



KLS-1 Therapy for Oncology Patients

MAKING CHEMOTHERAPIES MORE EFFECTIVE WHILE REDUCING SIDE-EFFECTS

Isotope-Selective Modulation Therapy

July, 2024

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Our lead drug compound, KLS-1, enhances the killing of cancer cells by >150% and reduces inflammation and oxidative stress, leading to significantly improved patient outcomes

- ✓ Safe at therapeutic doses
- ✓ Makes chemotherapy more effective
- ✓ Reduces treatment-related side effects
- ✓ Reduces tumor metastasis invasion
- ✓ Active against multi-tumor types



Metallomix Inc. is a clinical-stage biopharmaceutical company developing a proprietary, new class of inherently safe and clinically derisked medicines to treat unmet medical needs by modulating scientifically validated pathways on an atomic level.

THE OPPORTUNITY

- Multi-billion in pro-forma licensable revenue
- Strong unmet medical need
- Cancers feature a complex zinc biology due to dysregulated zinc uptake and metabolism
- Multiple new molecules in preclinical stage
- Accelerated 505(b)(2) regulatory pathway
- Multiple disease applications and new addressable markets beyond oncology
- Raising \$15M for Phase 1 clinical trials

THE BREAKTHROUGH

- Conceptually new mechanism of action
- 150% enhancement of anti-tumor activity
- Reduced post-chemo & radiation side effects
- Versatile drug development platform with 98+ patents and proprietary know-how
- First-in-class isotopically enriched zinc compound and therapy
- Systemic, disease-modifying effect
- Published & peer-reviewed research data

THE PROGRESS

- Unique scientific stance & vision
- Preclinical studies completed
- First-in-human clinical safety confirmed
- Phase 1/2 trials initiated
- CMC file completed to EU standards

Formed
in 2021

Focused on
Metallome

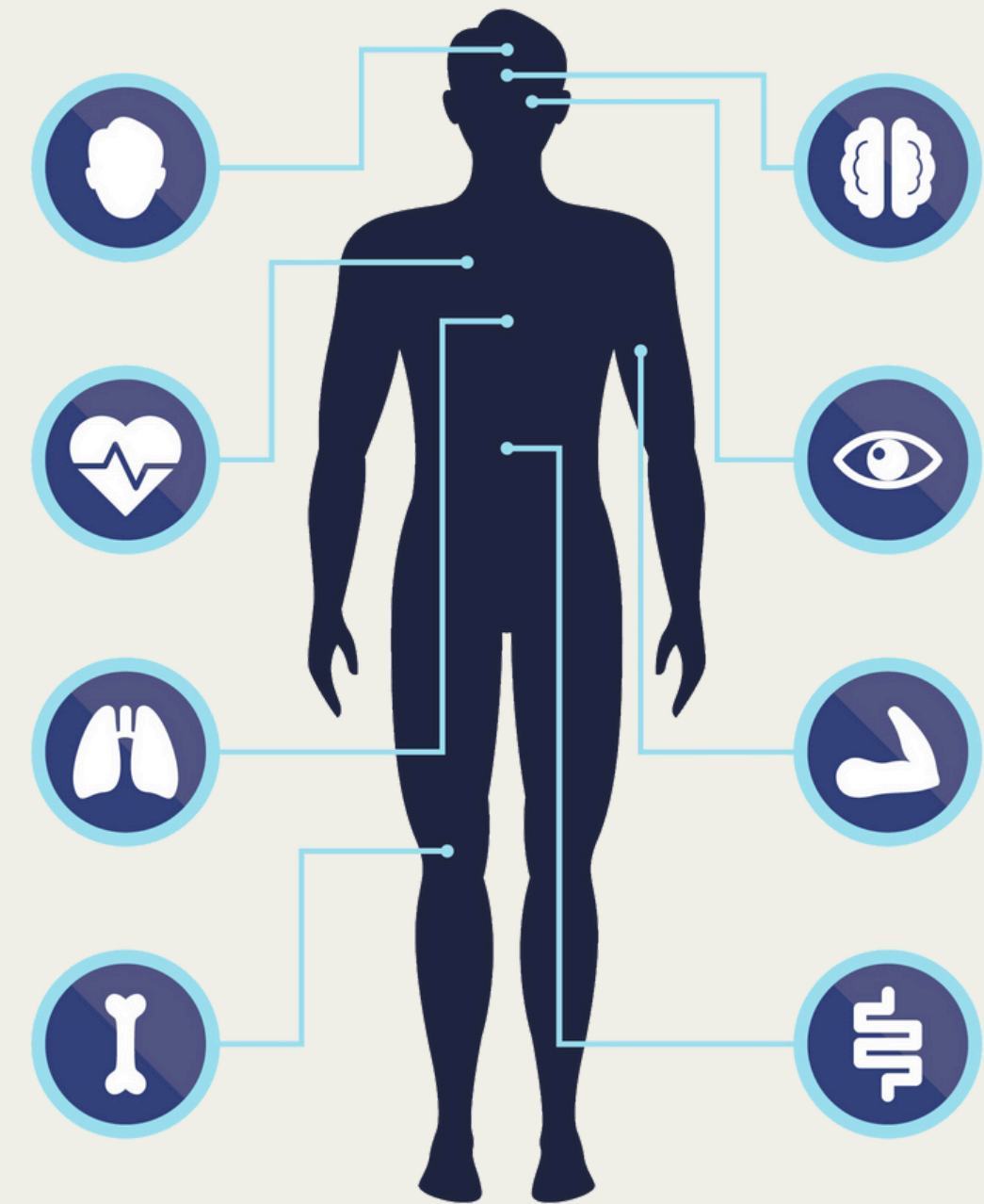
Experienced
Team

Lead Drug
in Clinical
Phase

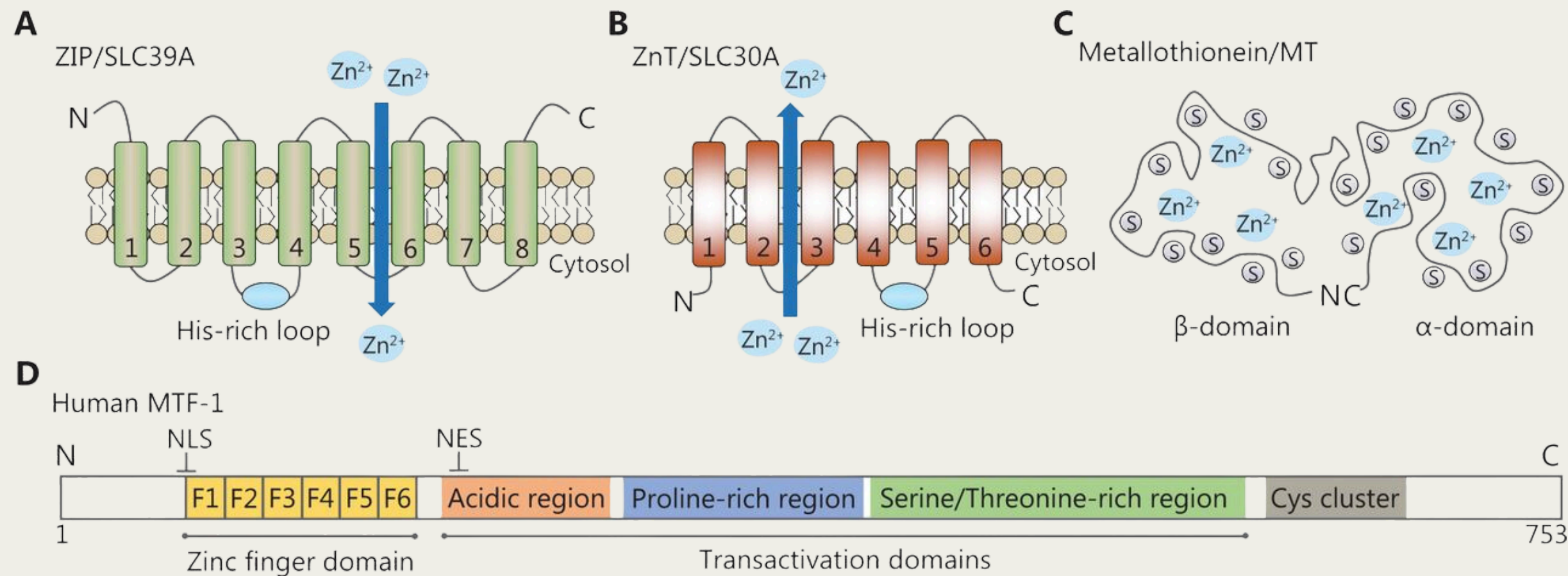
First Mover
in New Niche

WHY TARGET INTRACELLULAR ZINC

- Intracellular zinc plays structural and catalytic roles in over 3,000 proteins, and is essential for p53-mediated tumor suppression, DNA protection and repair, and many other functions
- Dysregulation of zinc transporters and metallothioneins are associated with over 35% of cancers and many autoimmune, neurological, cardiovascular, and metabolic diseases
- By targeting the cells with downregulated zinc transporters and silenced metallothionein genes, we aim to dramatically improve survival and the efficacy of standard-of-care cancer therapies, and to reduce chemo- and radiation therapy related side effects.

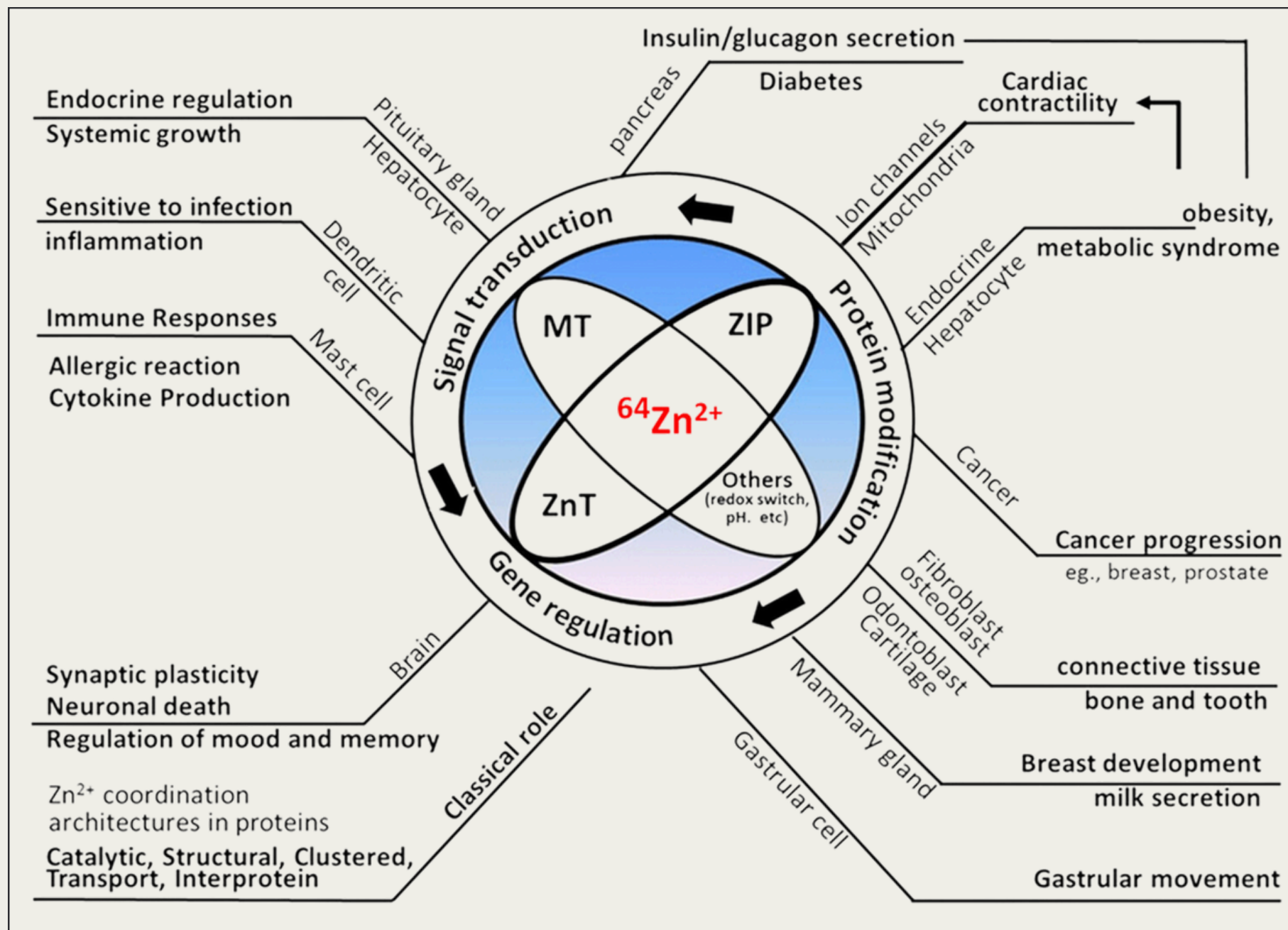


Zinc Transporters & Buffering



26	27	28	29	30	31	32
Fe	Co	Ni	Cu	Zn	Ga	Ge
Iron	Cobalt	Nickel	Copper	Zinc	Gallium	Germanium
44	45	46	47	48	49	50
Ru	Rh	Pd	Ag	Cd	In	Sn
Ruthenium	Rhodium	Palladium	Silver	Cadmium	Indium	Tin
76	77	78	79	80	81	82
Pt	Au	Hg	Tl	Pb	Bi	Po
Platinum	Gold	Mercury	Thallium	Lead	Bismuth	Polonium

THE ROLE OF ZINC IN ONCOLOGY & OTHER DISEASE AREAS



THE CELLULAR TRANSPORT PROBLEM:

- ZIP transporters are downregulated in disease states
- Intracellular zinc depletion occurs despite normal serum levels
- Standard therapies fail to address transport dysfunction
- A targeted precision medicine approach is needed

CURRENT TREATMENT LIMITATIONS:

- ✗ Oral zinc supplements: Poor bioavailability; no efficacy
- ✗ IV zinc sulfate: Limited efficacy, side effects, dose-limiting toxicities
- ✗ Dietary approaches: Insufficient for therapeutic needs
- ✗ No precision targeting: Standard-of-care ignores cellular deficiency

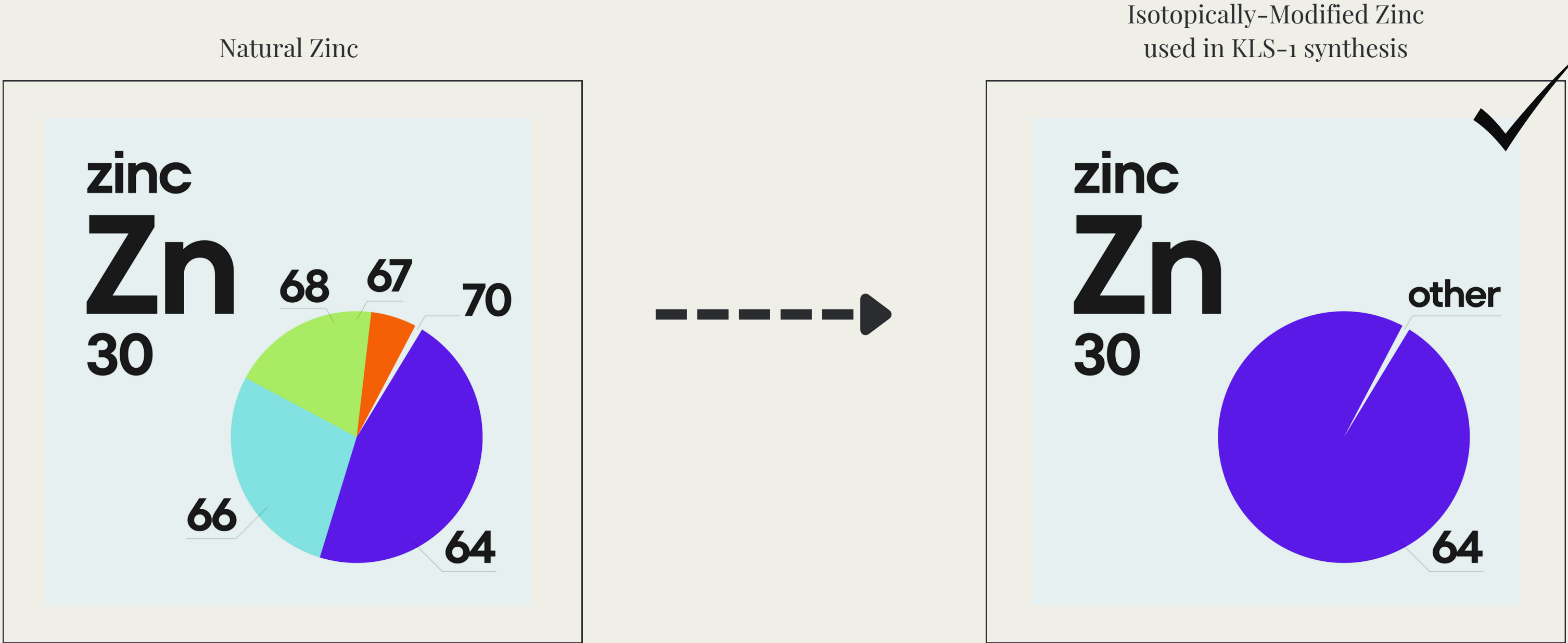
Intracellular zinc exerts anti-tumor effect through:



THE SOLUTION: TARGETING INTRACELLULAR ZINC HOMEOSTASIS

Our proprietary isotope-selective modulation therapies offer solutions in the form of isotopically-modified zinc formulations that combine the therapeutic mechanisms of ionophores and metallochaperones. This allows us to supply isotopically light zinc into the cytoplasm independent of dysregulated zinc transporters and buffering functions, reactivate mutant p53 protein, and to modulate cellular functions with isotope effects.

Zinc coordination provides targeted release in tumor microenvironments

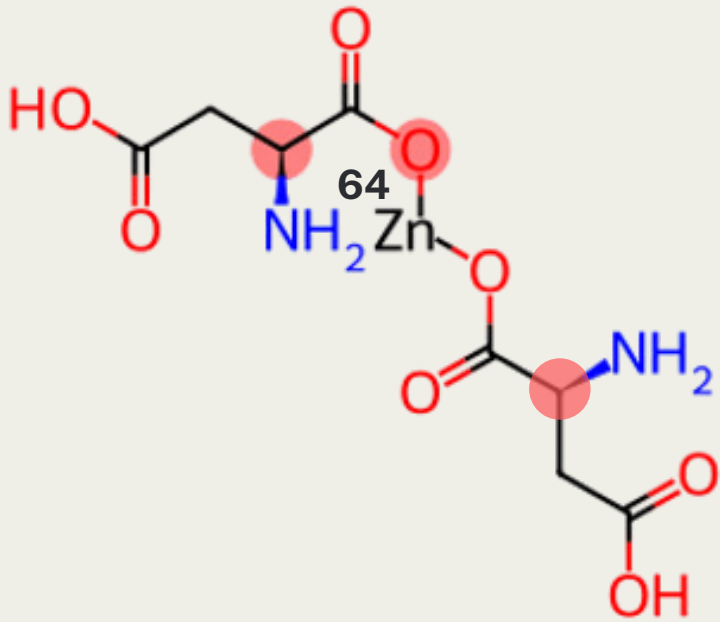



THE SOLUTION: LEAD DRUG CANDIDATE

The identification of MT silencing and ZIP/ZnT dysregulation opens new therapeutic avenues, including epigenetic therapies to restore intracellular zinc homeostasis and targeted approaches to reactivate the p53 antitumor/DNA repair and zinc transporter functions.

KLS-1 shown promise in treating various forms of cancer, neurodegenerative, and metabolic diseases.

KLS-1 vs. Natural Zinc	Competitive Advantages
<ul style="list-style-type: none"> 64Zn Enrichment: 64Zn>99% vs. 48.6% natural Zn Enhanced cytotoxicity >1.5x greater vs. natural Zn Superior bioavailability due to optimized uptake Faster enzymatic reactions due to isotope effects 	<ul style="list-style-type: none"> First Mover: The only enriched zinc isotope therapy in clinical phase Systemic Effect: Reduces systemic and local cellular stress and inflammation; Disease-modifying effect Multiple indications in onco, neuro, and metabolic Strong IP position: 98 patents protecting technology





5

Issued **composition of matter** and **methods of use** patents
 (Exp. 2035-2049)

64Zn-Enriched Precision Medicine Platform

68

Pending **indication-specific** patent applications including international counterparts (PCT)

16+

Provisional patent applications

Isotopically-natural zinc aspartate covered by our patents pending



Isotopically Modified Zn-Aspartate

Metallothionein expression and activities

Induced Bax expression and BCL-2 reduction



Induced wtp53 expression/activation and functioning of zinc fingers/zinc proteins

Inhibition of NF-kB activation



Induced structural integrity of A2o and PPAR-α and cleaved PARP1 expression



Bax pathway

Interleukins' pathway

Mn-SOD pathway

ERK / MAPK pathway

TGF betta & CRP pathways



Reduced Local and Systemic Inflammation and Oxidative Stress, Cell Cycle and Apoptosis Regulation

Neuroprotective Effects, Memory Improvement, Possible Neurogenesis, Improved Liver / Pancreas Function



Enhanced Cellular Energy, Mitophagy, Autophagy

Antitumor Action, DNA Repair, Liver Fat Reduction



Repair of Cellular Functions => Disease Modifying Effect

SIGNIFICANT PRECLINICAL RESULTS

Type of Investigation	KLS-1 Dose	BCL-2	Bax	wtp53	NF-κB	pro-MMP9	MMP2	MMP9
MM-4 Cell Line, in-vitro	25 µg/ml	No effect	890%↑	950%↑	Not studied	Not studied	76%↓	19%↓
L1210 Mouse Model, in-vivo	28 mg/kg	330%↑	780%↑	900%↑	Not studied	72%↓	40%↓	32%↓
EAC Mouse Model, in-vivo	28 mg/kg	130%↑	780%↑	900%↑	57%↓	36%↓	67%↓	54%↓

L1210 Leukemia Model

Cytotoxic Effect of KLS-1

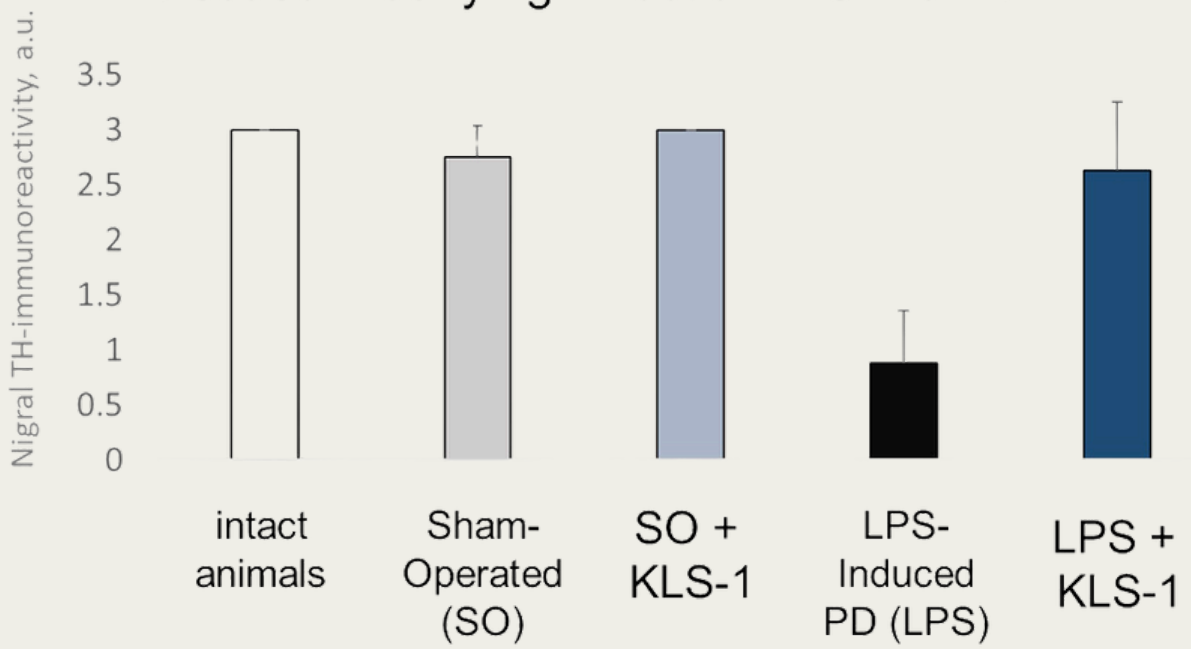
A. L1210 Control

B. L1210 + ⁶⁴Zn_e(Asp)

Experimental animals on Day 14 after KLS-1 injection into tumor

LPS-Induced PD Mouse Model

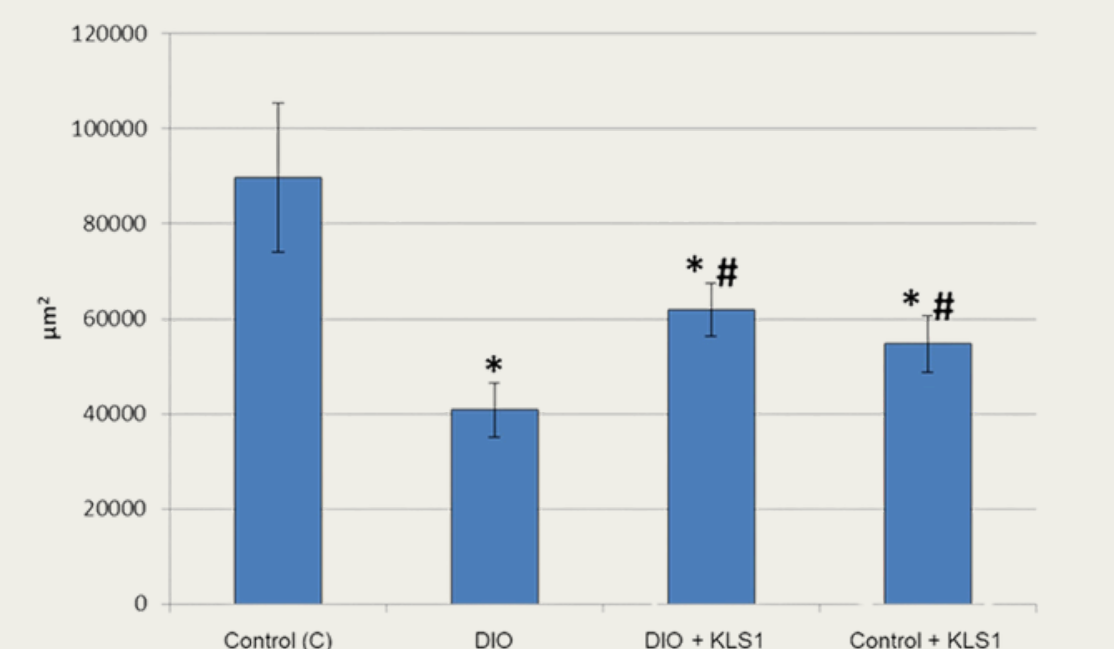
Disease Modifying Effect of KLS-1 on DN



KLS-1 monotherapy resulted in significant revival of TH-positive dopaminergic neurons (DN, #). Combination with Levodopa will be studied next.

DIO-Induced Obesity Mouse Model

Disease Modifying Effect on the Pancreas



A 12-week KLS-1 monotherapy resulted in a 43% increase in cross-sectional surface area of the islets of the pancreas vs. obesity group



A single injection of KLS-1 led to a significant antitumor effect in experimental model of mice melanoma, B16, accompanied by a revival of skin tissue as evidenced by hair growth.

Company data



Control mouse
3 weeks post treatment

KLS1 single injection
3 weeks post treatment

KLS1 single injection
5 weeks post treatment

KLS-1 administered sequentially to dacarbazine, doxorubicin, paclitaxel, and vinorelbine resulted in a significant synergistic effect.

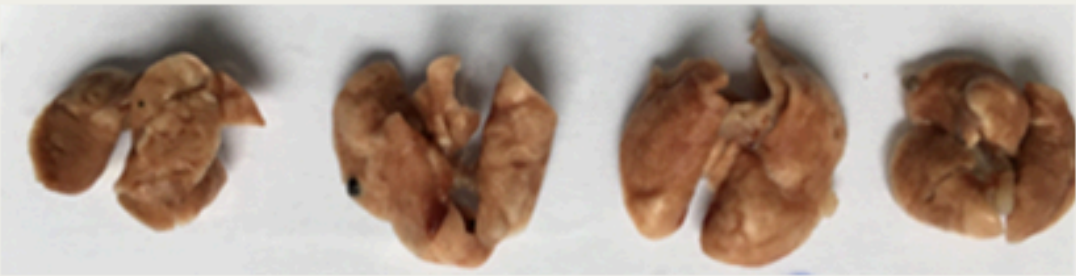
Effective Dose (IC50) [KLS1 administered sequential to chemo agent]	% Surviving Malignant Cells (monotherapy)	% Surviving Malignant Cells (combotherapy)	% Improved Efficacy
KLS-1, 5 mcg/ml	27.2%		
Dacarbazine, 7.5 mcg/ml	41.0%	2.1%	1464% (~14x)
Doxorubicin, 150 ng/ml	91.0%	6.0%	1516% (~15x)
Paclitaxel, 1 ng/ml	98.0%	7.8%	1256% (~12x)
Vinorelbine, 1 ng/ml	85.2%	7.8%	1092% (~11x)
Cisplatin, 1 mcg/ml	31.0%	21.0%	147% (~1.5x)

KLS-1's Anti-Metastatic Effect

Administration of KLS-1 suppressed metastases into lungs in mouse melanoma model B16. This experiment shows that KLS-1 therapy may be used for prevention of metastases in human melanoma



Control



KLS1.1
Tx started 45 min
after injecting
tumor cells



KLS1.1
Tx started 24 hrs
after injecting
tumor cells

Company data



Indication		Discovery	Preclinical	Phase 1	U.S. IND	Phase 2	Phase 3
ONCOLOGY	Cutaneous Melanoma						
	Prostate Cancer						
	Pancreatic Cancer						
	Chronic Lymphocytic Leukemia						

Recruiting ⓘ

Safety and Efficacy of **KLS-1** Monotherapy in Malignant Neoplasms

ClinicalTrials.gov ID ⓘ NCT06506643

Sponsor ⓘ Vector Vitale LLC

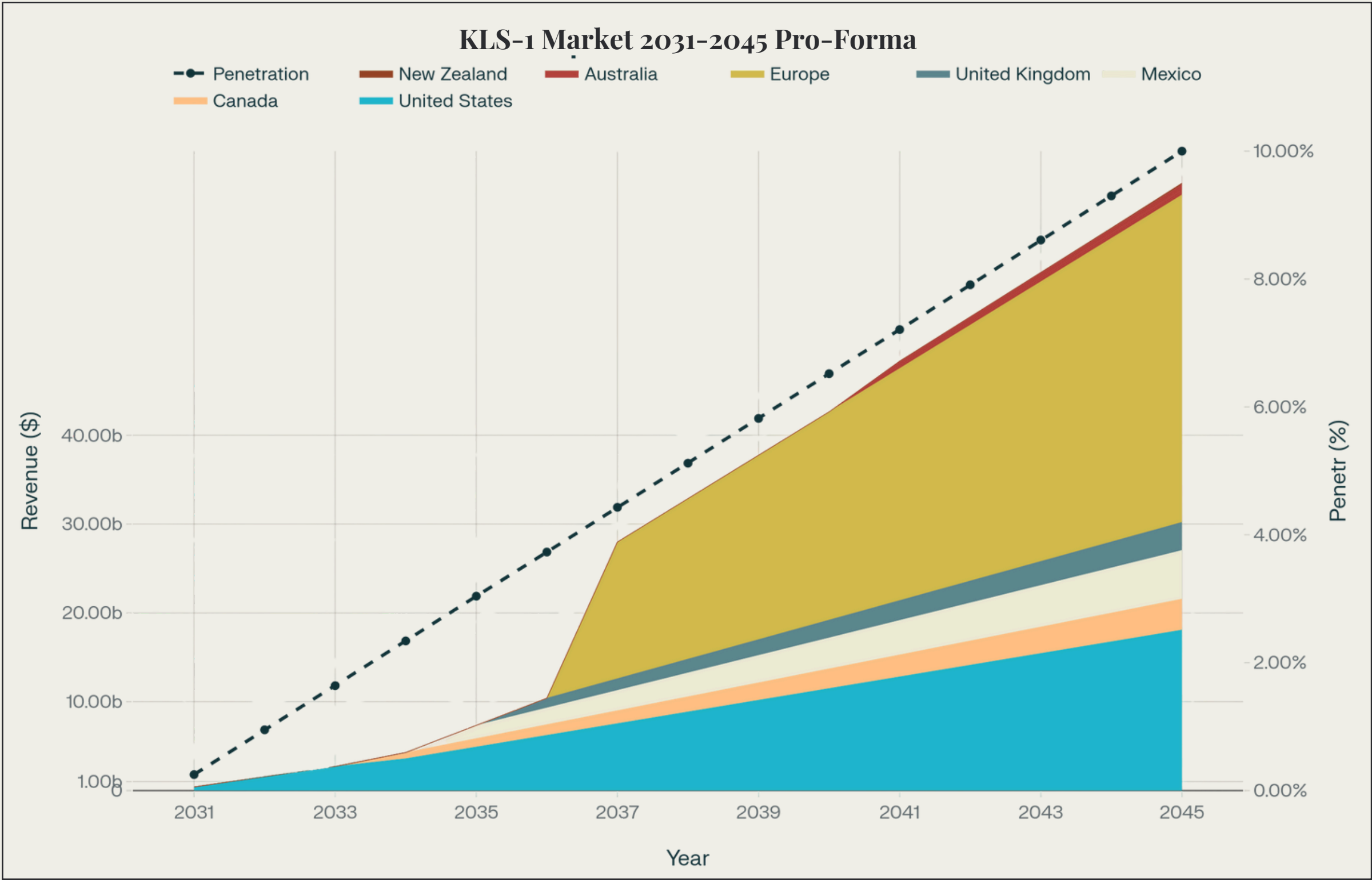
Information provided by ⓘ Vector Vitale LLC (Responsible Party)

Last Update Posted ⓘ 2024-10-01

- Lead candidate KLS-1 in human clinical trials in oncology. Phase 1 (safety) SAD and MAD planned 3Q2025
- Completed Phase 1-2 monotherapy trials are expandable into Phase 1-2 combination therapies
- CMC file completed. KLS-1 production scheduled for 2Q2025 to be completed in 2Q2025
- Animal toxicology completed & first-in-human MTD/toxicity tested. Phase 2 clinical protocols, combination therapies in oncology, and IND filings are in the works
- Mechanistic studies are in development
- Four new molecules are in development

THE MASSIVE MARKET OPPORTUNITY

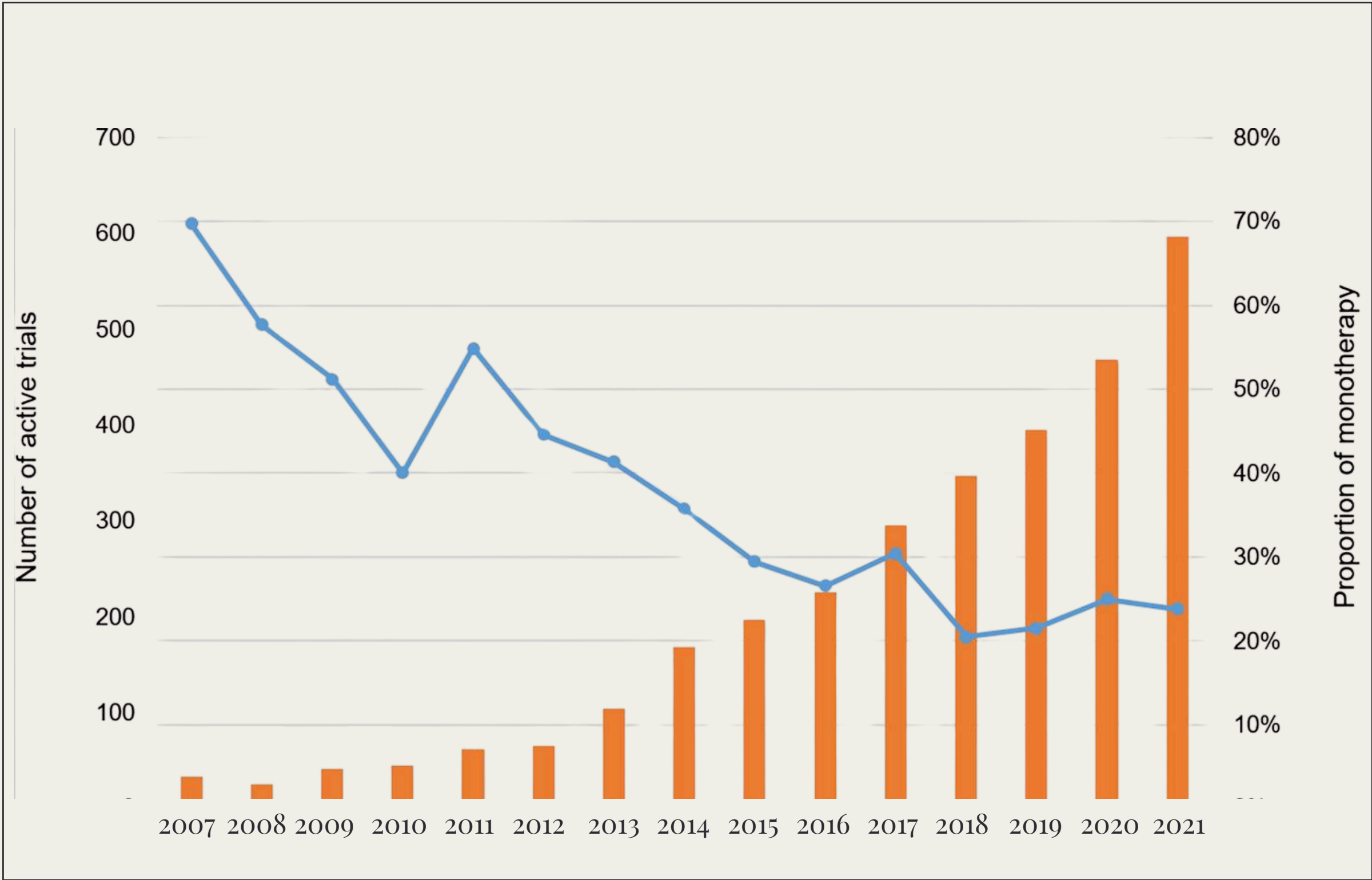
Intracellular zinc treatment represents a massive, largely unrecognized catalytic factor exacerbating diseases affecting nearly 94 million patients with definitive disease and 124 million individuals with functional impairment across the US, Canada, and Europe.



- ✓ Massive, underserved medical need with clear commercial viability across multiple therapeutic areas. The sequential geographic expansion mitigates execution risk while the 15-year post-NDA exclusivity period provides substantial IP protection for return on investment
- ✓ The multi-billion dollar product revenue over 15 years of forward-looking post-NDA exclusivity period represents a substantial commercial opportunity supporting a high likelihood of attracting a strong, established pharmaceutical company partnership
- ✓ Licensing fee potential of \$12.5-28.3 billion NPV represents a transformative value creation opportunity, with multiple scenarios providing attractive returns

Isotopically-natural zinc aspartate covered by our patents pending

FAVORABLE MARKET TRENDS



Combination therapies are on the rise.

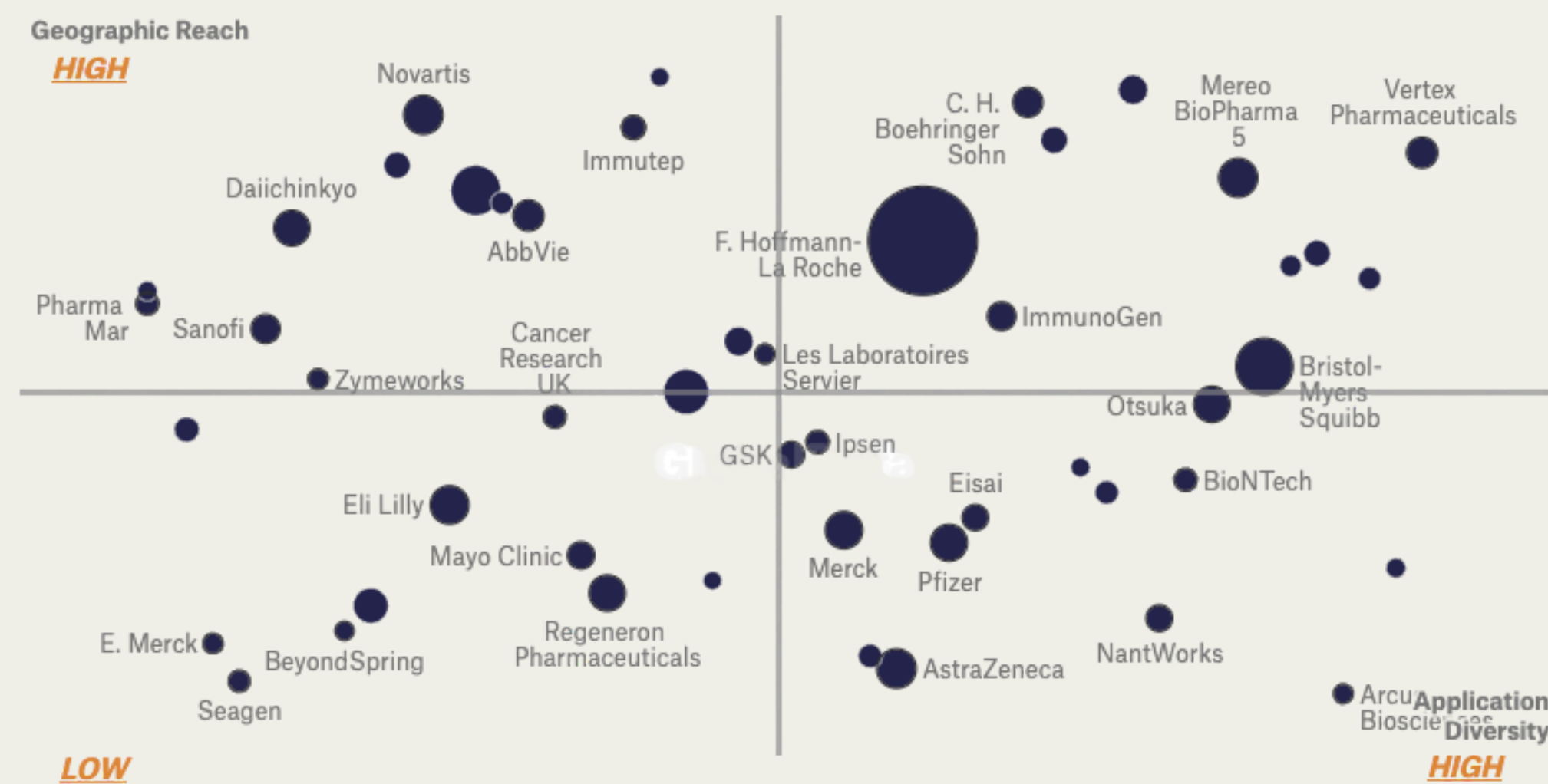
The total number of yearly initiated human clinical trials has increased over time, while the proportion of monotherapy trials have fallen sharply from 70 to 20–30%.

However, it is estimated that the available patients could not support the explosion of mono-therapy oncology clinical trials. Taking melanoma as an example, there are no more than 1,500 melanoma patients who can be recruited globally, which will be far from enough to meet the nearly 600 melanoma trials in progress.

Developing newly patented treatments delivering better outcomes than those of the known drugs alone

Cancer combination therapy is a key innovation area in the pharmaceutical industry from 2025 forward

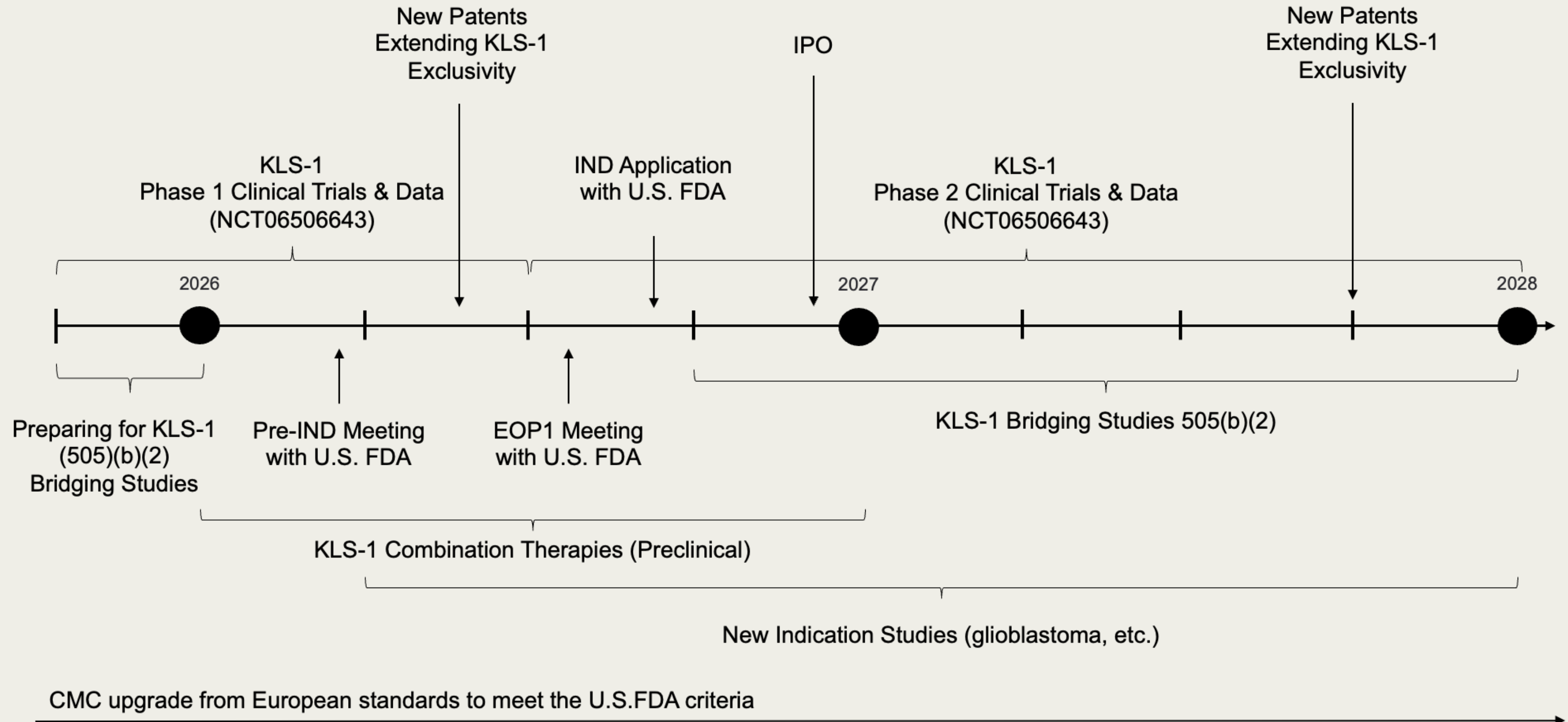
Patent volumes related to cancer combination therapy



- Bubble size = patent volumes between 2021 and 2023
- Application diversity and geographic reach scores are normalised and ranked on a scale between 0 and 1

Company	Total patents (2021 - 2023)
F. Hoffmann-La Roche	<div></div>
Bristol-Myers Squibb	<div></div>
Amgen	<div></div>
Johnson & Johnson	<div></div>
Mereo BioPharma 5	<div></div>
AstraZeneca	<div></div>
Eli Lilly	<div></div>
Novartis	<div></div>
Merck	<div></div>
Pfizer	<div></div>

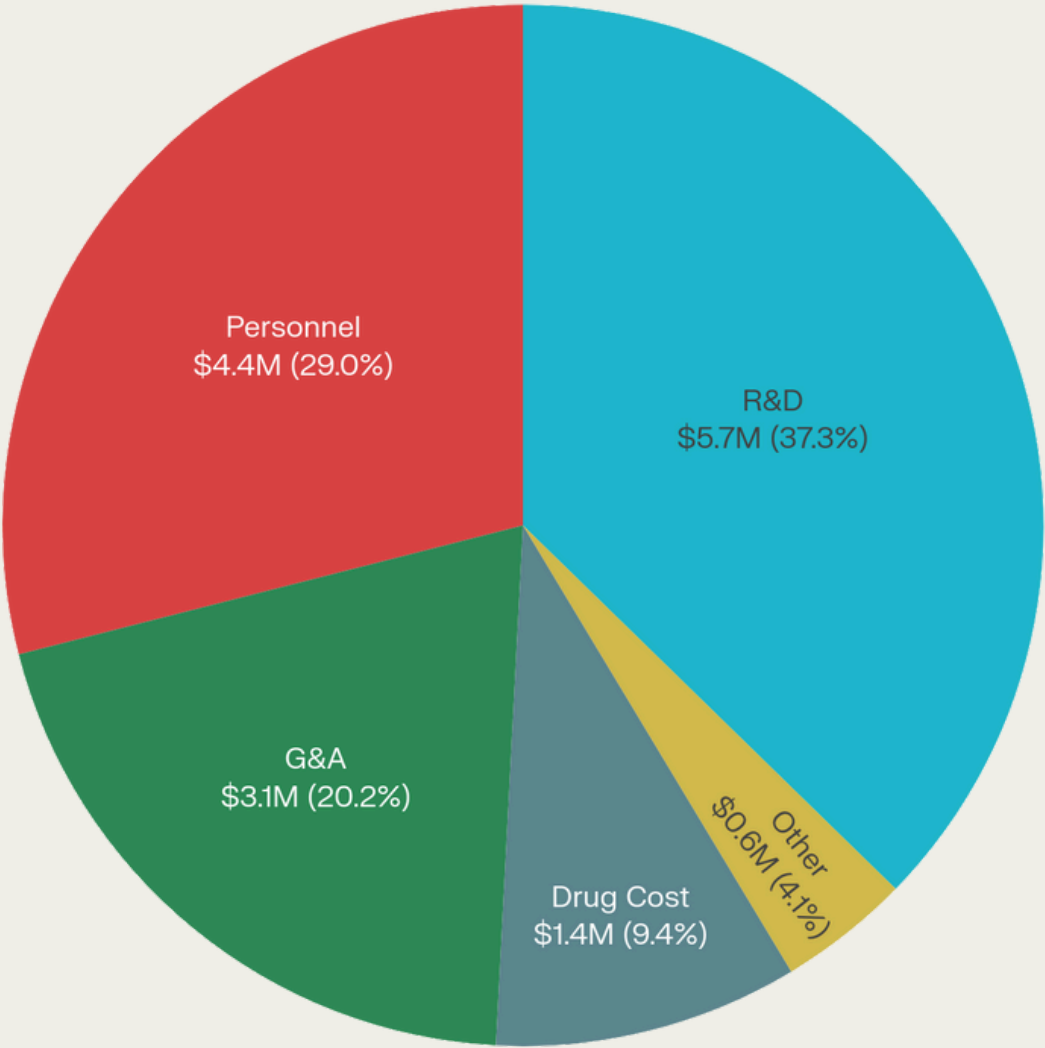
NEAR-TERM MILESTONES & INFLECTION POINTS



USE OF PROCEEDS & CAPITAL REQUIREMENTS

KLS-1 Phase 1 & US Bridging Cost

\$15.1 Million



CAPITAL REQUIREMENTS TO REVENUE

- Phase 1 & US Bridging: 21 month, \$15.2 million
- Phase 2 Development: 36 months, \$45.9 million
- Phase 3 & Registration: 46 months, \$104.5 million
- Label Expansion: 51 monhts, \$46.2 million

COST EFFICIENCY HIGHLIGHTS

- 75% below industry average (\$203.4M vs. \$800M+ traditional)
- 3+ years faster than traditional drug development timeline
- 21.1% drug costs reflecting premium isotopically enriched compound
- 505(b)(2) pathway enabling accelerated, cost-efficient development

Phase I clinical trials and bridging studies will establish safety and dosing across all indications.

Phase II efficacy studies will provide proof-of-concept data and inform Phase III trial design.

Pivotal Phase III trials will demonstrate clinical benefit and support regulatory approval across multiple indications.



THE COMPANY

- Privately-held, founder-financed, C-corp (FL)
- Contemplating an IPO in 2026-2027
- Differentiated business model and R&D strategy with 505(b)(2) in focus.
- Proprietary I.P. for using isotopically modified non-radioactive zinc formulations
- Multiple new molecules in conceptual stage
- Multiple new molecules in conceptual stage
- Based in Miami, FL with R&D oversight from U.S. performed by top researchers in Ukraine

THE PLATFORM

- A new paradigm across multiple diseases
- Focus on new frontier: the metallome biology
- Leading new niche: Isotopic metallome
- Core innovations in isotopic dysfractionation
- Multi-omic approach
- Targets root-cause in diseases vs. symptoms
- Helps the immune system vs. suppression
- Versatile drug development platform with 97+ patents and proprietary know-how

THE LEAD PRODUCT

- Essential preclinical studies completed
- Clinical safety in humans confirmed (Mexico)
- Phase 1/2 trials authorized (Ukraine)
- IND preparation in progress (U.S.)
- CMC compliant with European regulations
- 5-year supply secured through 2030
- 6-year time-to-market plan under 505(b)(2)
- Priority for oncology. Plans for expanding into metabolic and neurological indications

Proven track record of execution and near-term data readout



Generated robust preclinical data and substantial I.P. portfolio



Developed and initiated Phase 1 trials in oncology patients



Filed additional composition of matter and methods of use IP



Bridging studies to RLD under 505(b)(2) NDA pathway



CMC package completed. KLS-1 drug supply produced till 2030



Preparing for 505(b)(2) bridging study in healthy volunteers



Several peer-reviewed publications in professional media



Phase 1/2 oncology trial top line data readout 3Q 2025



Founder, President, COO & Director

Max Temnik, PhD

Investor in several biotech startups, experienced entrepreneur with multiple business ventures, expert in chemistry.



Co-Founder & CEO

Sergei Petukhov, DVM, MSc

Distinguished venture capitalist in the biotech sector, noted for securing "unicorn" IPO exits and M&As, serving as a board member for various biotech companies.



Co-Founder, EVP & Interim CFO

Sergey Gurin, MBA

Accomplished serial entrepreneur, investor and inventor with proficiency in management, business growth, intellectual properties, and securities offerings.



VP, Product Development, Oncology, Neurology

Santosh Kesari, MD, PhD

Leading neuro-oncologist in the U.S., distinguished by extensive research and development expertise coupled with practical experience.



VP, Product Development, Internal Diseases

Leonid Magilenko, MD

Boaard-certified physician in internal medicine with 25+ years of clinical experience.



Board Member

Walter Olesiak, BS, MBA

Over 28 years experience in business development, healthcare consulting and venture investment with Remiges Ventures, Mitsui, Cambridge Pharma Consultancy (an IMS Health company), Genzyme Japan and SRL, Inc.



Chair of Advisory Board

Al Beardsley, PhD

30+ years of creating and leading complex, highly successful public and private sector biopharma companies including Galera, MSDC, Kereos, President & CEO Cirius Therapeutics



Isotope Effects in Biological Organisms

Roman Zubarev, PhD

Professor of medicinal proteomics in the Department of Medical Biochemistry and Biophysics at the Karolinska Institutet.



Regulatory Affairs and Compliance

Andreia Collier, MSc

Over 80 successful INDs and 60 NDAs with the FDA, in oncology, dermatology and cardiology divisions; regulatory approvals in Europe, Australia, Latin America, Japan and Asia; worked at Gilead, BTG, Johnson & Johnson and Merck.

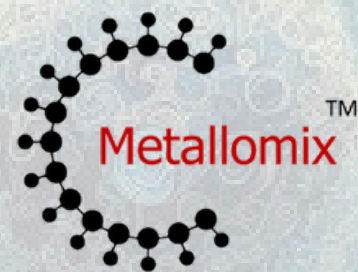


Analytical/Bioanalytical Chemistry

James Blackledge, PhD

Expert in biological mass spectroscopy, 20+ years in pharmaceutical drug development, founder of Capella Imaging, R&D at BMS, Parke-Davis, Kereos, Inc, Mallinckrodt Pharmaceuticals and Galera Therapeutics.

Thank you!



Dr. Sergei Petukhov, CEO
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