

Developing Therapies to Address Serious Cancers Impacting Women



What is the Problem?

Women are dying at an alarming rate from two of the most difficult to treat cancers —platinum-resistant ovarian cancer and triple-negative breast cancer— because few effective treatments exist.

We must change this!



CureLab is Fighting Two Lethal Female Cancers: PROC and TNBC

Elenagen: Investigational DNA Therapy Encoding Protein, p62/SQSTM1 (p62)

- Elenagen acts through multiple novel synergistic mechanisms of action (MOAs)
- Lead Program: Ex-US Phase 2 PROC trial demonstrated significant increase of progression-free and overall survival; good safety profile
- 2nd Program: TNBC: good safety profile; promising case study

Large Market Opportunities

- Both PROC & TNBC each represent \$1B+ markets
- Strategic partnership with Gynecologic Oncology Group Foundation, (GOG)
- Partnerships: MD Andersen Cancer Center, NYU Medical School, globally

Started ex-US using grants; now US/Major Markets (FDA+EMA)

Extensive IP protection in more than 20 markets

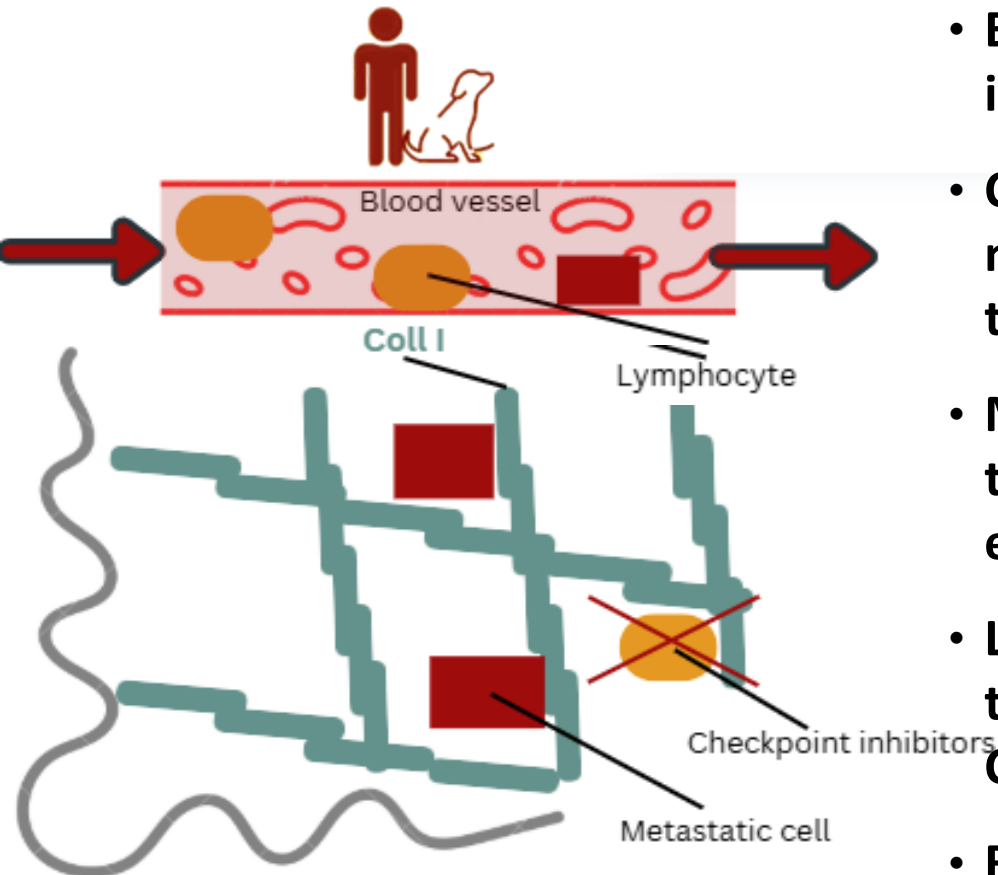
**Exit 0-3 Yrs post
IND**

**Help Us Bring
Hope**



Elenagen Acts Through Synergistic Mode of Actions

Chronic Inflammation



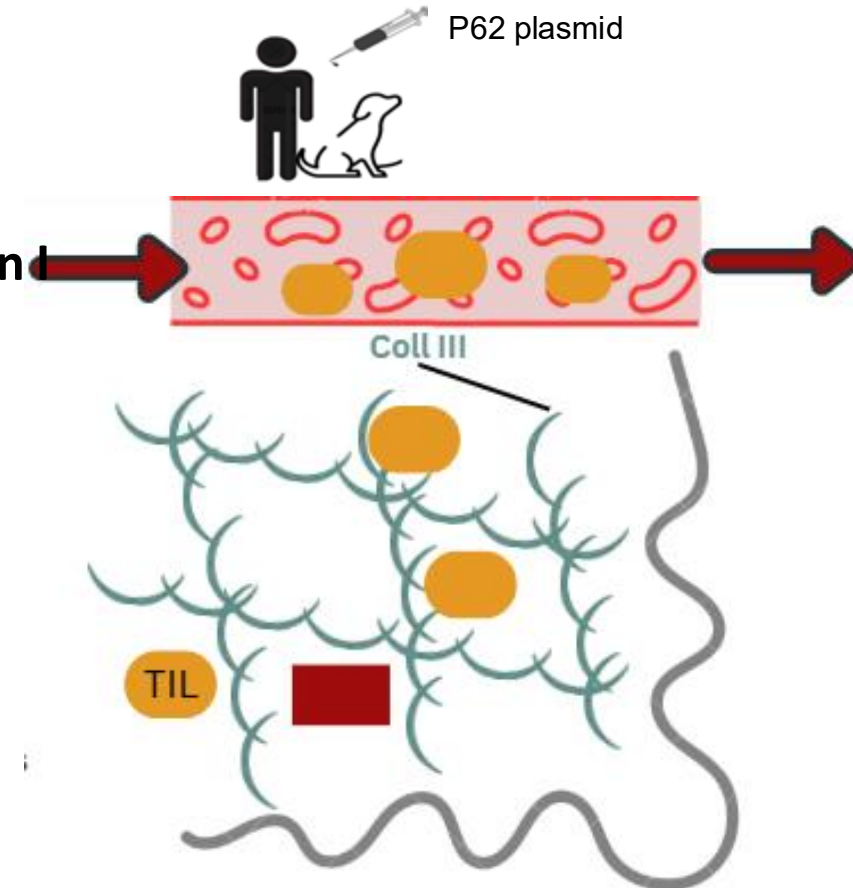
Cold Tumor

Lymphocytes do not infiltrate a tumor

Metastatic cells exit tumor

- Elenagen reduces chronic inflammation, thus
- Changes intra-tumoral microenvironment (e.g. Collagen I to Collagen III), thus
- Metastatic cells cannot exit the tumor (as they use Col I more efficiently) and
- Lymphocytes start infiltrating a tumor forming TILs (as they use Col III more efficiently)
- Reduced chronic inflammation reduces intra-tumoral immunosuppression (e.g. via checkpoint inhibitors)

No Chronic Inflammation

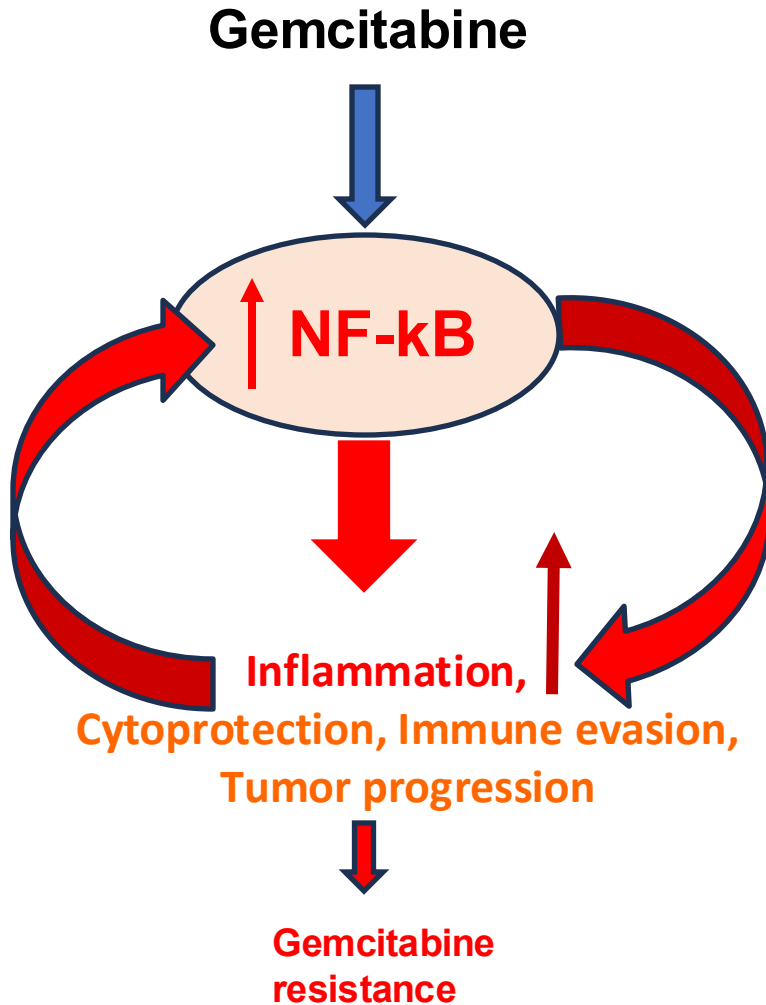


Hot Tumor

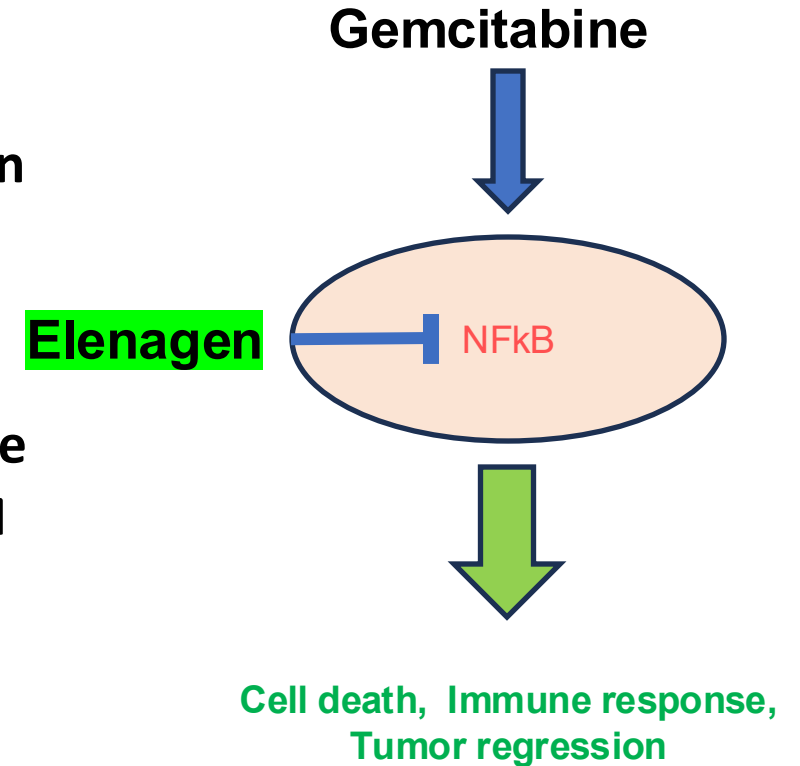
Lymphocytes do infiltrate a tumor

Metastatic cells do not exit tumor

Elenagen Prevents Development of Gemcitabine (GEM) Resistance by Blocking NF-kB Pathway

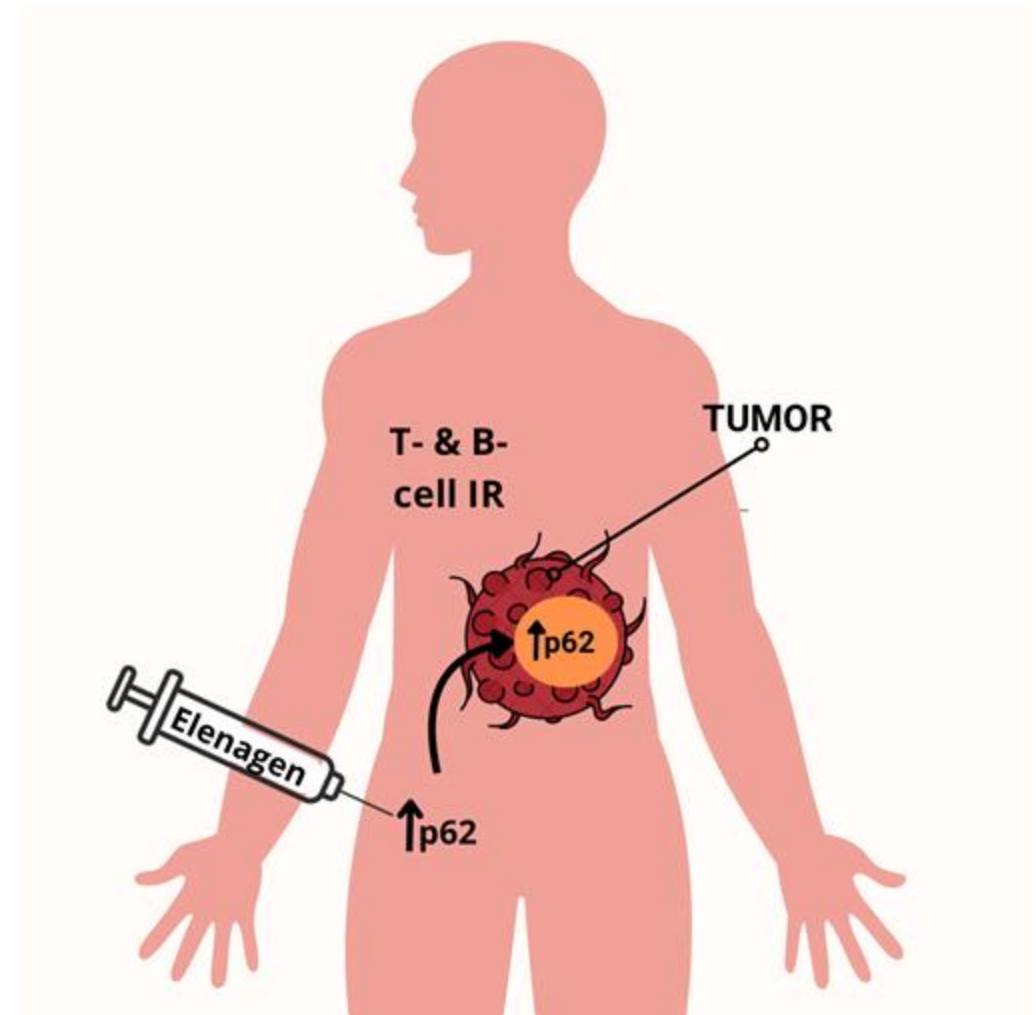


- GEM activates NF-kB which increases chronic inflammation in the tumour
- Activation of NF-kB reduces GEM efficacy
- Elenagen disrupts this negative feedback, which protects GEM activity
- This effect is expected for multiple other cancer therapies

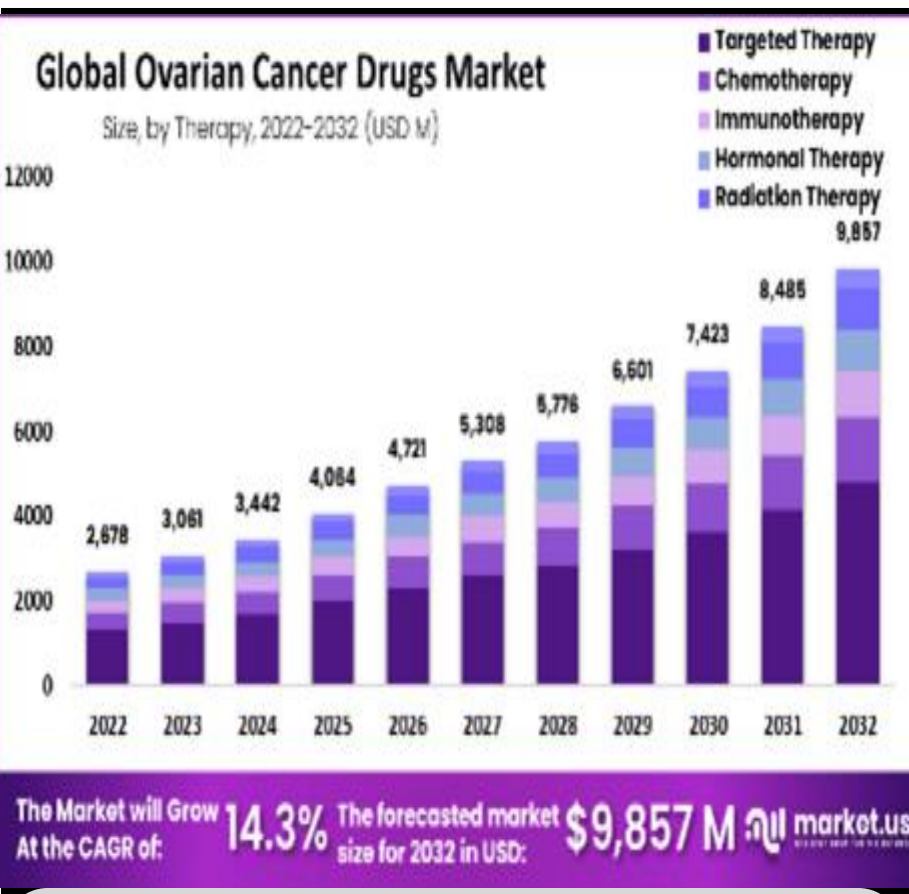


Elenagen: Anti-Cancer Vaccine Activity

- Tumors selectively overexpress the p62 protein, while normal tissues exhibit low expression.
- Overexpressed p62 acts as a cancer-specific antigen—a unique target for immunotherapy.
- Elenagen injections elicits T- and B-cell immune responses specifically against p62-overexpressing cells.
- Tumors cannot evade this immune response, as they rely on high p62 levels for survival:
 - Without overexpressed p62, cancer cells become vulnerable to chemotherapy and radiation.
 - Unlike normal cells, cancer cells are dependent on p62 for their survival.

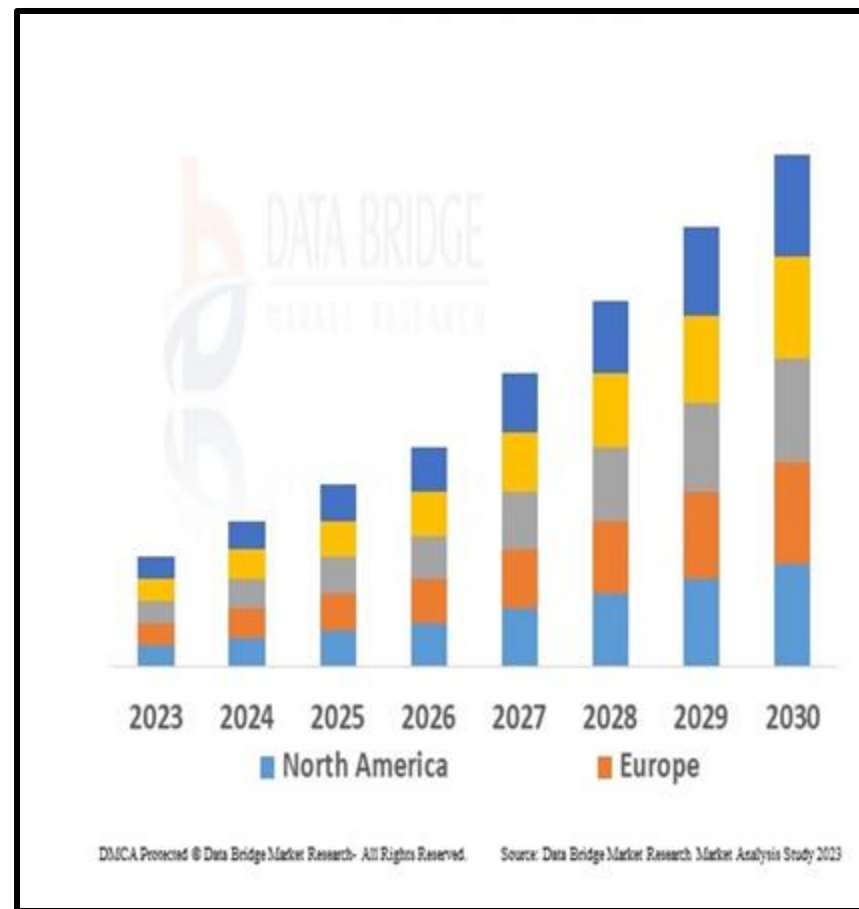


What is the Opportunity? – Extending Life & Significant Returns



CureLab started with the deadliest types of Ovarian and Breast cancer with the highest unmet medical need.

We plan to target the other forms of these diseases in future studies and expect to demonstrate a strong therapeutic effect.



PROC = Approx. 20% of OC market =

\$1.4B



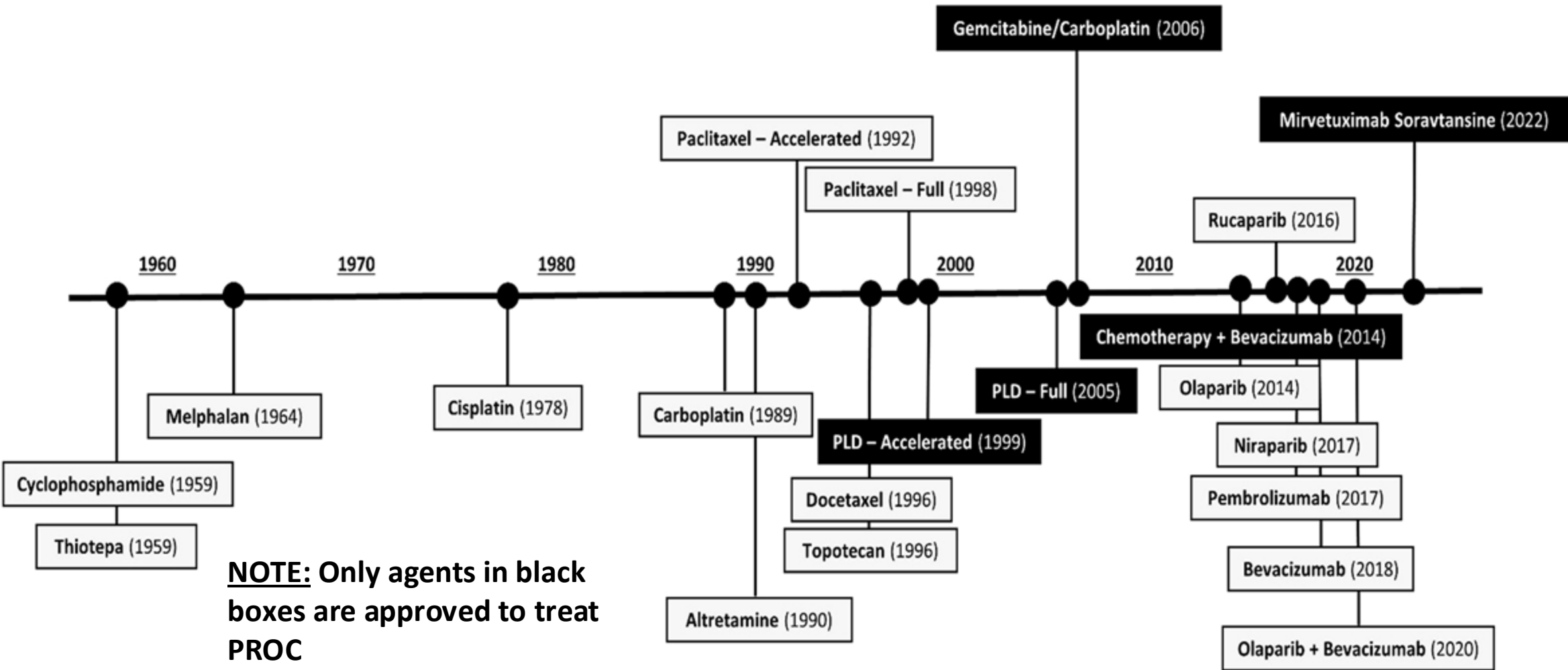
Global TNBC Market

\$1.4B

TNBC = 15% of Breast Cancer Cases

Competition? – Stark Reality for Women w/PROC: Options Are Limited

There are only very few treatment options for PROC, none of which gives a satisfactory results (poor survival; poor quality of life).



FDA-Approved Agents in Ovarian Cancer by Initial Approval Date ((10, 20, 21) and currently approved, as of November 2022) for the treatment of ovarian cancer. Agents in black boxes are indicated for the treatment of platinum-resistant ovarian cancer. FDA, US Food and Drug Administration; PLD, pegylated liposomal doxorubicin.

Phase 2 PROC Results: Statistically Significant Improvement in PFS

Gemcitabine + Elenagen (20 patients, median 7.2 months)² versus
Gemcitabine (20 patients, median 2.7 months)

Conclusion:

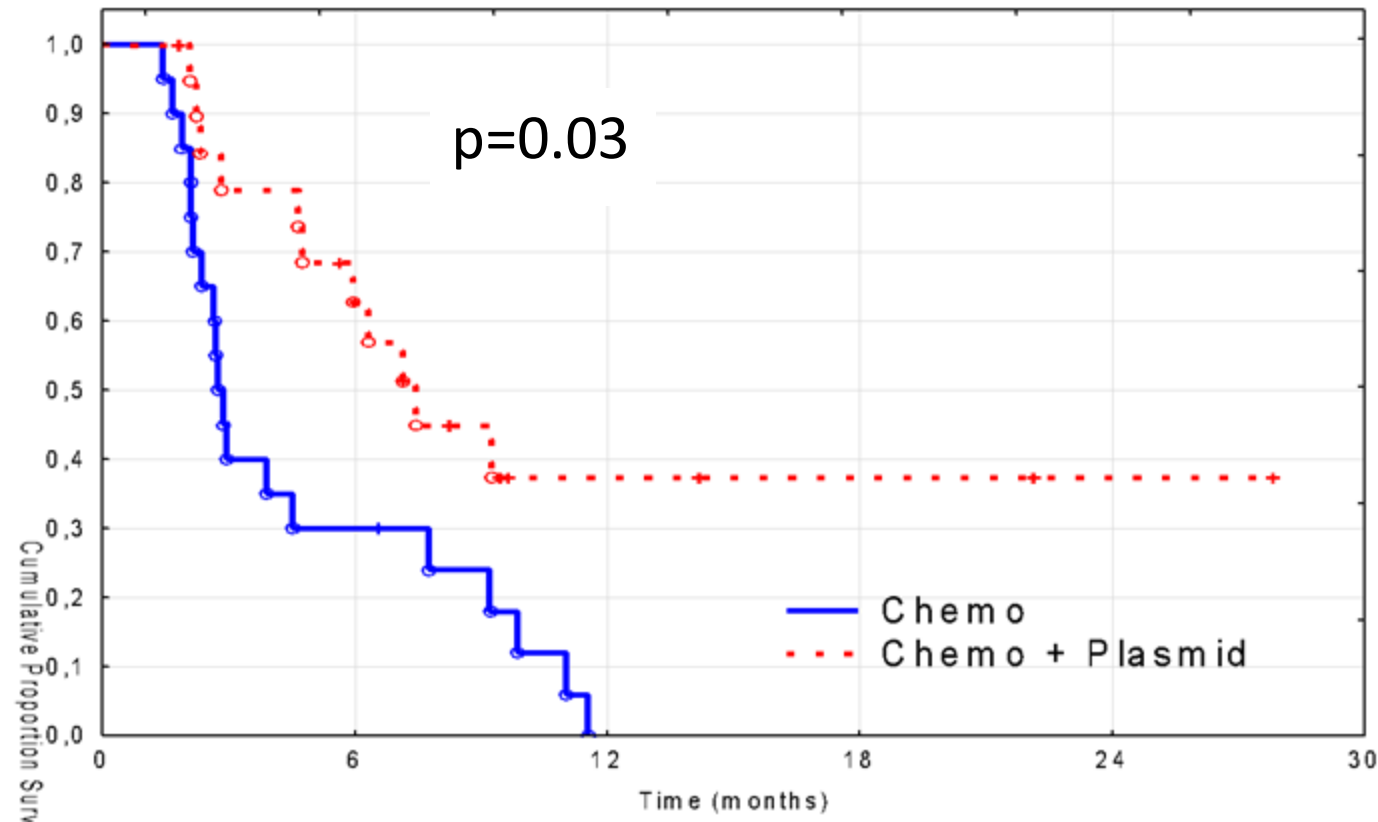
Gemcitabine + Elenagen provides a significant progression-free survival benefit over gemcitabine alone.

Results:

Median follow-up = 13.8 months
Median PFS was 2.8 & 7.2 mo
(p Log-Rank = 0.03)

No SAEs or high-grade AEs related to p62

Single death, investigation determined unlikely to be related to therapy.



1. Clinical efficacy of plasmid encoding p62/SQSTM1 in combination with gemcitabine in patients with platinum-resistant ovarian cancer: a randomized controlled trial. *Frontiers in Oncology*, 14:1343023.
2. Phase I, II trials conducted ex-US

Elenagen Increases Overall Survival (OS) of PROC Patients with Higher-than-normal Levels of CA-125 (>35 units)

Gemcitabine + Elenagen (15 patients, median 24.5 months) versus Gemcitabine (15 patients, median 12.5 months)

Elevated level of CA-125 is a negative prognosis factor associated with lower life expectancy.

Conclusion:

Gemcitabine + Elenagen provides a significant OS benefit over gemcitabine alone for the patients with high CA-125.

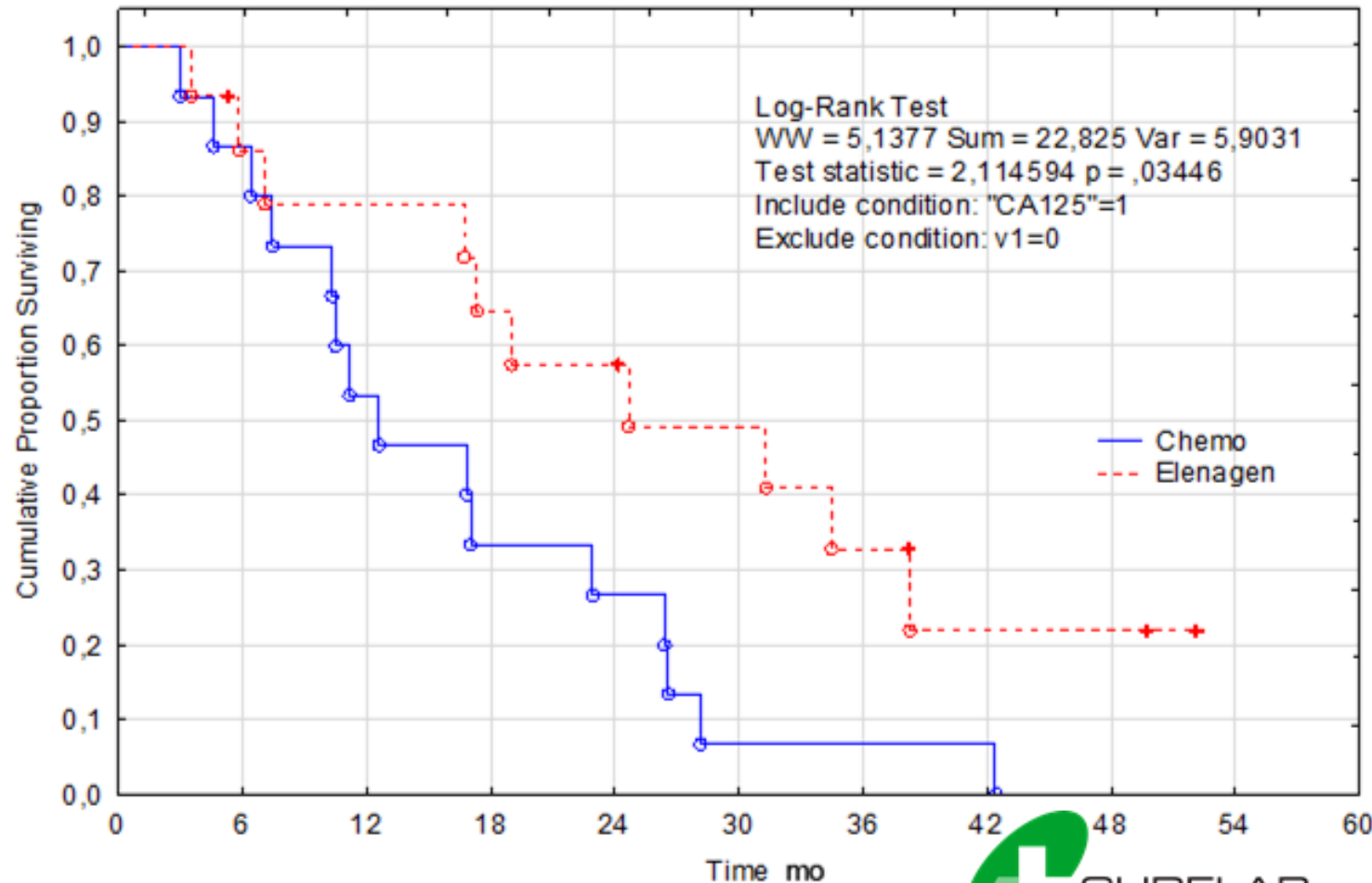
Results:

Follow-up = 52 months

Median OS was 12 & 24 mo

(p Log-Rank = 0.03)

The observed effect is lower than the real one as all patients synchronously stopped receiving Elenagen due to the Russia-Ukraine conflict, and OS was proportionate to duration of Elenagen treatment.



Trial for PROC – Adaptive Design (into Pivotal) to be initiated: 2025/2026

Bhavana Pothuri, MD, PI



*Professor, Department of Medicine
Professor, Obstetrics and Gynecology
Director, Gynecologic Oncology Research
Director, Gynecologic Oncology Group Clinical Trials
NYU Grossman School of Medicine*

**Protocol: Adaptive Ph. II, Primary Endpoint: Overall Response Rate (ORR)
Ph. III Pivotal Trial Endpoint: Progression-Free Survival (PFS)**

Trial initiates with 80 patients total, comparing Gemcitabine chemotherapy vs. Gemcitabine + p62/SQSTM1:

Control Group: 40 Patients
Gemcitabine + Placebo

Test Group: 40 Patients
Gemcitabine + **p62/SQSTM1**

ORR Achieved



If statistical significance is achieved with the primary endpoint, Overall Response Rate (ORR), then the study will be expanded to a total of 400 (150/250) subjects. Progression-Free Survival (PFS) is the final endpoint for Pivotal Ph. III FDA approval

Control Group: 150 Patients
Gemcitabine + Placebo

Test Group: 250 Patients
Gemcitabine + **p62/SQSTM1**

(US + EU)

Trial for TNBC - Phase II US Trial

Virginia Kaklamani, MD, PI



Ph II, Primary Endpoint = PFS & Safety

40 vs. 40 (Total = 80 patients)

Timing: Q1/2026 (US + EU)

Control Group: 40 Patients
Standard of Care

Test Group: 40 Patients
Standard of Care + p62



Statistical Significance in PFS Leads to future Pivotal Trial

Professor of Medicine, University of Texas Health Science Center San Antonio
Ruth McLean Bowman Bowers Chair in Breast Cancer Research and Treatment
A.B. Alexander Distinguished Chair in Oncology
Leader, Breast Cancer Program, UT Health San Antonio MD Anderson

Leading Experts in Gynecologic Malignancies

- Conducted > 350 clinical trials, with > 115,000 patients

Leadership – Some of the Best Treating Physicians in the World

- GOG Partners: *Dr. Bradley Monk, Dr. Kathleen Moore, Dr. Larry J. Copeland, Dr. Robert Coleman*
- Clinical Trials Advisors: *Dr. Ramez Eskander, **Dr. Bhavana Pothuri***
- *Dr. Thomas Herzog, President, Deputy Director of the U. of Cincinnati Cancer Center, Obstetrics & Gynecology*
- *Dr. Robert S. Mannel, Senior Vice President, NRG Oncology Group Chair, U. of Oklahoma Health Sciences Center*
- Ovarian Cancer Leadership: *Dr. David O'Malley, Dr. Kathleen Moore, Dr. Joyce Liu*

CureLab Is Partnered With the GOG

- GOG facilitated CureLab's first Clinical Advisory Board; ten leading experts
- Bhavana Pothuri, MD, NYU Grossman School of Medicine and GOG physician - PI for PROC Adaptive/Pivotal Trial
- GOG will assist CureLab with clinical trial strategy, sites, & implementation; FDA strategy & communication

CureLab Team

Executives



Alex Shneider, PhD
Founder and CEO



Charles Legg
COO



Aubrey Galloway, MD
CMO



Gabriel Levin, MD
Director of Oncology



Ricarda Cramer, MBA
Director BD, EU



Jihad Fakhreddine
Director BD, GCC



Vlad Zayets-Volshin
Director BD, FSU



Vlad Gabai, PhD
VP Research



Ilya Lapshin, Esq.
General Counsel



Trevor Olsen
Controller

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Michael Burns, MCEE: Independent Director
Andrew Morozov, Ph.D., MBA: Independent Director

Scientific Advisory Board

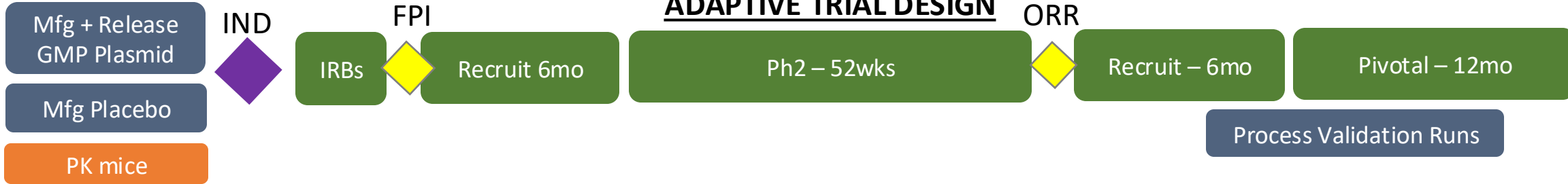
David Shulkin, MD, President & CEO of Beth Israel Medical Center
Kim Lewis, Director of Antimicrobial Drug Discovery Center, Northeastern University
Michael Sherman: Professor of Biochemistry, Boston University School of Medicine
Roland Baron, DDS, PhD: Harvard School of Dental Medicine, U.S.
Dr. Marvin Gilmore, Jr.: Board member, Mount Auburn Hospital, UMass Boston,
Prof. Sergei Krasny, MD, PhD.: Deputy Director for Research, N.N. Alexandrov National Cancer Center

Development timeline

Timeline of Quarters After Investment

Q1 Q2 Q3 Q4 Q5 Q6 Q7 Q8 Q9 Q10 Q11 Q12 Q13 Q14 Q15 Q16

PROC
Platinum Resistant Ovarian Cancer



TNBC
Triple Negative Breast Cancer



ONCOLOGY COLLABORATIONS

Exploratory ex-US clinical trials for other cancer types and other therapeutic combinations for Elenagen

Regional Licensing to non-Western Markets

ANTI-INFLAMMATORY INDICATIONS

Exploratory ex-US Clinical Trials

RESEARCH / PRECLINICAL

MOA Studies; Next Gen Elenagen; Exploratory ex-US Clinical Trials



Includes costs associated with initiating and conducting:

- Phase II/III PROC clinical trial in the US + EU (~\$22M)
- Phase IIb TNBC clinical trial in the US + EU (~\$8M)
- BD & Consulting for Exit (\$5M over 3 years)
- Headcount/Facilities/Ancillaries (~\$14M over 3 years)



Comparables & Exit Strategy

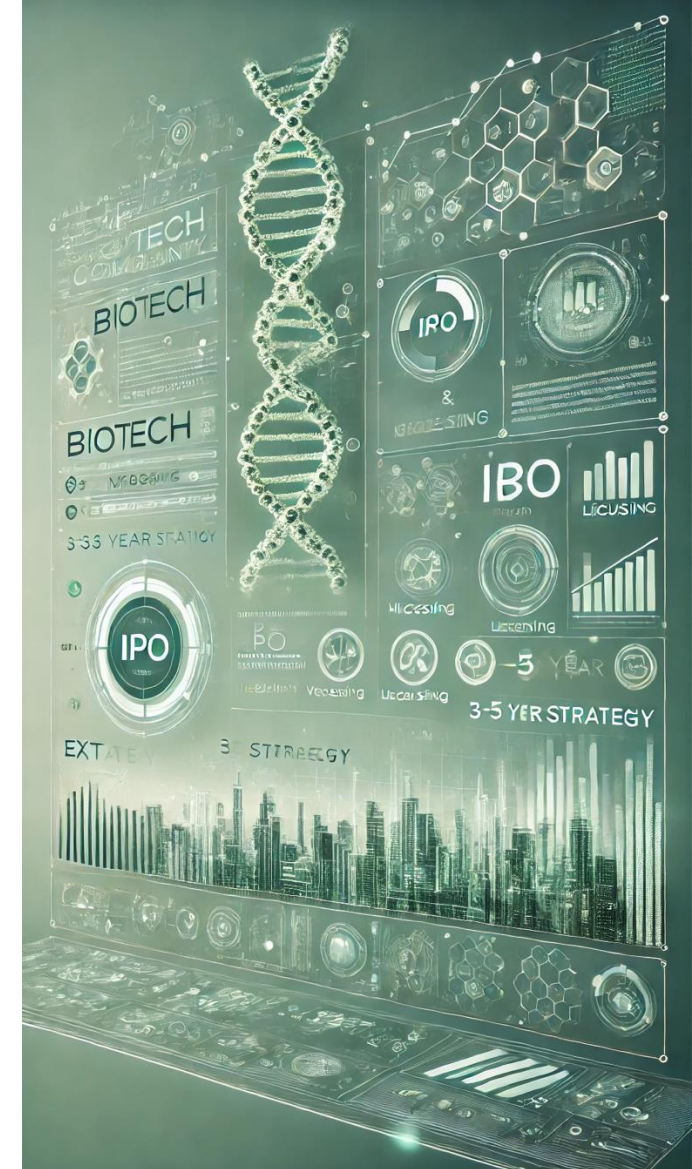
Market Example: Abbvie acquired Immunogen

Cancer Therapy ELAHERE® (PROC)

- \$10.1B; treats a subset of the market based on a biomarker
- 5% complete response; 40% partial response rate
- Approved on PFS endpoint

Exit Strategy:

- License/sell Elenagen PROC & TNBC oncology rights to larger company
- Receive up-front payment, milestone payments, single digit royalties
- Out-Licensing will begin post IND Open
- CureLab will continue to develop p62-based therapies in other oncology and non-oncology indications (osteoporosis, Alzheimer's, psoriasis, diabetic ulcers, etc.)



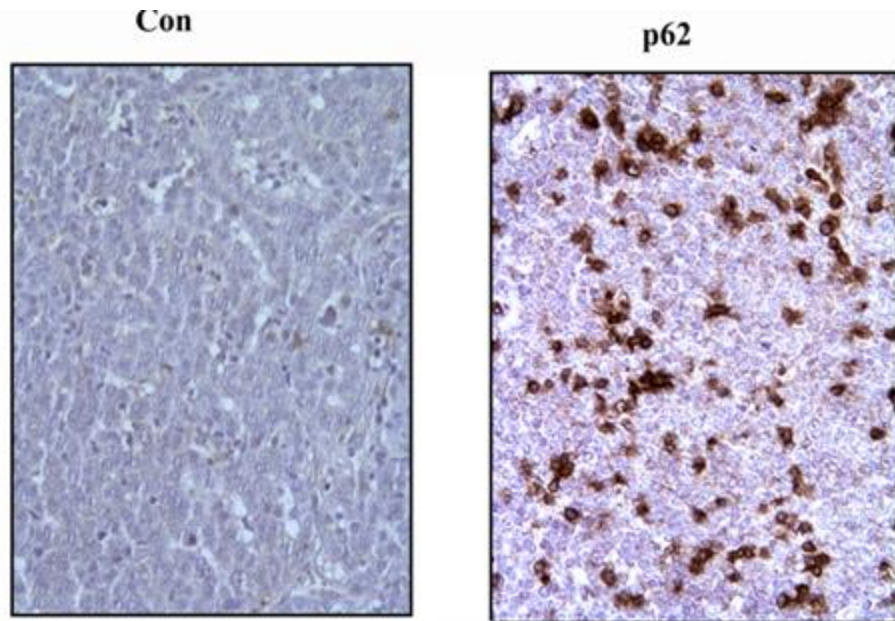


Thank you!

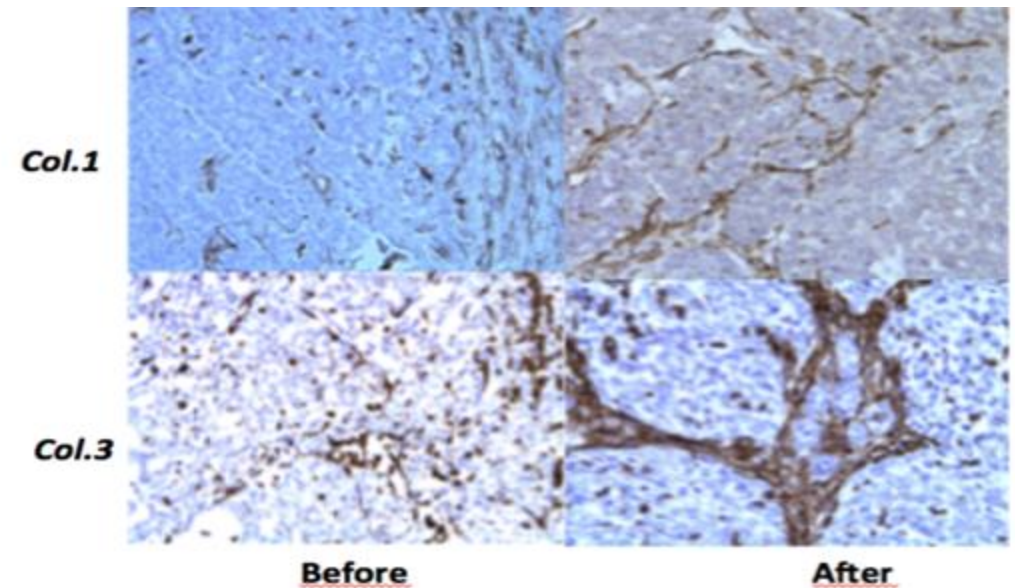
*www.cureLab.com
info@curelab.com*

Elenagen Turns “Cold” Tumors into “Hot” Ones

Accumulation of T-lymphocytes in canine mammary tumors after p62-plasmid treatment



Higher levels of Col3 in the tumor = positive disease prognosis

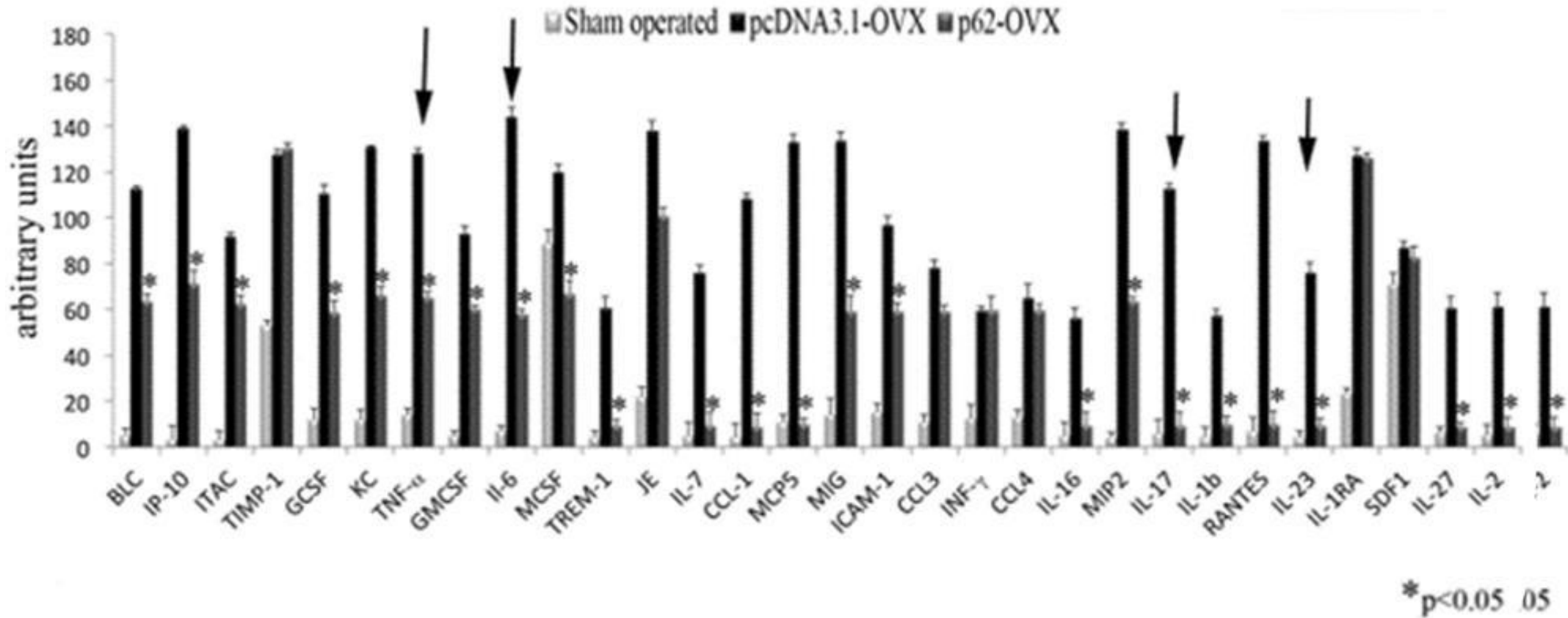


Evaluation of Col.1 and Col.3 expression in tumor biopsies in tumor extracellular matrix

A. before

B. after p62 DNA treatment

P62 Plasmid Suppresses Inflammatory Cytokines Induced by Ovariectomy



Plasmid DNA-coding p62 as a bone effective anti-inflammatory/ anabolic agent

Maria Giovanna Sabbieti^{1,*}, Dimitrios Agas^{1,*}, Melania Capitani¹, Luigi Marchetti¹, Antonio Concetti¹, Cecilia Vullo¹, Giuseppe Catone¹, Vladimir Gabai², Victor Shifrin², Michael Y Sherman³, Alexander Shneider², Franco M Venanzi¹. *Oncotarget* 6 (6):3590-3599 (2015)

Elenagen Acts Indirectly

Modulating Secretome of MSCs and Macrophages

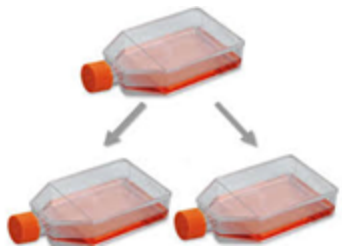
Elenagen acts on MSC remotely via a yet unknown signal



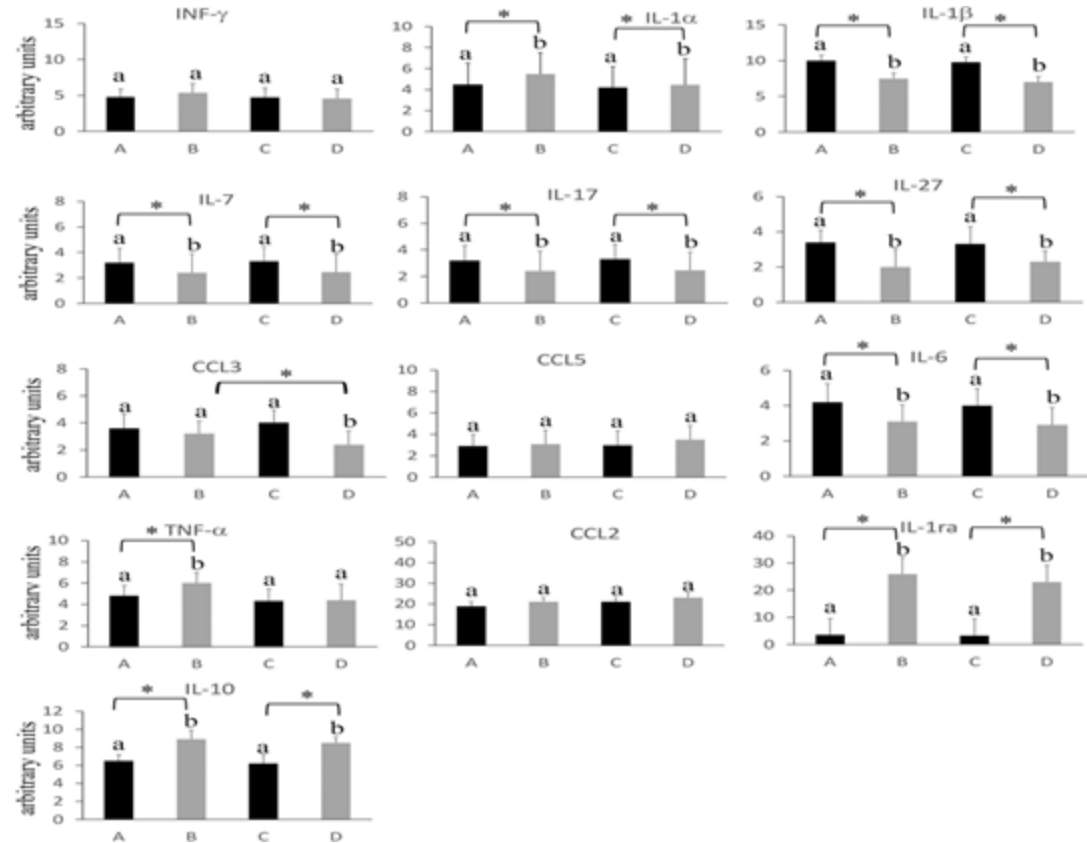
- Transfection of MSCs with p62 plasmid
- Transfection media is substituted with a fresh one w/o the plasmid



- Supernatant collected after 2 days
- Supernatant added to naïve MSCs



Anti-inflammatory cytokines are secreted by MSCs grown under the media collected from p62-transfected cell



p62-transfected cells secrete soluble factors polarizing MSC toward to an anti-inflammatory phenotype. (A) pcDNA 3.1 transfected MSCs, (B) p62-plasmid transfected MSCs, (C) untransfected MSCs treated with condition medium obtained from "(A)", (D) untransfected MSCs treated from condition medium obtained from "(B)". Lowercase letters denote homogeneous subsets ($p < 0.05$).

Case Report: Anti-psoriasis Effect of Elenagen

Picture 1



Before



After 4 wks
(5 weekly injections of 2.5 mg of Elenagen)

Case Report: Diabetic Foot Ulcer



Pipeline of Future Clinical Application

1. Bladder cancer
2. Pancreatic cancer
3. Metastatic hormone-resistant prostate cancer
4. Head and neck cancer
5. Lung cancer
6. Melanoma
7. Psoriasis
8. Diabetic foot
9. Arthrosis/Arthritis
10. Crohn's disease
11. Inflammatory bowel disease
12. Alzheimer
13. Hypertonic disease
14. Lupus
15. Metabolic syndrome
16. Depression and psychiatric disorders



Comprehensive Patent Protection

Oncology patents

Granted

-  Australia
-  Chile
-  Russia
-  Belarus
-  Belgium
-  Switzerland
-  Lichtenstein
-  Germany
-  Spain
-  France
-  UK
-  Ireland
-  Italy
-  Luxembourg
-  Netherlands
-  Hong Kong
-  Japan
-  South Korea
-  Mexico
-  Singapore
-  USA
-  India
-  Canada

Pending







-  USA
-  Brazil

Inflammation patents

Granted

-  Australia
-  Hong Kong
-  Japan
-  Singapore
-  Belgium
-  Switzerland
-  Lichtenstein
-  Germany
-  France
-  UK
-  Luxembourg
-  Monaco
-  Netherlands
-  Japan
-  South Korea
-  Mexico
-  Singapore
-  USA
-  Canada

Pending

-  China
-  India
-  South Korea
-  USA
-  Italy
-  Spain

Forward Looking Statements

This presentation contain forward-looking statements do not relate strictly to historical or current facts and they may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “possible,” “will” and other words and terms of similar meaning.

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