were reviewed by FDA as part of the clearance of the IND.

About TARA-002

TARA-002 is an investigational cell therapy in development for the treatment of non-muscle invasive bladder cancer and lymphatic malformations (LMs) for which it has been granted Rare Pediatric Disease Designation by the U.S. Food and Drug Administration. TARA-002 was developed from the same master cell bank of genetically distinct group A Streptococcus pyogenes as OK-432, a broad immunopotentiator marketed as Picibanil® in Japan and Taiwan by Chugai Pharmaceutical Co., Ltd. Protara has successfully demonstrated manufacturing comparability between TARA-002 and OK-432.

When TARA-002 is administered, it is hypothesized that innate and adaptive immune cells within the cyst or tumor are activated and produce a strong immune cascade. Neutrophils, monocytes and lymphocytes infiltrate the abnormal cells and various cytokines, including interleukins IL-6, IL-8, IL-12, interferon-gamma (IFN-γ)-, tumor necrosis factor-alpha (TNF-α), and vascular endothelial growth factor (VEGF) are secreted by immune cells to induce a strong local inflammatory reaction and destroy the abnormal cells.

About Non-Muscle Invasive Bladder Cancer

Bladder cancer is the 6th most common cancer in the United States, with NMIBC representing approximately 80% of bladder cancer diagnoses. Approximately 65,000 patients are diagnosed with NMIBC in the United States each year. NMIBC is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle.

About Protara Therapeutics, Inc.

Protara is committed to identifying and advancing transformative therapies for people with cancer and rare diseases with limited treatment options. Protara's portfolio includes its lead program, TARA-002, an investigational cell-based therapy being developed for the treatment of non-muscle invasive bladder cancer and lymphatic malformations, and IV Choline Chloride, an investigational phospholipid substrate replacement therapy for the treatment of intestinal failure-associated liver disease. For more information, visit www.protaratx.com.

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 non-clinical studies and clinical trials, and statements regarding the anticipated safety or efficacy of Protara’s product candidates. 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 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; 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; 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.

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Company Contact:
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Protara Therapeutics
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646-817-2836

PROTARA THERAPEUTICS

Corporate Presentation

October 2021

Forward Looking Statements

Statements contained in this presentation 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, Protara's manufacturing and development plans for its product candidates and related interactions with the FDA, ex-U.S. development plans, Protara's financial footing, the impact of the COVID-19 pandemic and related governmental responses on Protara's business and clinical programs. 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 sales, revenue, expense and other 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, clinical supply chain, clinical trials, and the global economy; 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; 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. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. 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.

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
- FDA confirmed initial comparability to Japanese predecessor OK-432
- NMIBC: Promising existing clinical data in patients and a proven MOA generally similar to current standard of care; Planning to initiate Phase 1 clinical study 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

- $145M of cash, cash equivalents and investments as of June 30, 2021

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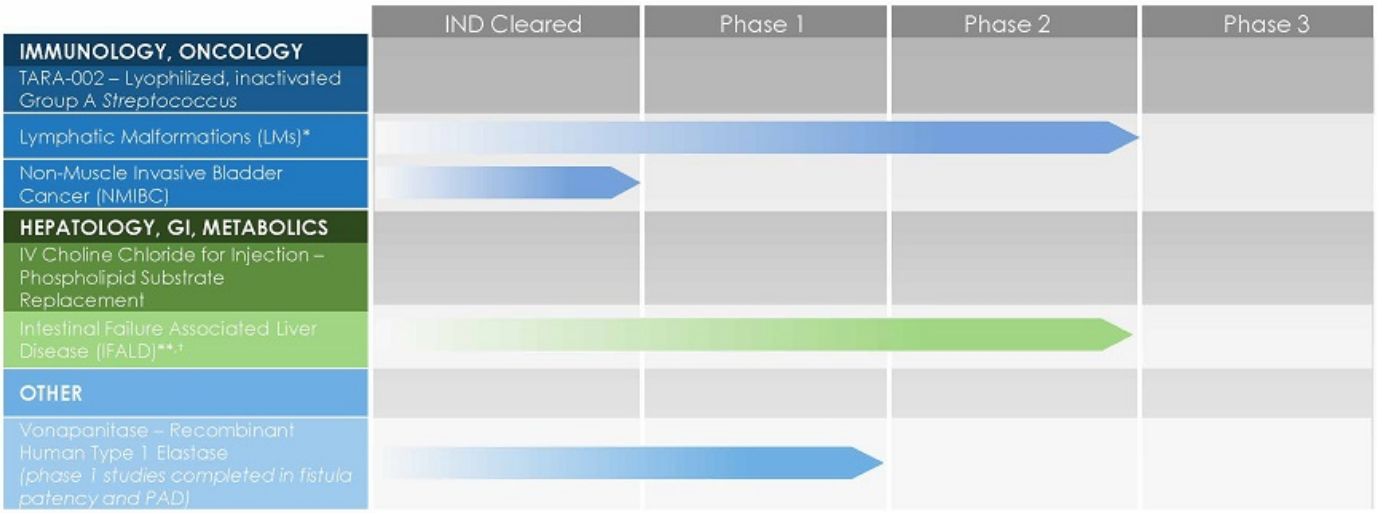
Pipeline Addresses Multiple Indications With High Unmet Need



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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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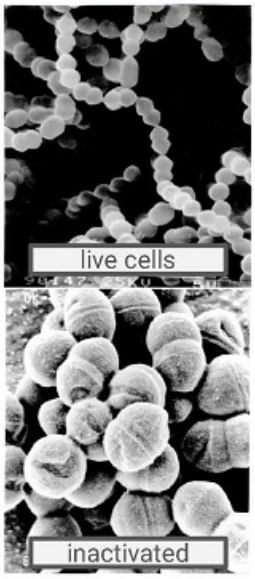
TARA-002

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 OK-432[1], which is approved for 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®.

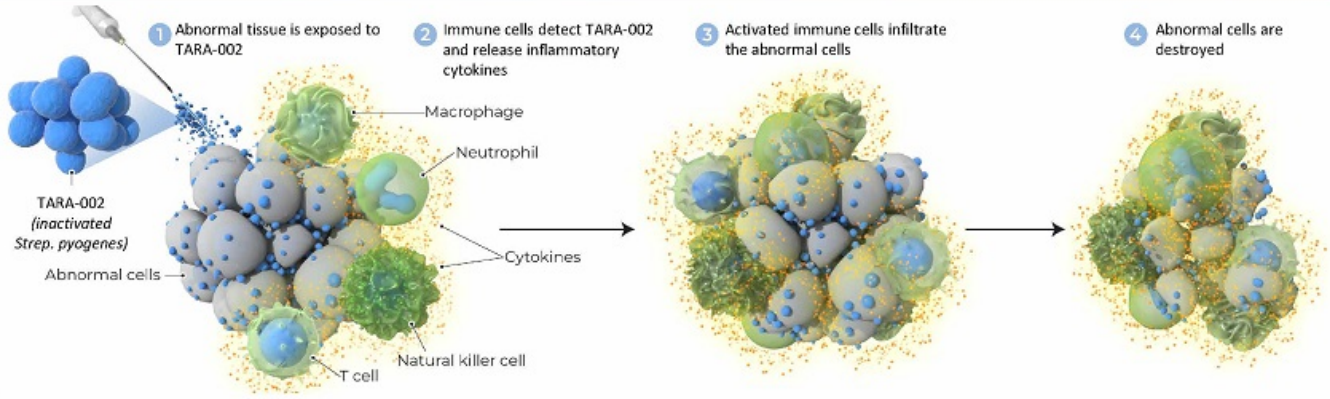
Note: Manufacturing modifications reflect manufacturing to U.S. cGMP standards

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



PROTARA THERAPEUTICS

(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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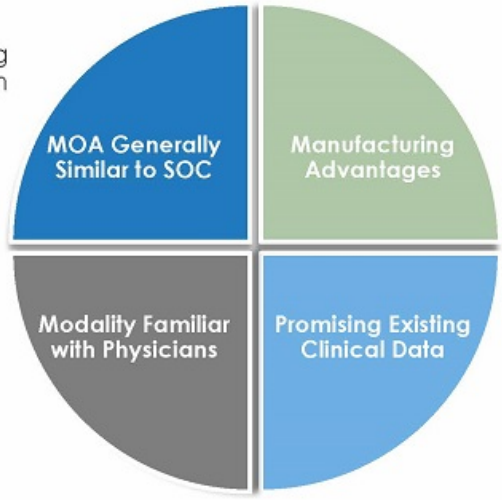
TARA-002

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)



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

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

- ~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 investigator-initiated 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

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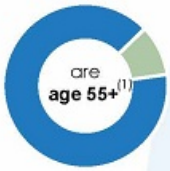
NMIBC Represents the Most Common Form of Bladder Cancer

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]

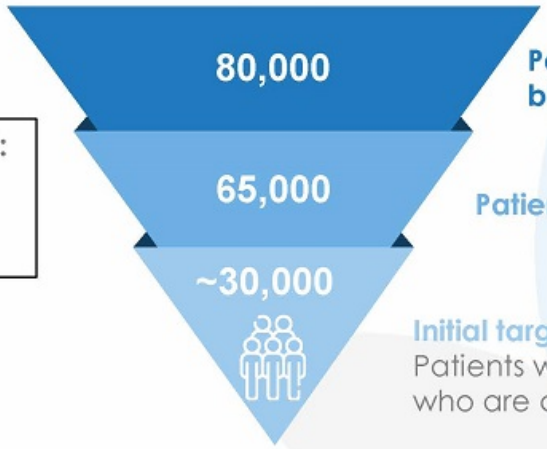
PROTARA THERAPEUTICS

(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]

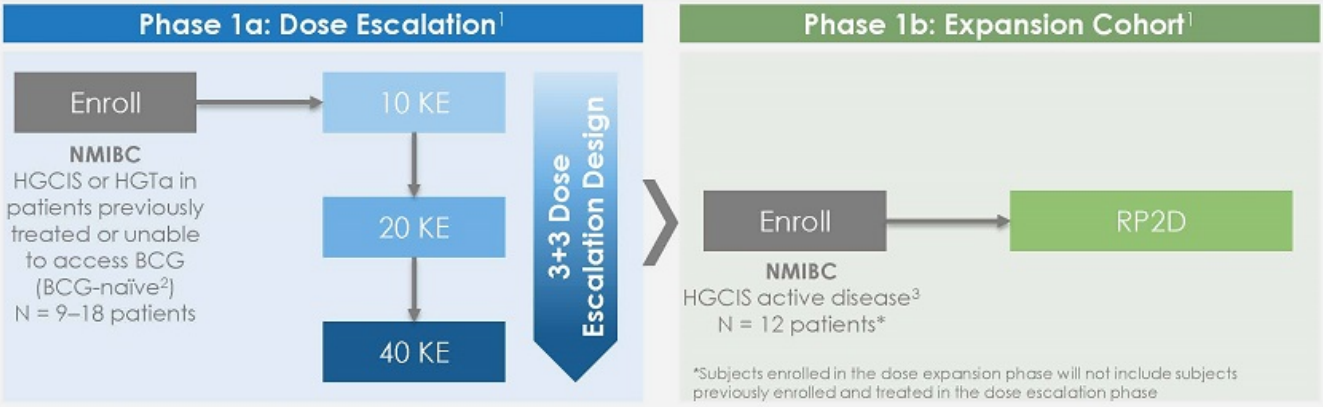
Initial target patient population:
Patients with high grade NMIBC who are candidates for immunotherapy[1-3]

PROTARA THERAPEUTICS

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



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

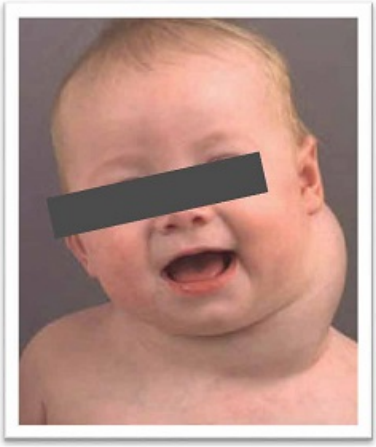
Epidemiology: incidence of lymphatic malformations is ≈1,400-1,800 LM cases per year[2]

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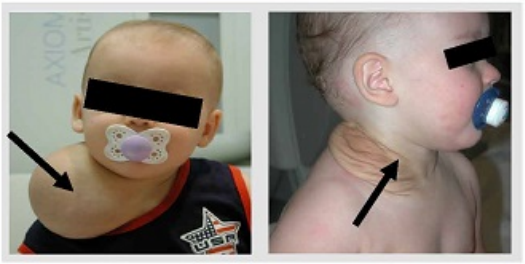
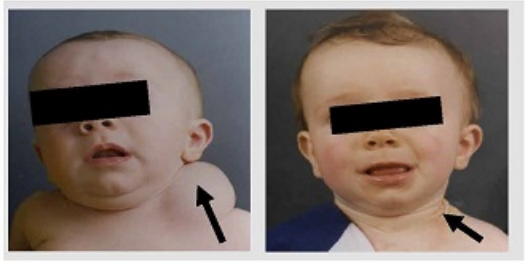
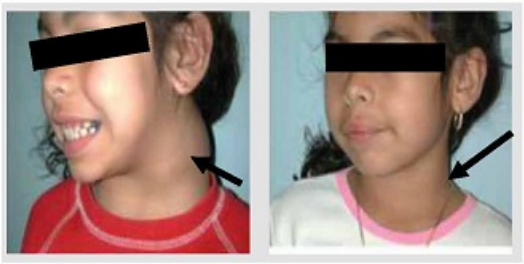
(1) Brouillard P, et al. J Clin Invest. 2014;124:898-904.
(2) Internal company estimates
(3) Ha J, et al. Curr Ped Rev. 2014;10:238-248.

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

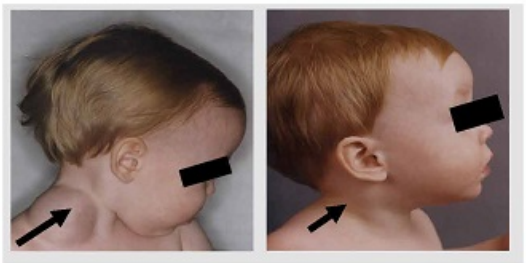


Before After





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

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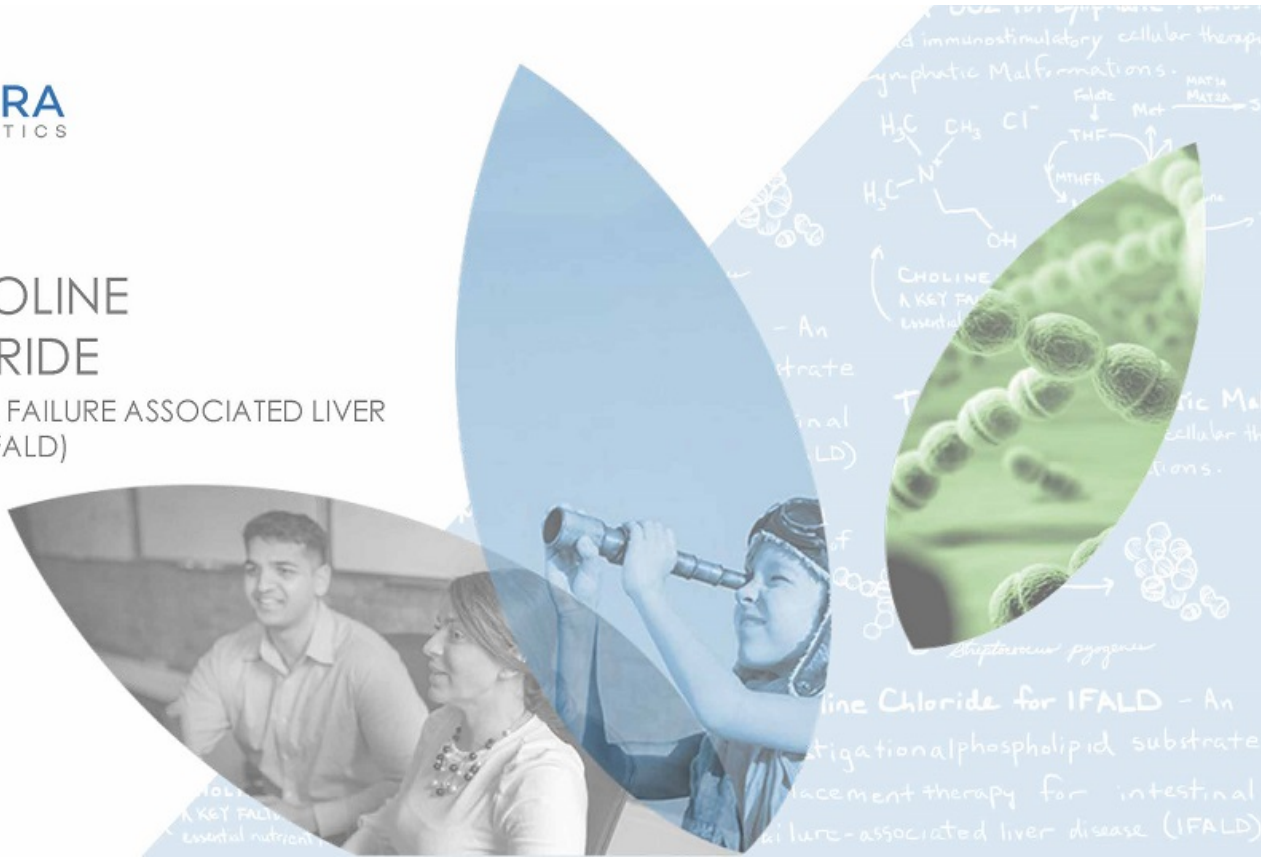
IV CHOLINE CHLORIDE

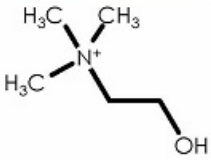
INTESTINAL FAILURE ASSOCIATED LIVER DISEASE (IFALD)



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

PROTARA THERAPEUTICS

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

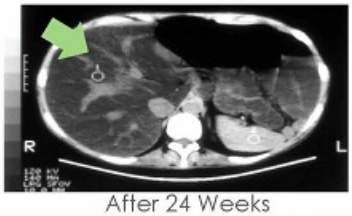
DESIGN	Retrospective, observational study of patients in both academic & community settings
POPULATION	Patients dependent on PN for 6 or more months
OBJECTIVE	• Understand the incidence of cholestasis, a hallmark pathology of IFALD in this patient population • Measuring serum alkaline phosphatase (ALP) 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

IV Choline in IFALD : Phase 2 Results

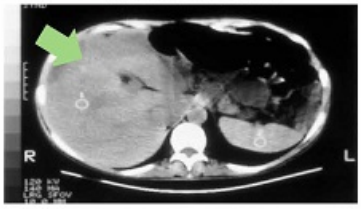
Improvement in Steatosis and Cholestasis

CLINICALLY MEANINGFUL IMPROVEMENT IN STEATOSIS

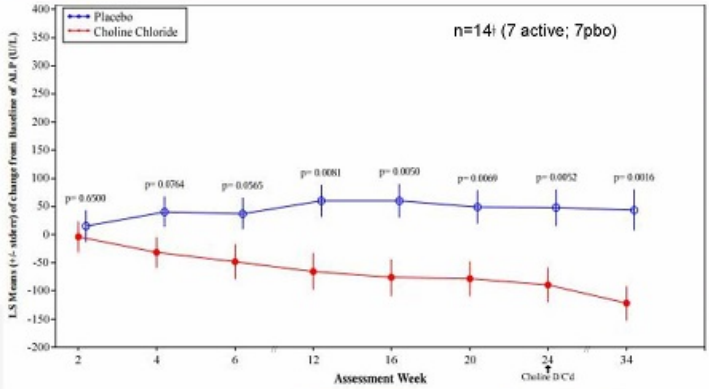
At Baseline



After 24 Weeks



CHOLESTASIS IMPROVEMENT: ALL PATIENTS*(1)



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

PROTARA THERAPEUTICS

(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	• $145M of cash, cash equivalents and investments as of June 30, 2021 • 19.2M Common Share Equivalents:11.2M Common + 8.0M Preferred on as-converted basis as of June 30, 2021

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THERAPEUTICS

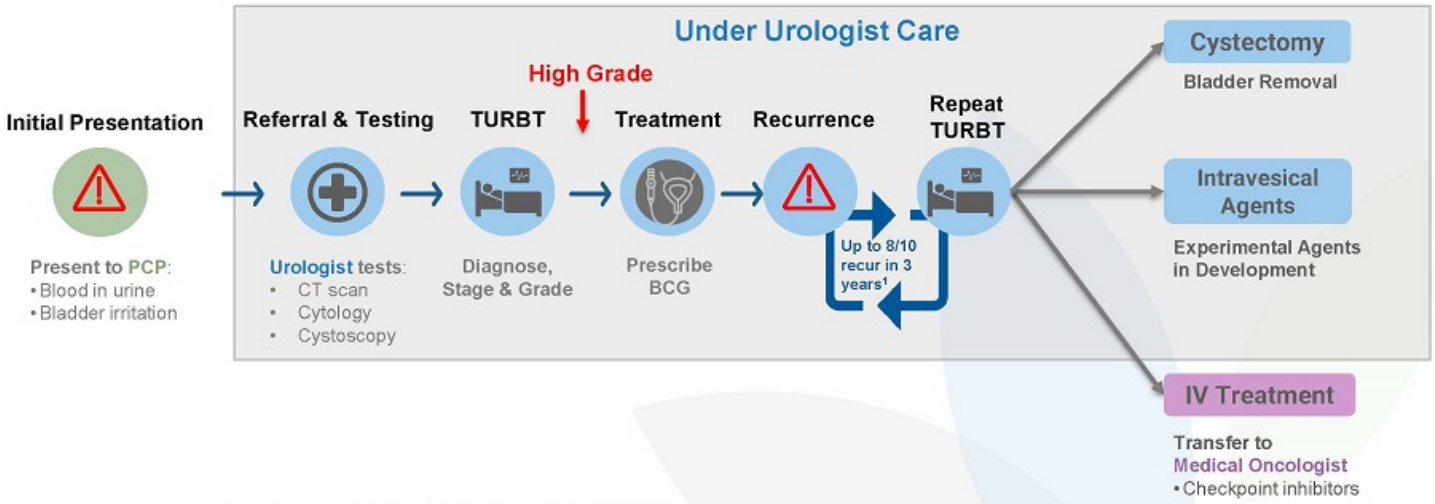
Corporate Presentation

October 2021

PROTARA
THERAPEUTICS

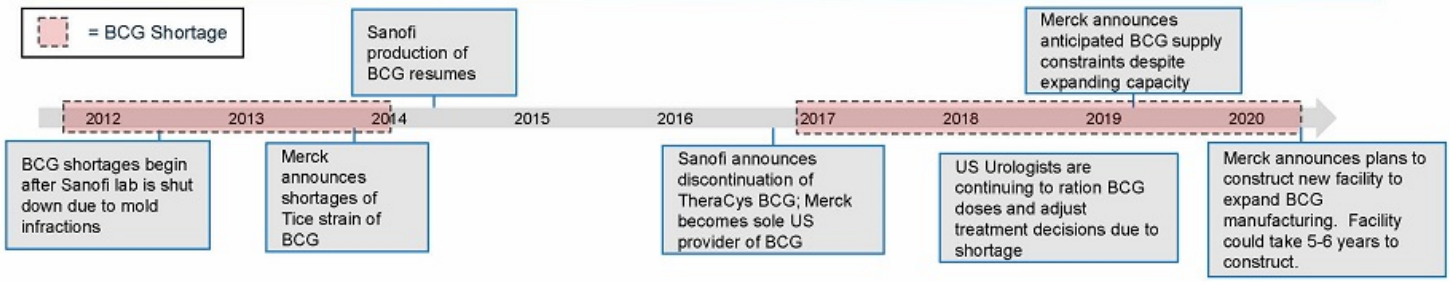
Appendix

Current Standard of Care Highlights High Unmet Need for Patients



(1) Campbell Walsh 11th edition, Elsevier.

BCG Shortage Causes Significant Impact on Care



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 | 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.**"*

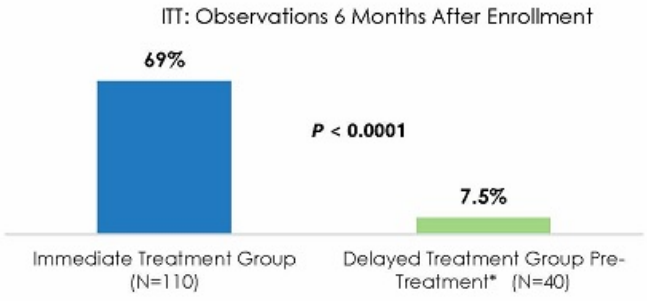
-Academic Hospital Urologist

PROTARA THERAPEUTICS

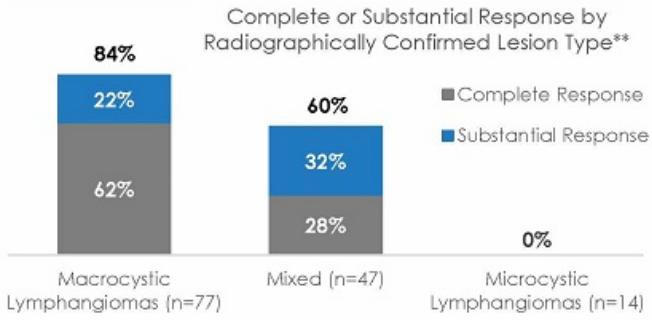
(1) AUA/SUO Joint Guideline: Published 2016; Amended 2020
(2) Market Research Conducted by Protara Therapeutics

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

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‡ 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.

OK-432 in LMs: Compelling Safety Record

Safety Profile*

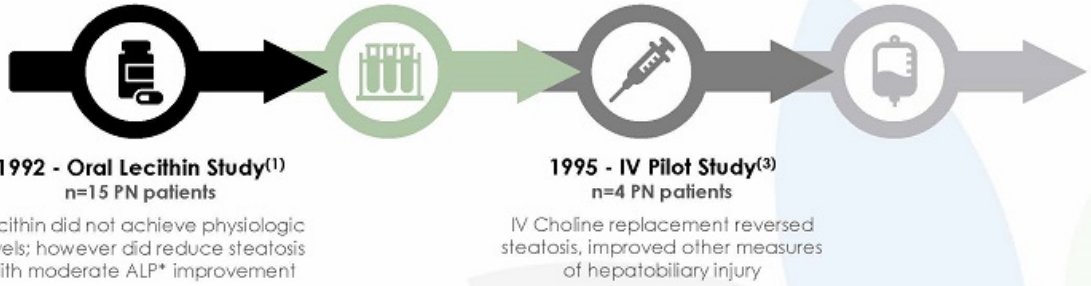
- Most common AEs with treatment were local injection site reactions, fever, fatigue, decreased appetite, with resolution within two weeks
- Treatment emergent SAEs **related** to OK-432: reported in 4.1% of patients, with the most severe events being airway obstruction and facial paralysis due to massive 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

PROTARA THERAPEUTICS

*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.

IV Choline in IFALD: Informative Clinical History

A significant body of supportive evidence across 4 studies



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

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

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

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

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

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

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

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

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.