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): November 12, 2020

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.)

1 Little West 12th Street New York, NY	10014
(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 November 12, 2020, the U.S. Food and Drug Administration Division of Vaccines and Related Products Applications (the "Division") notified Protara Therapeutics, Inc. (the "Company") that an update and the accompanying clarification questions that the Company previously submitted to the Division related to the Company's Investigational New Drug Application for TARA-002 in Lymphatic Malformations are being reviewed and that the Division is in the process of generating responses to the Company's clarifying questions. The Division indicated that it will not grant the Company's request for an End of Phase 2 meeting at this time and that a meeting may be appropriate following the Division's responses to the Company's clarifying questions.

In connection with the Division notification, on November 17, 2020, the Company made available an updated 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 Number	Exhibit Description
99.1	Protara Therapeutics, Inc. Corporate Presentation, November 2020.

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.

Dated: November 17, 2020

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

PROTARA THERAPEUTICS

Corporate Presentation

November 2020

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.

PROTARA THERAPEUTICS

Investment Summary

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 clinical development plan in place following Pre-Investigational New Drug (PIND) engagement with FDA
- TARA-002/OK-432 is standard of care in Japan for LMs; completed Phase 2 study in U.S. supports treatment effect with strong safety profile

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

- IV Choline in intestinal failure associated liver disease (IFALD): Completed End Of Phase 2 dialogue with FDA and aligned on Phase 3 design

Company well funded through anticipated key milestones through early 2023

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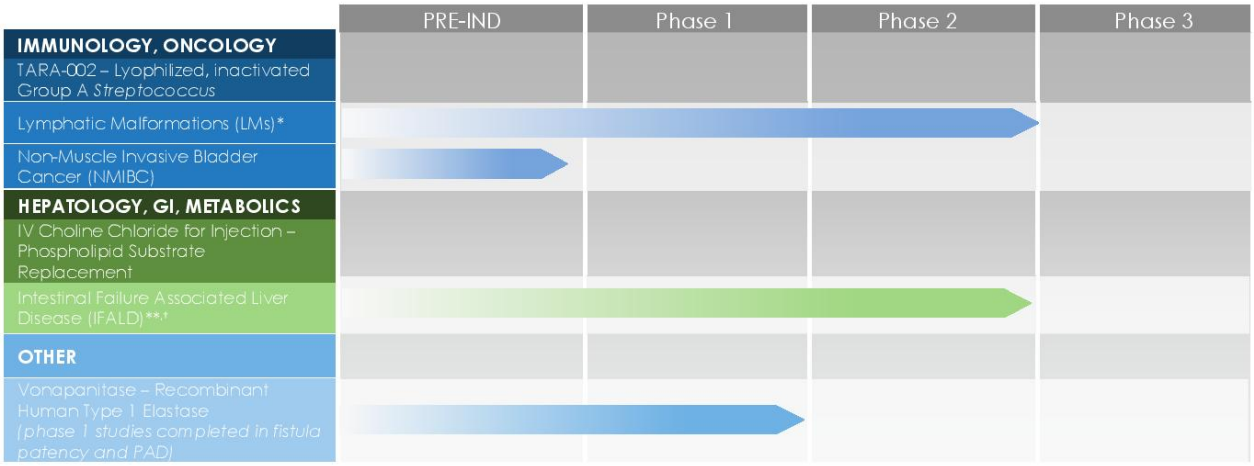
Pipeline Addresses Multiple Indications With High Unmet Need



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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

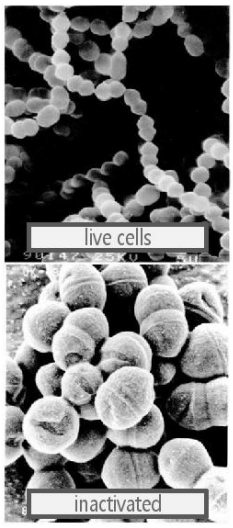
PROTARA THERAPEUTICS

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], once one of the largest selling oncology products in Japan
- FDA has confirmed initial comparability between TARA-002 and OK-432 and path forward to completion of GMP comparability
- Having established initial comparability to OK-432, the extensive data generated by OK-432 will help support TARA-002
- Protara has worldwide rights ex-Japan & Taiwan for TARA-002/OK-432



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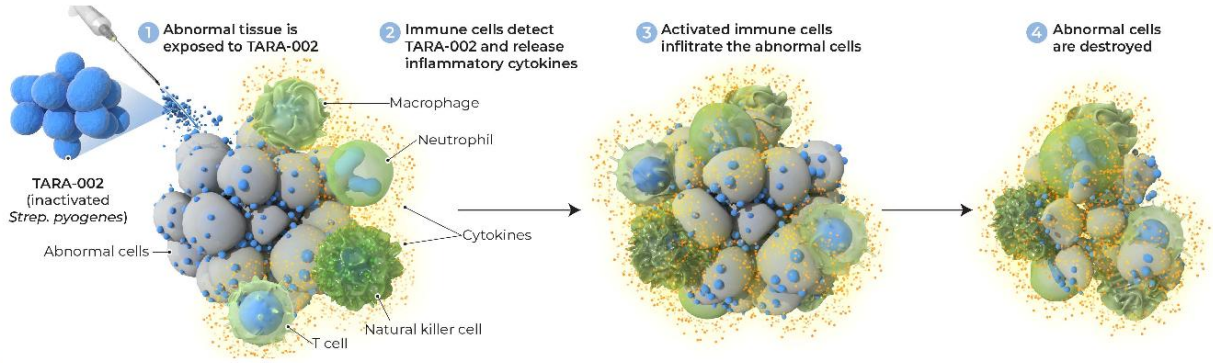
(1) Marketed in Japan and Taiwan as Picibanil®.
Note: Manufacturing modifications reflect manufacturing to U.S. cGMP standards

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

PROTARA THERAPEUTICS

(1) Full Prescribing Information. Chugai Pharmaceuticals. 2016

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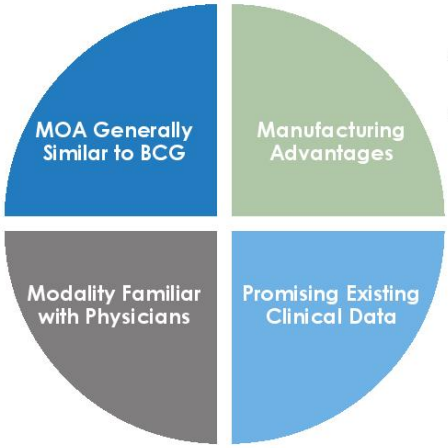
TARA-002

NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)

TARA-002 in NMIBC: Profile Supports Potential in NMIBC

Similar mechanism to BCG, notable patient experience in Asia and manufacturing advantages

- Prompts a predominantly Th1 type cytokine response
- Mechanistically similar to Bacille Calmette-Guérin (BCG)



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

- Urologists have been using an attenuated bacteria, BCG, as immunotherapy 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

PROTARA THERAPEUTICS

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

Clinical Evidence with 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:

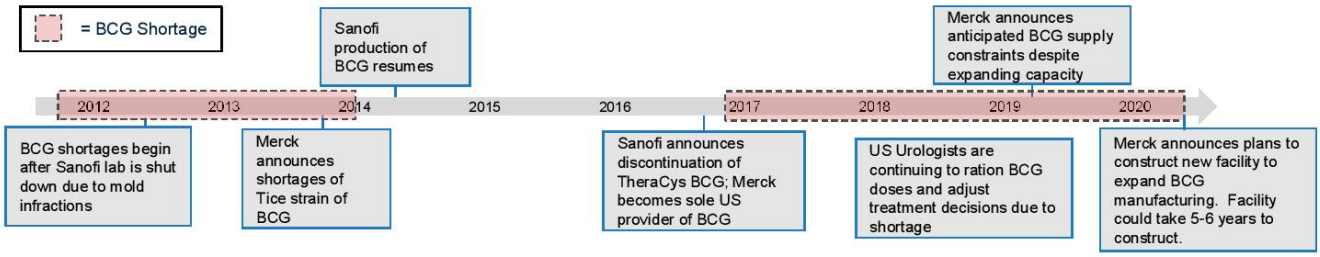
- Was generally well-tolerated, with safety and tolerability observed across a range of doses
- Demonstrated efficacy and lower rates of recurrence vs. control group, including in the randomized, controlled setting

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 over in the control arm ($p<0.05$) at 36 months cut off. 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).
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.
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.

PROTARA THERAPEUTICS

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

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

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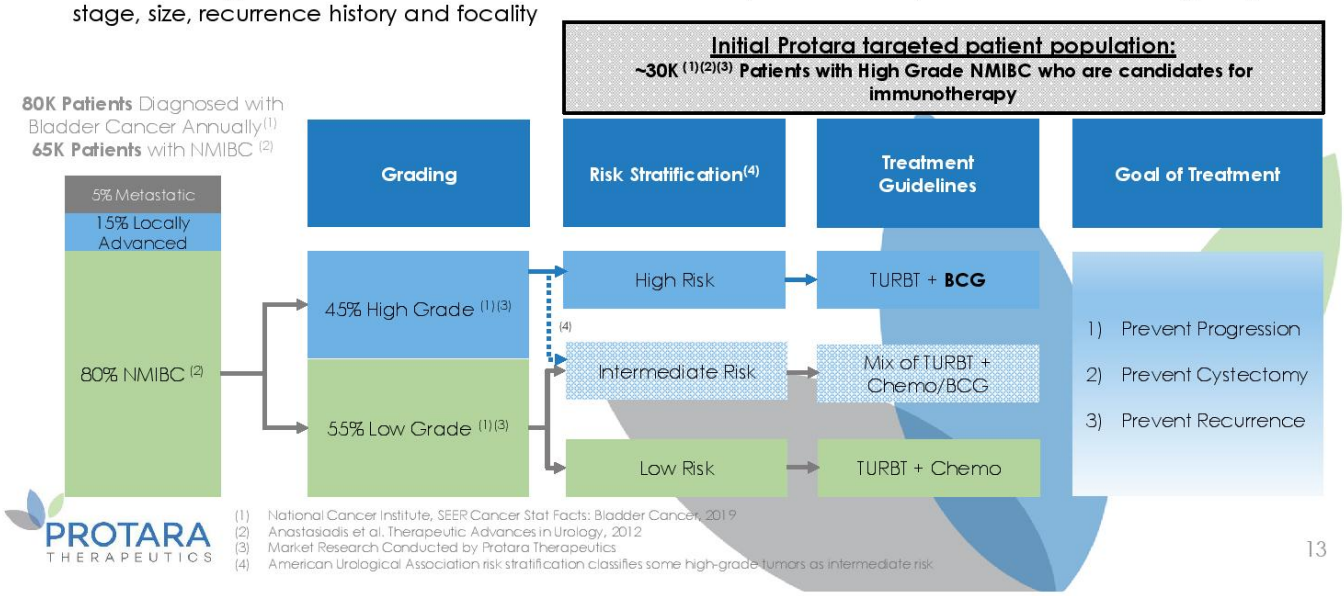
(1) AUA/SUO Joint Guideline: Published 2016; Amended 2020
(2) Market Research Conducted by Protara Therapeutics

TARA-002 in NMIBC: Overview of U.S. NMIBC & Target Population

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



(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
(4) American Urological Association risk stratification classifies some high-grade tumors as intermediate risk

TARA-002 in NMIBC: Highlights of PIND FDA Interaction

Supportive feedback on multiple facets of NMIBC program

CMC:	▪ **Initial comparability established** – GMP scale up in process to complete full comparability testing ▪ Modernized release criteria for large scale (3 batch) comparability
Non-Clinical:	▪ Aligned on 6-week local (intravesical instillation) toxicology design with recommendations for IND content preparation ▪ Requested MOA characterization & immunogenicity studies
Phase 1:	▪ Initial dose escalation in papillary patients ▪ Clear to enroll CIS patients in Phase 1
Phase 2	▪ Support for study in CIS patients ▪ Obtained alignment on clinically meaningful endpoints ▪ Papillary patient study suggested comparator to be a chemotherapeutic agent

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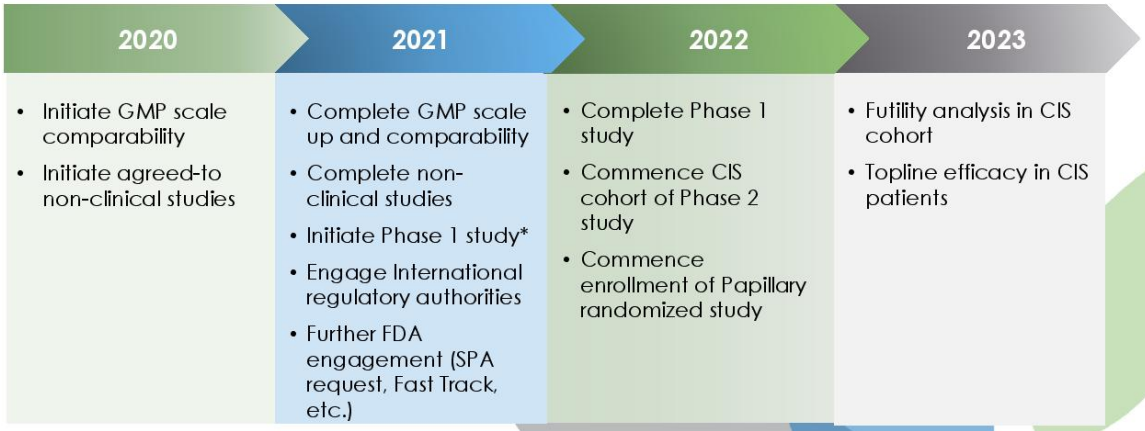
TARA-002 in NMIBC: Estimated Development Timeline



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*Subject to acceptance of IND filing

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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

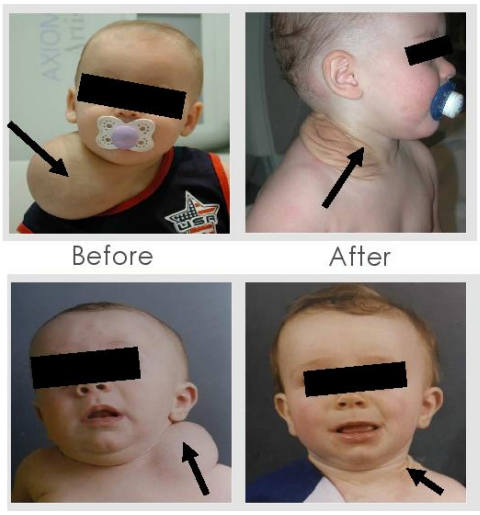
FDA Granted Pediatric Rare Disease Designation

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

PROTARA THERAPEUTICS

(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



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Protara Therapeutics data on file

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

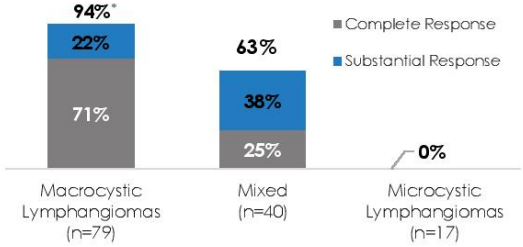
68% CLINICAL SUCCESS‡ IN IMMEDIATE TREATMENT GROUP 6 MONTHS AFTER ENROLLMENT

ITT: Observations 6 months after enrollment

- None of these patients required surgery
- During this same period, no patients in the delayed treatment group experienced spontaneous regression of LM ($p<0.001$)
- Treatment: 1-4 injections at 8-week intervals max of 0.2mg/session (2KE)

94%* CLINICAL SUCCESS‡ IN PATIENTS WITH MACROCYSTIC LESION TYPES

Complete or Substantial Response by Radiographically Confirmed Lesion Type



- Patients with radiographically confirmed appropriate 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
*Numbers do not sum due to rounding
**Reflects data prior to dosing with OK-432. After dosing, the clinical success rate was 58%, which was not statistically different from the Immediate Treatment Group

(1) Smith M, et al. Laryngoscope. 2009;119:107-115.

OK-432 in LMs: Compelling Safety Record

Long-term safety data in 99 patients with up to 8 years of follow up

Safety Profile

- Most common AEs with treatment were local injection site reactions, fever, fatigue, decreased appetite, with resolution within two weeks
- SAEs **related** to OK-432: re-hospitalization for infection (n=3) and severe edema (n=3), airway obstruction necessitating tracheostomy tube placement (n=4), and submental intra-cystic hemorrhage necessitating surgical excision (n=1)
- Minor AEs **related** to OK-432: temporary brachial plexus compression, myalgia, infections treated with oral antibiotics, intra-cystic hemorrhage, and dehydration
- Two SAEs **not related** to OK-432: death due to tracheotomy tube obstruction and vision loss following proptosis

PROTARA THERAPEUTICS

Smith M, et al. Laryngoscope. 2009;119:107-115.

TARA-002 in LMs: Regulatory Update

1. IND update completed and filed with FDA Division of Vaccines and Related Products
2. IND update included clarifying questions related to the regulatory pathway in LMs as well as the confirmation of initial comparability between TARA-002 and OK-432 received from FDA's Office of Tissues and Advanced Therapies in August
3. In October, EOP2 meeting request submitted to FDA to discuss regulatory pathway in LMs
4. FDA denied the company's EOP2 meeting request, at this time, in order to provide answers to clarifying questions posed in the IND update prior to engaging in a meeting
5. FDA notified the company the information submitted to the IND update is still being reviewed and FDA is generating responses to the company's clarifying questions

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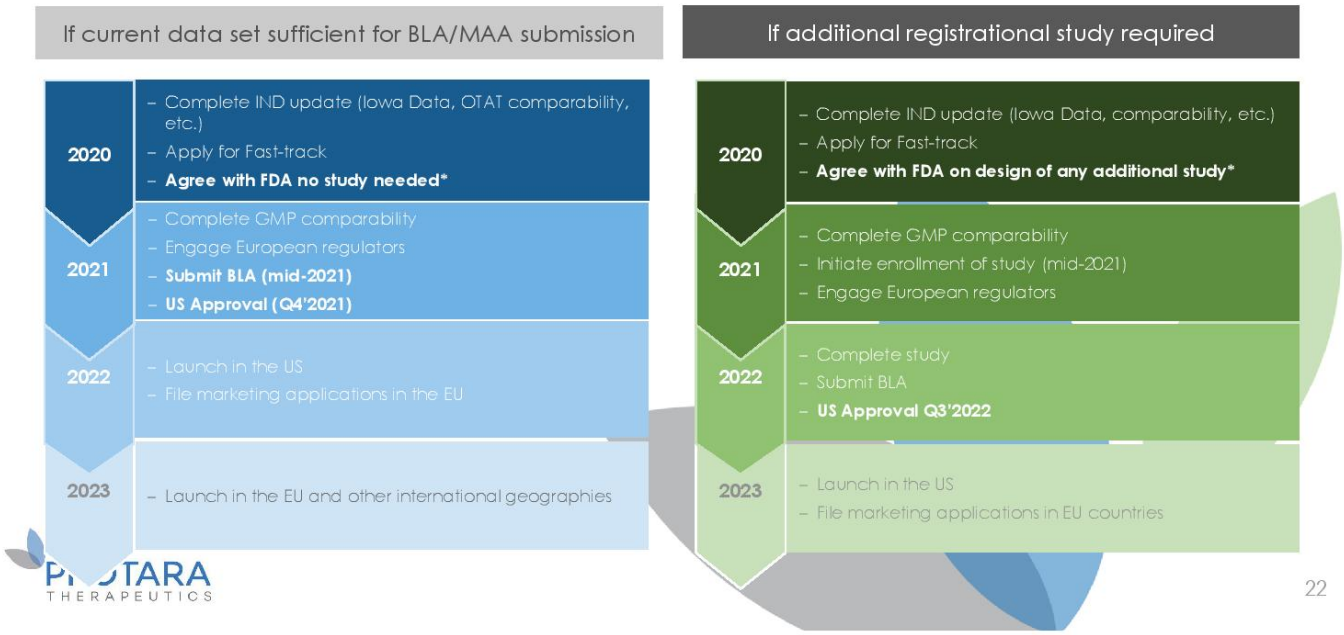
TARA-002 in LMs: Planned Next Steps



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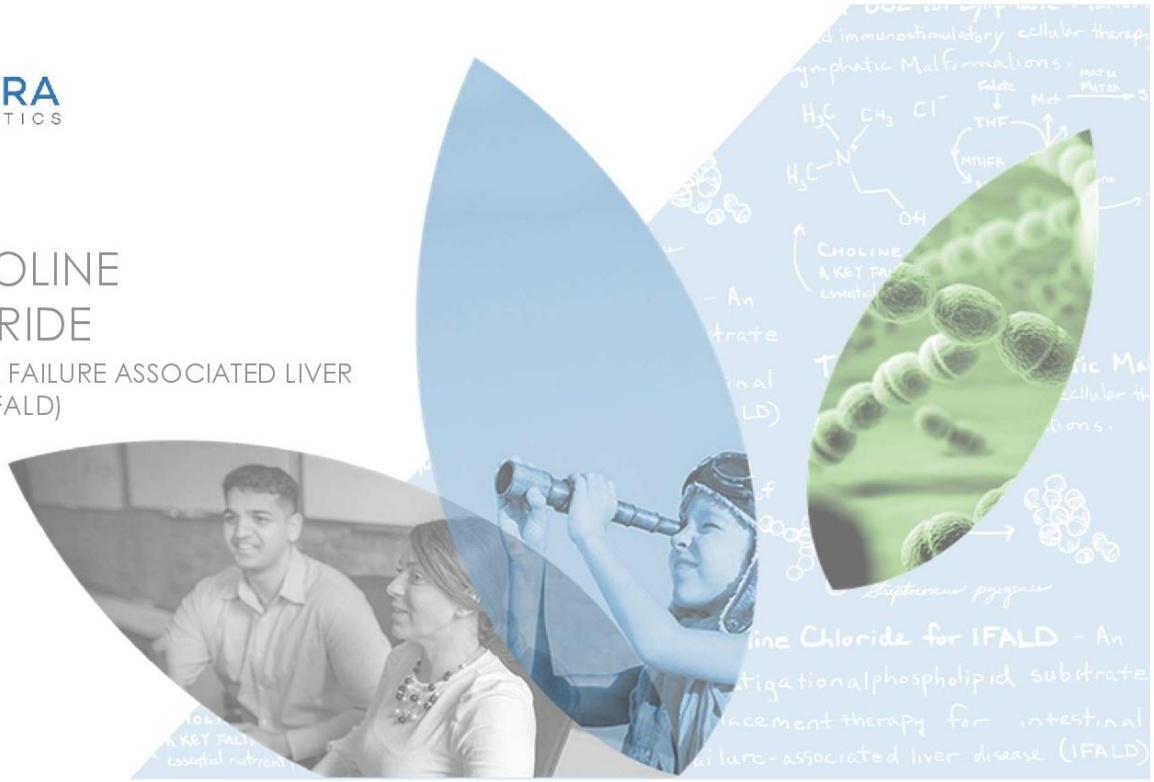
IV CHOLINE CHLORIDE

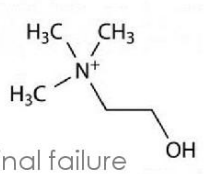
INTESTINAL FAILURE ASSOCIATED LIVER DISEASE (IFALD)



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

An Essential Molecule in Several Metabolic Processes

Patients dependent on Parenteral Nutrition (PN) cannot absorb sufficient levels of choline. Data confirms that choline deficient diets results in steatosis and cholestasis[1]



Clinical History Supporting Choline Substrate Replacement in IFALD (intestinal failure associated liver disease) Patients

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

FDA designations (Orphan Drug Designation, Fast Track Designation) combined with encouraging feedback from End of Phase 2 meeting for Phase 1 PK study followed by Phase 3 trial

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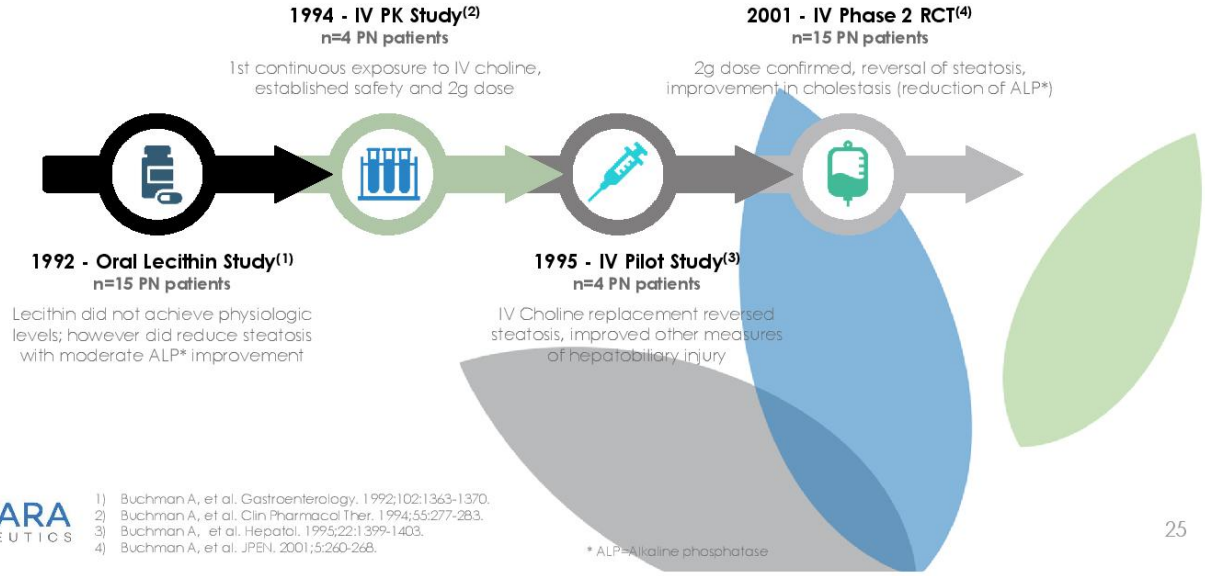
(1) Buchman A, et al. JPEN. 2001;5:260-268.
(2) Mundi M, et al. ASEPN. 2017;32:799-805.
(3) Internal Protara market research

IV Choline in IFALD: Informative Clinical History

A significant body of supportive evidence across 4 studies



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.

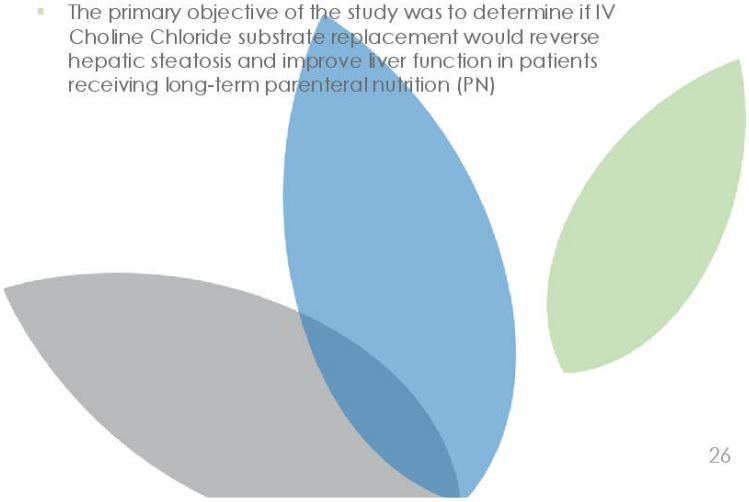
* ALP=Alkaline phosphatase

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 proof-of-concept, 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 parenteral nutrition (PN)



PROTARA THERAPEUTICS

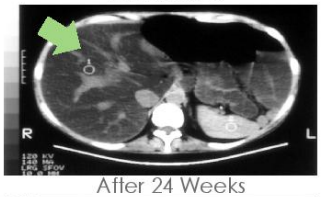
1) Buchman A, et al. JPEN. 2001;5:260-268.

IV Choline in IFALD : Phase 2 Results

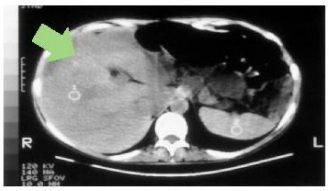
Improvement in Steatosis and Cholestasis

CLINICALLY MEANINGFUL IMPROVEMENT IN STEATOSIS

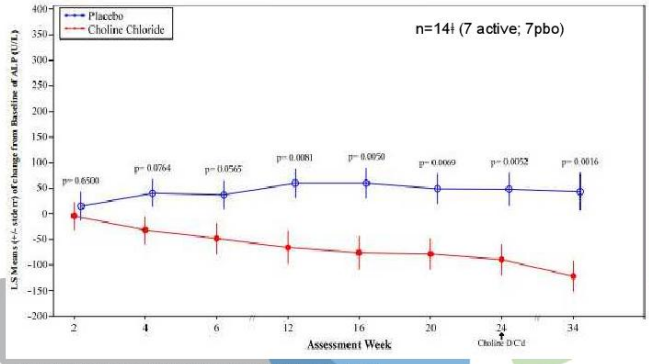
At Baseline



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

PROTARA THERAPEUTICS

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

IV Choline in IFALD: Prevalence Study

Prevalence study underway 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 presence/incidence of liver disease in this population to enhance value of development potential
QUESTIONS	How many individuals currently on service have been dependent on PN for 6 or more months? What percentage of these have elevated ALP levels (> 1.5x ULN) as an indicator of liver disease?

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FINANCIAL OVERVIEW

Finance Overview

$166M

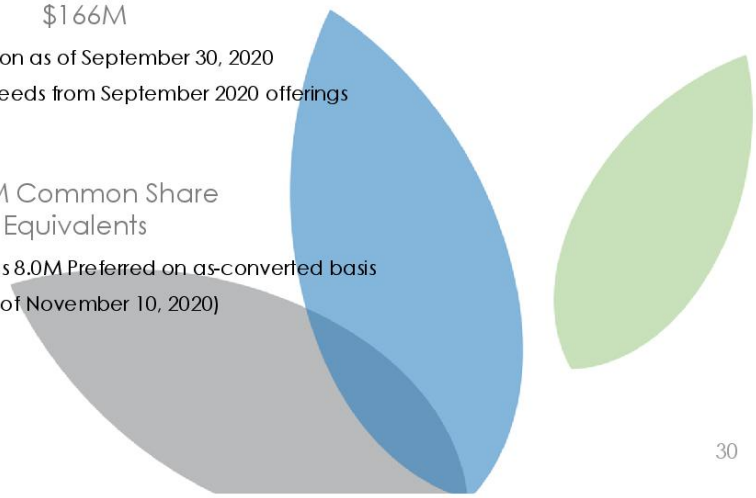
Cash position as of September 30, 2020

- $151M net proceeds from September 2020 offerings

19.2M Common Share Equivalents

11.2M Common plus 8.0M Preferred on as-converted basis

(as of November 10, 2020)



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Investment Summary

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 clinical development plan in place following Pre-Investigational New Drug (PIND) engagement with FDA
- TARA-002/OK-432 is standard of care in Japan for LMs; completed Phase 2 study in U.S. supports treatment effect with strong safety profile

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

- IV Choline in intestinal failure associated liver disease (IFALD): Completed End Of Phase 2 dialogue with FDA and aligned on Phase 3 design

Company well funded through anticipated key milestones through early 2023

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APPENDIX

OK-432 in LMs: Overview of Completed Phase 2 Study

Randomized, Controlled Study (N=117)[1]	
Age	6 months – 18 yrs
Inclusion Criteria	LMs of the head and/or neck confirmed by MRI or CT ▪ Radiographically confirmed macrocystic LM or mixed macrocystic-microcystic LM with >50% macrocystic component At least 6 months since prior surgery for lymphangioma
Exclusion Criteria	Penicillin allergy, pregnancy and/or nursing, personal or family history of rheumatic heart disease, post-streptococcal glomerulonephritis, PANDAS, history of significant cardiac, pulmonary, hepatic, renal, or hematologic disease
Treatment Groups	Immediate Treatment Group (ITG): Received OK-432 shortly after enrollment Delayed Treatment Group (DTG): Observed for 6 months for spontaneous regression, then treated with OK-432 Open Label Group (OLG): nonrandomized, included infants <6 months, adults >18 yrs, patients with LMs in sites other than the head/neck, and patients treated on an emergent basis
Randomization	2:1 Randomization (per blocks of 6 enrollees) 2/3 in ITG and 1/3 in DTG (control group)
Duration of Treatment	1-4 injections 8 weeks apart
Dose	Max of 0.2mg/session (i.e. 2 Klinische Einheit)

Primary Endpoint: Response to treatment in the ITG compared to the spontaneous resolution rate observed in the DTG, 6 months after enrollment

Definition of Response

Response to therapy was measured radiographically (MRI or CT) by quantitating change in lesion size and graded as:

- Complete (90%–100%),
- Substantial (60%–89%),
- Intermediate (20%–59%),
- None (<20%)

Secondary Endpoints:

1) The proportion of ITG patients versus DTG patients who demonstrated a complete response (90%–100%) 6 months following enrollment
2) The proportion of randomized patients who demonstrated at least a substantial response (60%–100%) greater than 6 months following the last injection (i.e. persistence of response)
3) The proportion of patients in the OLG who demonstrated at least a substantial response (60%–100%) 6 months following enrollment and 6 months following the last injection (i.e. persistence of response)

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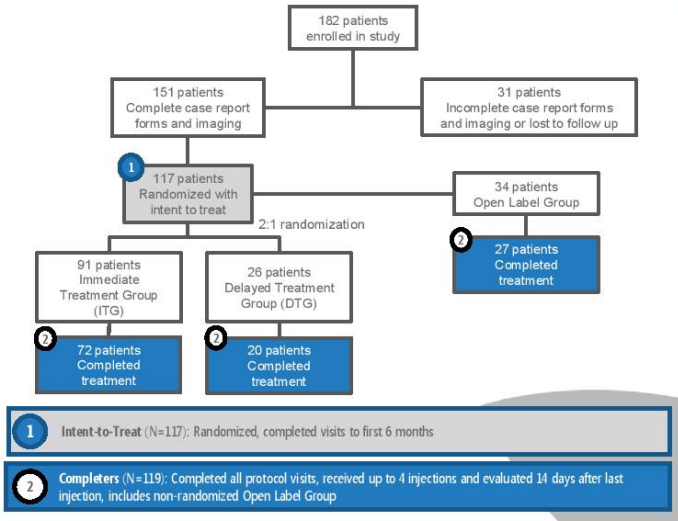
(1) Smith M, et al. Laryngoscope. 2009;119:107-11.5.

OK-432 in LMs: Patient Disposition of Completed Phase 2 Study[1]



Patient Demographics

Group	Patients Enrolled (n=182)	Patients Randomized Completing Treatment (n=92)	Open Label Group Completing Treatment (n=27)
Sex (F:M)	92 : 90	42 : 50	15 : 12
Age Range (years)	0-73.1	0.5-15.5	0-73.1
Mean/median age (years)	5.8/1.7	3.5/2.1	13.4/1.1
Race Demographics			
Caucasian	133	74	20
African-American	15	8	2
Asian-Pacific Islander	14	4	4
Hispanic	10	6	1
Unknown	10		

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(1) Smith M, et al. Laryngoscope. 2009;119:107-115.

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Corporate Presentation

November 2020