



**KAIROS
PHARMA**

INVESTOR PRESENTATION

NYSE American: KAPA

kairospharma.com



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OUR MISSION

Kairos Pharma is dedicated to advancing therapies to overcome critical challenges in cancer drug resistance and immune suppression.



Problem: Resistance develops for even blockbuster drugs like anti-androgen therapies (prostate cancer), Tagrisso (NSCLC)

Solution: CD105 elevated with resistance. Our antibody ENV 105 reverses resistance .

Big opportunities – resistance in prostate cancer, NSCLC, other tumor types

Three clinical programs already in progress

LEAD DRUG ENV 105 in **Phase 2 trial** treating

Prostate Cancer - with NIH grant funding

ENV 105 Phase 1 trial treating Non-Small Cell

Lung Cancer -with non-dilutive, donor funding

KROS 201 immunotherapy cleared IND for Glioblastoma

Goal to Partner with large pharma after phase 2 trial results

Experienced Team, Cedars Sinai to drive enrollment, Grant funding has created non-dilutive value

INNOVATIVE CANCER THERAPEUTICS

New technologies reverse key mechanisms of drug resistance and immune suppression of cancer.



June 2013 – Spun-off from Cedars-Sinai Medical Center

July 2016 – Name changed to Kairos Pharma and licensed immunotherapy technology from Cedars-Sinai Medical Center

November 2019 – Merged with AcTcell Biopharma

July 2021 – Merged with Enviro Therapeutics

Non-dilutive grants from NIH and Pennsylvania fund research

- Preclinical work for ENV105 Prostate Cancer Phase II, ENV105 Non-Small Cell Lung Cancer Phase I, KROS-201 Glioblastoma Phase I
- IND for KROS 201 cleared for recurrent glioblastoma

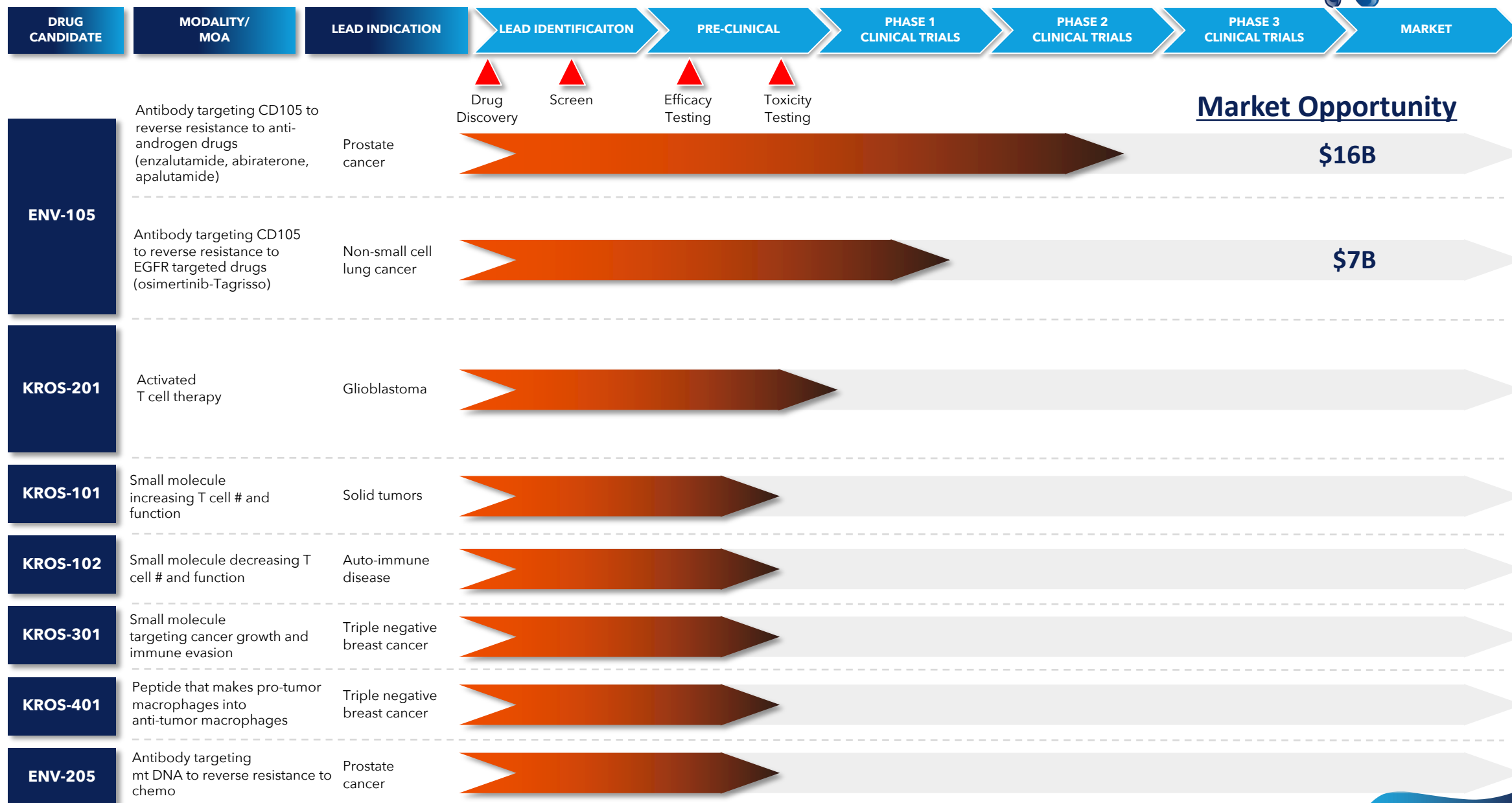
- KROS-101 G1TR agonist molecule and KROS-102 antagonist G1TR molecule Preclinical studies
- IND approved for Phase II Prostate Cancer Trial and for Phase I Non-Small Cell Lung Cancer for ENV 105

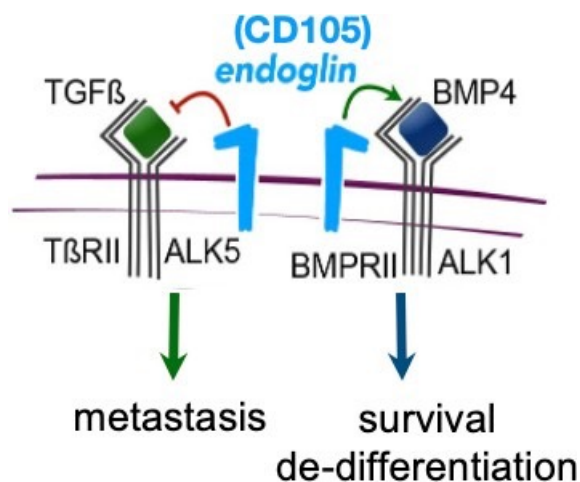
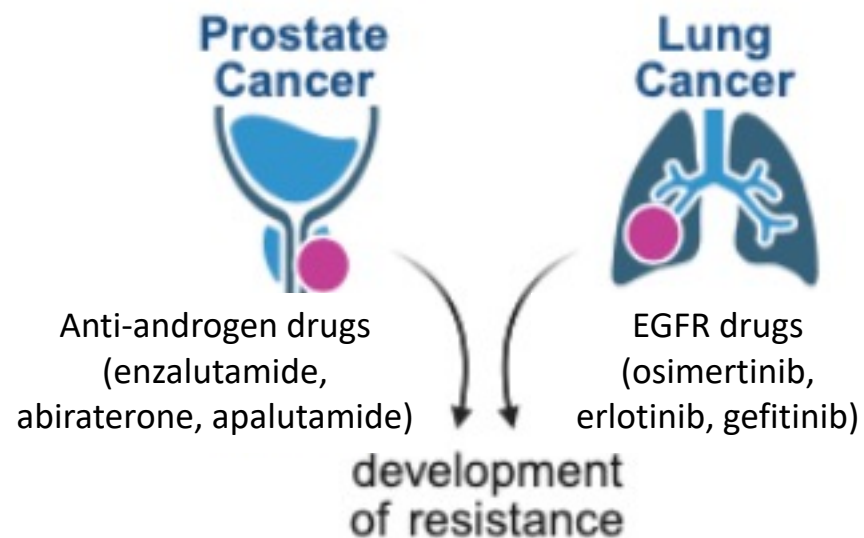
- Phase I and II trials with ENV 105 enrolling
- Preclinical development of KROS 101, 102, 301, 401

- Safety data from Phase II trial and Phase I trial
- Interim data of Phase II prostate cancer trial
- Efficacy data from Phase II trial and Phase I trial
- 5-year Horizon for ENV105 FDA Approval with a Maturing Pipeline of Broader Prospective Applications
- Phase I trials for KROS 101



PORTFOLIO OF INNOVATIVE DRUGS





THE PROBLEM: Resistance

As cancers become resistant to standard of care, their cancer cells make CD105 on the surface, that mediates tumor cell survival and therapy resistance.

CD105 is **elevated in resistant cancer cells that recur or are incompletely treated.**

THE SOLUTION: Block CD105

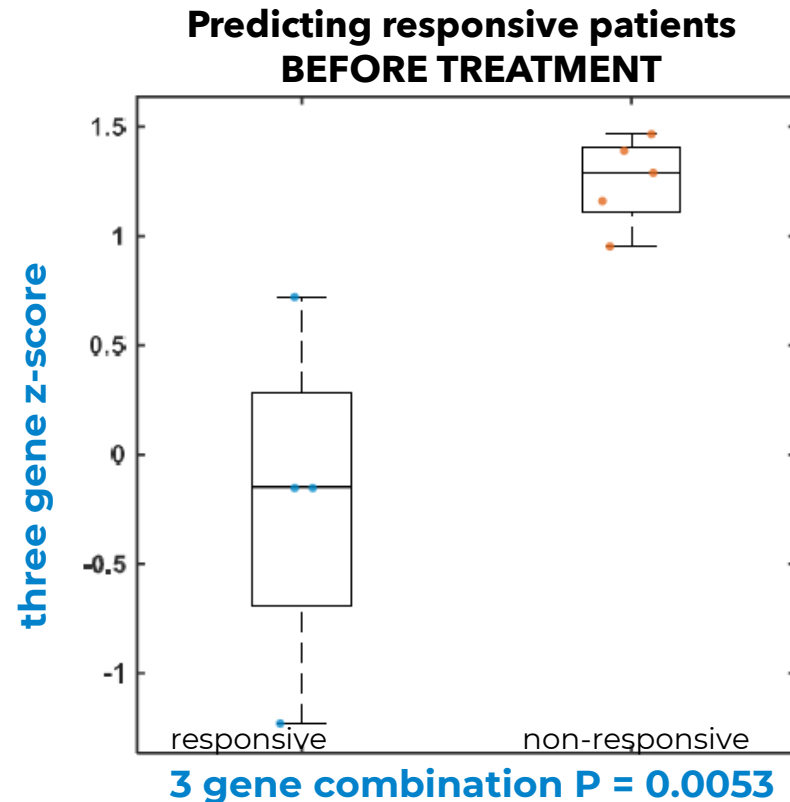
ENV105 blocks CD105 to restore sensitivity to the entire class of hormone therapies for prostate cancer patients (eg. enzalutamide, abiraterone and apalutamide) and EGFR-targeted therapies for lung cancer patients (e.g. Osimertinib, gefitinib)

Broadly applicable to reverse resistance in cancer:

Although prostate and lung cancer are the first indications for ENV 105, this drug has been shown to be effective in models of colon, breast cancers, and head & neck cancers in the resistance developed against radiation and chemotherapy.

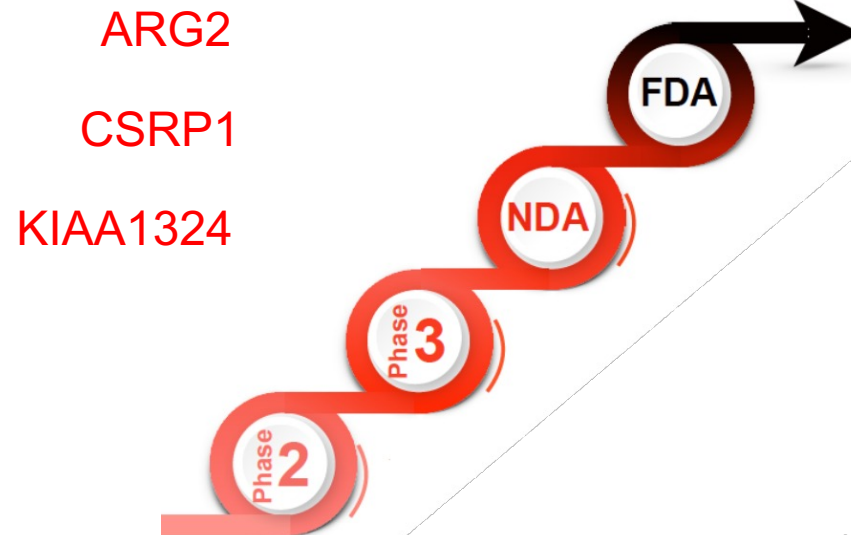
BIOMARKER TO PREDICT RESPONSIVENESS TO THERAPY

- Biomarker is a genetic test that distinguishes between responsive and non-responsive patients
- Identified biomarkers ensure more successful outcomes in new drug approval (NDA) success
- \$3.2 Million NIH grant to our CSO supports biomarker confirmation study in present phase 2 trial

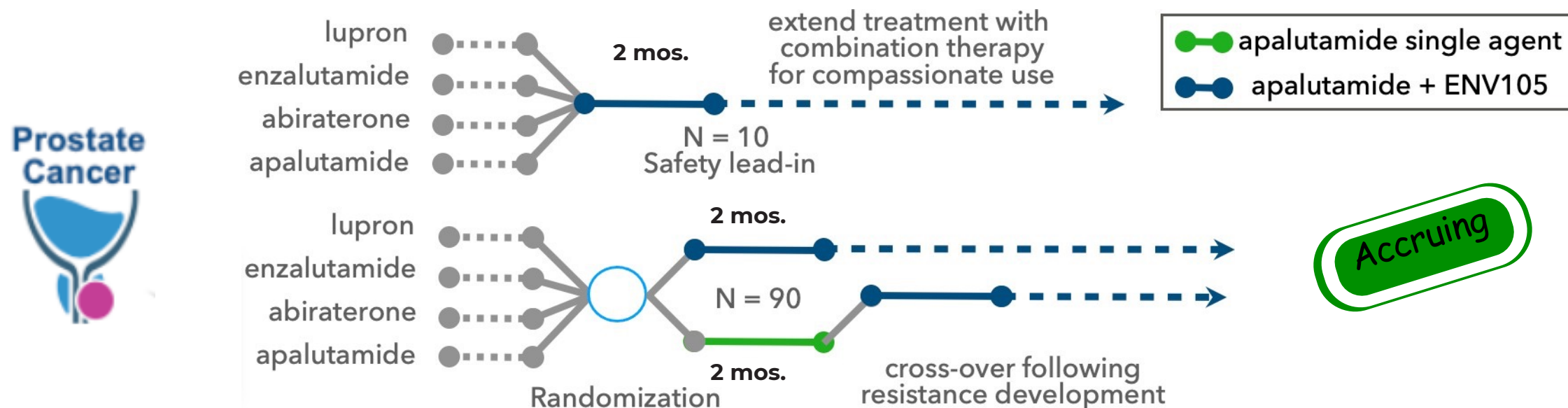


NEW DRUG APPROVAL SUCCESS

55% vs. 76% with biomarker



Mol Therapy (2023) 31:78

PRESENT RANDOMIZED PHASE 2 TRIAL: NCT03418324**Apalutamide with or without ENV105**

PRIMARY ENDPOINT: Progression free survival based on RECIST 1.1 and PCWG 3 criteria

SECONDARY ENDPOINT: Companion biomarker validation



Patient Summary

Phase 2 trial [NCT05534646](https://clinicaltrials.gov/ct2/show/study/NCT05534646)

Apalutamide and Carotuximab for the Treatment of Metastatic Castration-Resistant Prostate Cancer

Sponsored by:



Patient ID	Age at enrollment	Pre-treatment PSA	RECIST/PWCG @ week 16	Previous therapies
001	68	7.59	Stable disease	Abiraterone
002	76	278.55	Not assessable	Enzalutamide, Lu-PSMA
003	73	32.35	Stable disease	Enzalutamide
004	82	59.03	Stable disease RECIST	Enzalutamide, Abiraterone
005	60	4.49	Stable disease	Apalutamide
006	68	278.43	Stable disease	Abiraterone, Enzalutamide
007	79	5.63	Stable disease	Enzalutamide
008	71	3.37	Stable disease	Abiraterone
009	69	20.59	clinical PD at 3 months	Abiraterone
010	85	0.82	Stable disease	Enzalutamide, Darolutamide, Lu-PSMA

Patient Summary

Phase 2 trial [NCT05534646](https://clinicaltrials.gov/ct2/show/study/NCT05534646)

Apalutamide and Carotuximab for the Treatment of Metastatic Castration-Resistant Prostate Cancer

Event	All grades	Grade 3
Epistaxis	8	1
Headache	8	0
Gum bleeding	5	0
Fatigue	4	0
Nausea	4	0
Pruritis	3	0
Anemia	3	0
Anorexia	3	0
Dehydration	2	0
Dizziness	2	0

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No grade 4-5 AE noted

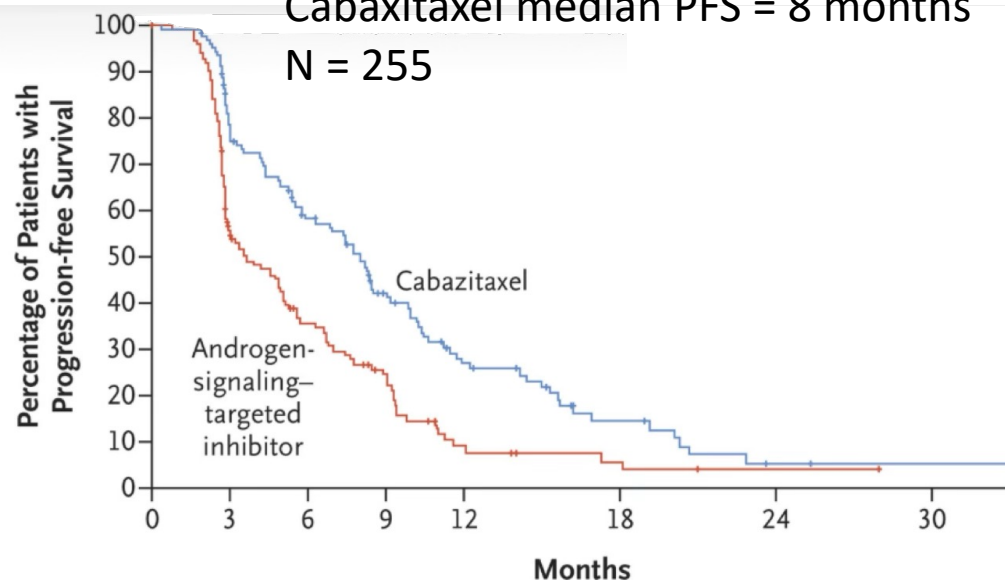
Radiographic PFS points of reference

CARD Trial

ARPI-switch median PFS = 3.7 months

Cabazitaxel median PFS = 8 months

N = 255



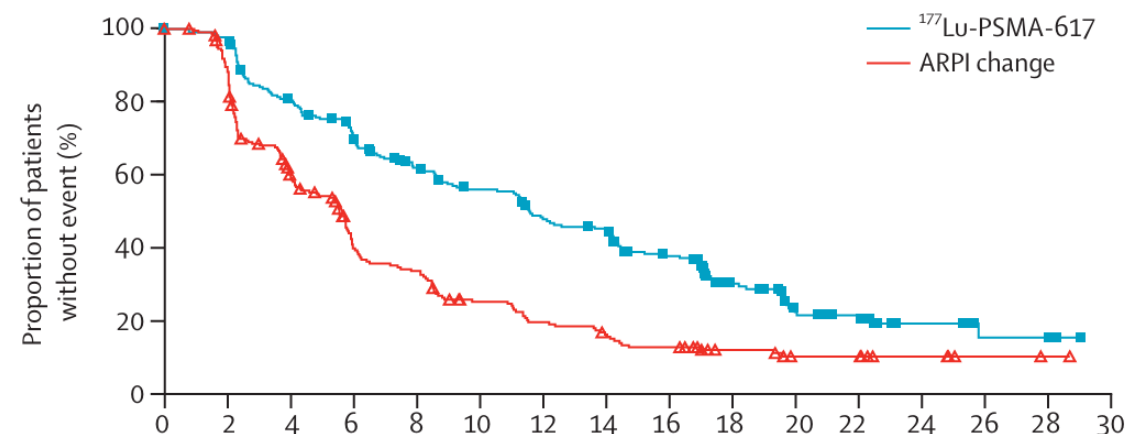
No. at Risk

	129	91	64	41	23	9	2	1
Cabazitaxel	129	91	64	41	23	9	2	1
Androgen-signaling-targeted inhibitor	126	61	36	22	7	3	1	0

ARPI-switch median PFS = 5.6 months

^{177}Lu -PSMA median PFS = 11.6 months

N = 468



Number at risk (number censored)

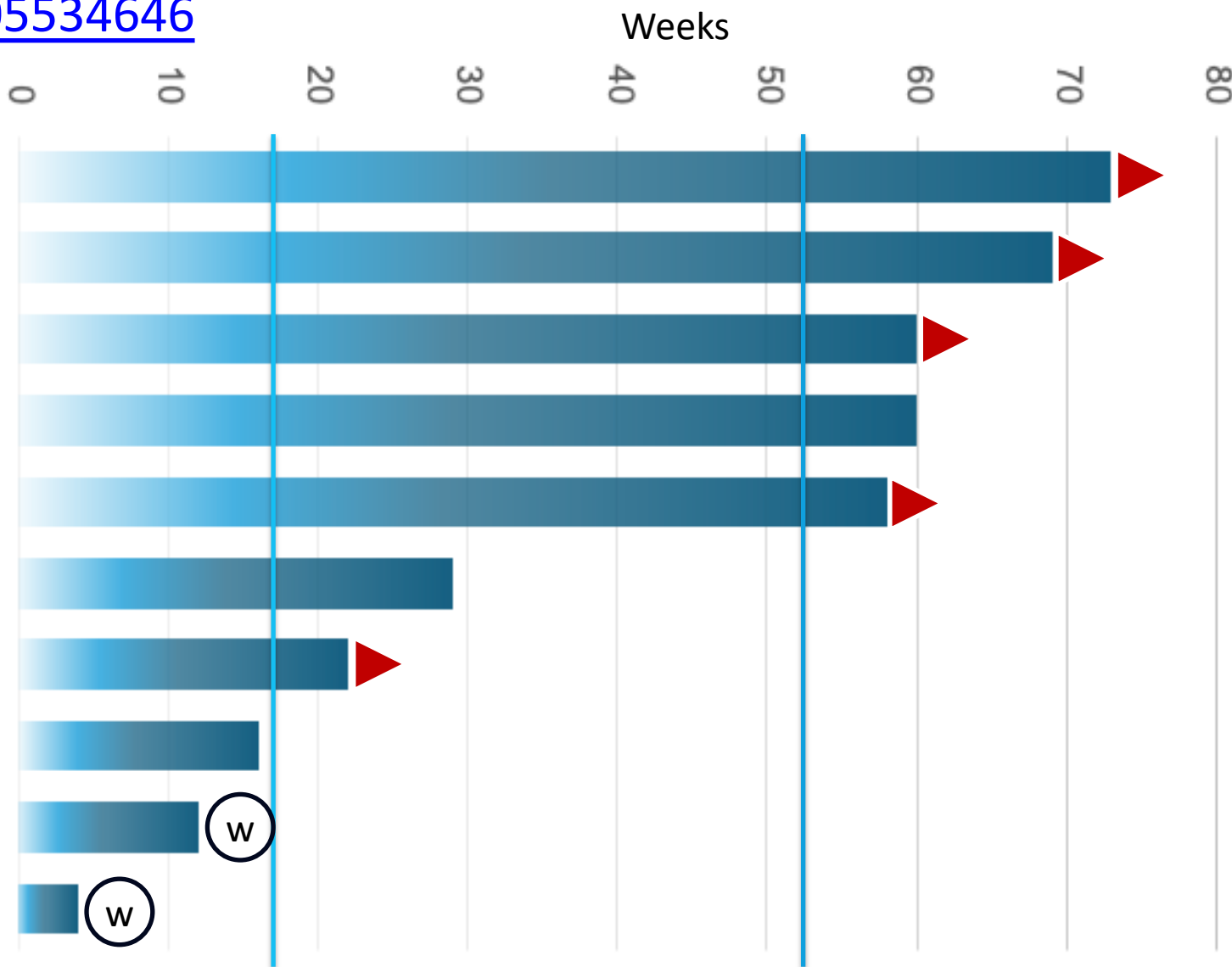
^{177}Lu -PSMA-617 group	234	217	175	152	126	111	94	86	67	39	25	20	8	4	4	0
	(0)	(12)	(5)	(3)	(6)	(3)	(2)	(1)	(6)	(16)	(6)	(3)	(10)	(3)	(0)	(4)
ARPI change group	234	197	126	79	65	45	35	28	22	14	9	9	5	2	1	0
	(0)	(14)	(7)	(9)	(0)	(4)	(0)	(1)	(0)	(7)	(3)	(0)	(4)	(3)	(1)	(1)

NEJM (2019) 318:2506

Lancet (2024) 44:1227

Progression Free Survival

[NCT05534646](#)



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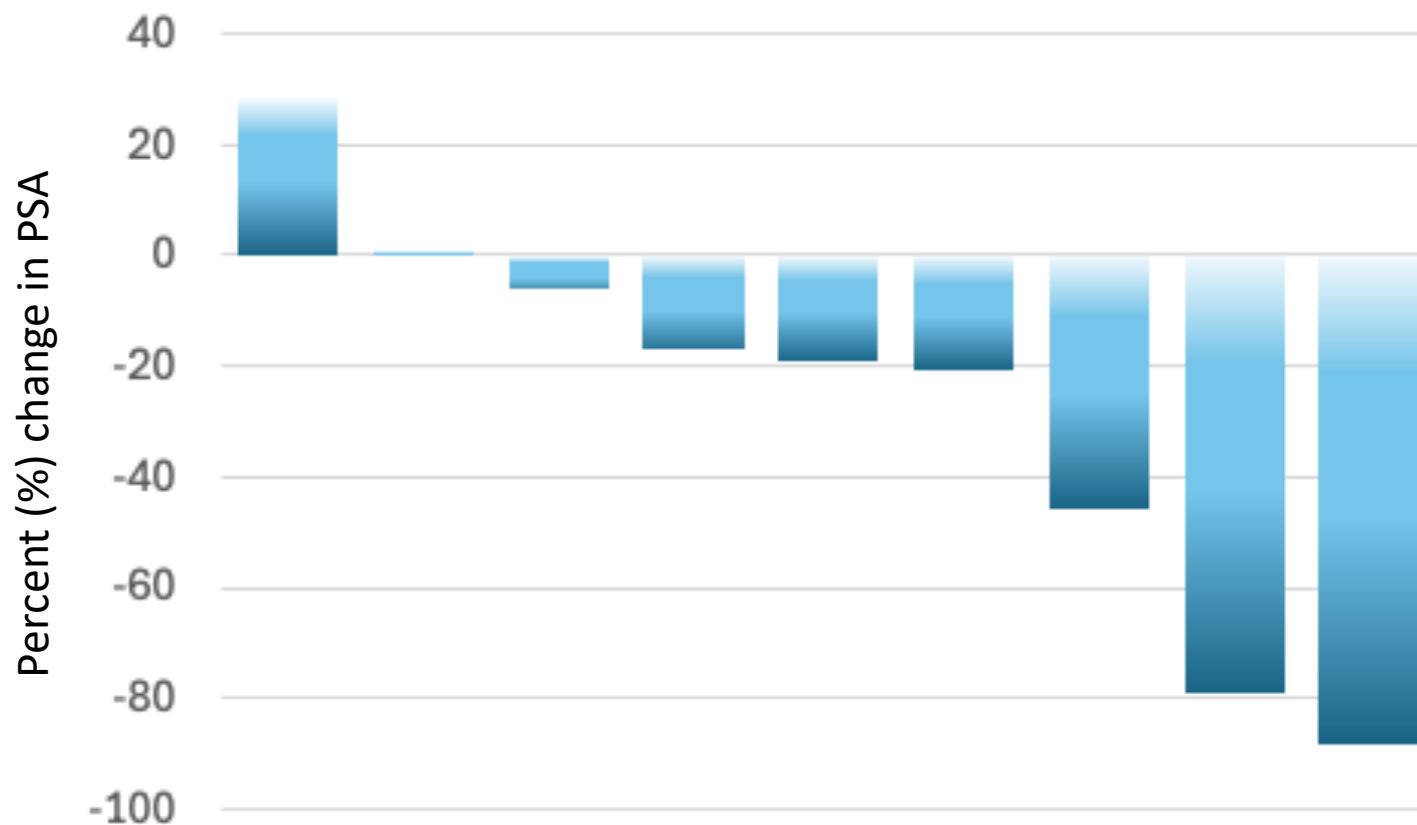
▶ Still on trial
Ⓜ Unrelated withdrawal

Median PFS = 59 weeks*

* Patients continue to be evaluated

Change in PSA

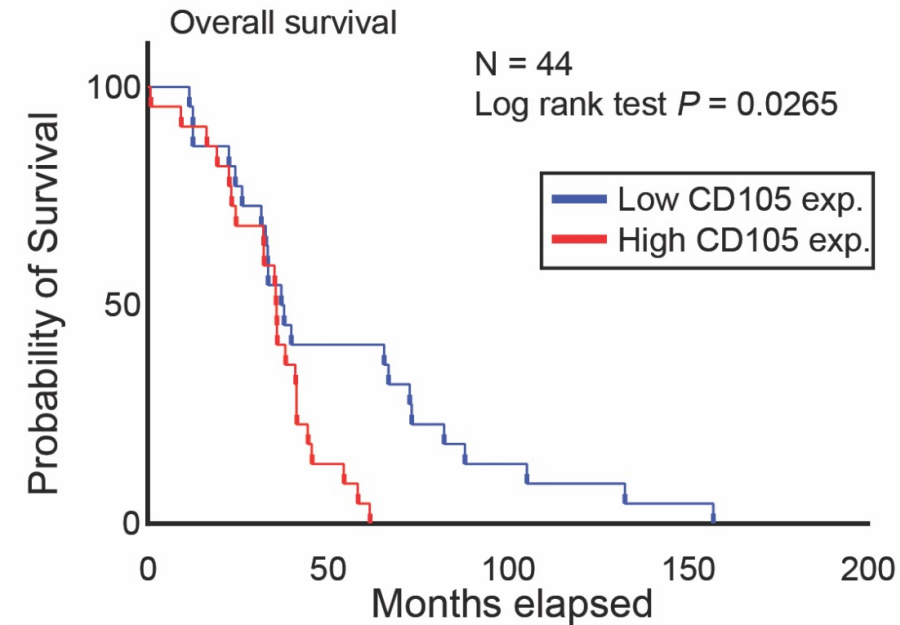
[NCT05534646](#)



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Comparing baseline pre-treatment PSA to nadir PSA values

NON-SMALL CELL LUNG CANCER BECOMES RESISTANT TO OSIMERTINIB (TAGRISSO)**OSIMERTINIB RESISTANCE IS DEPENDENT ON CD105**

- 45,000 EGFR driven NSCLC diagnosed last year
- Tagrisso is the standard of care for EGFR driven NSCLC, yet 80% of patients have only a partial response

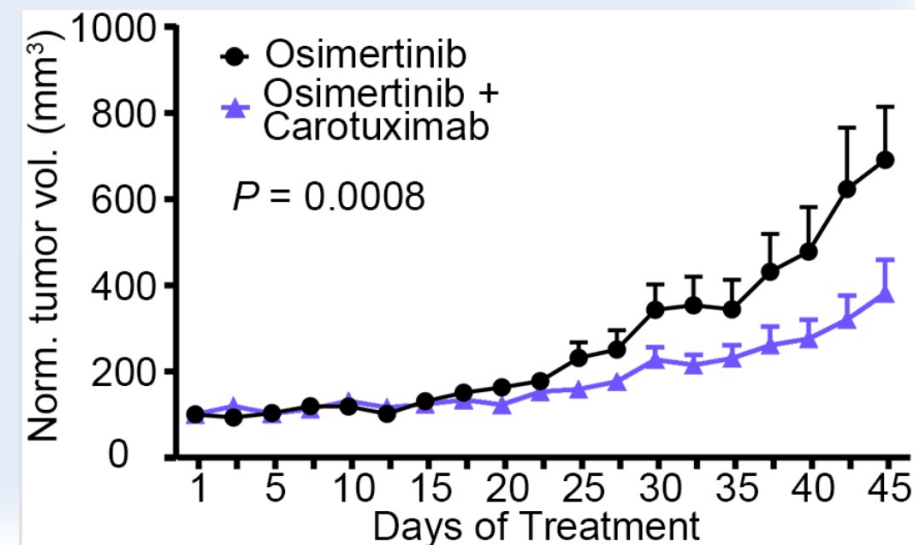
AstraZeneca's EGFR inhibitor Tagrisso (\$7B in 2024 sales) offers only a partial response in 80% of patients

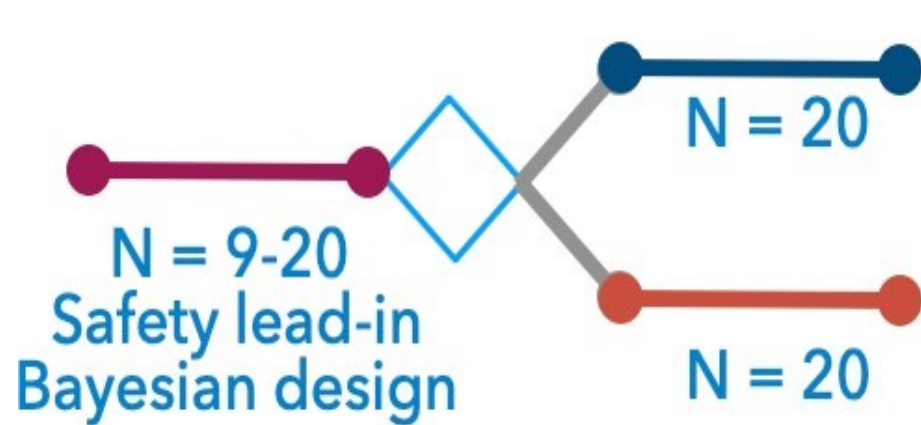
CD105 is elevated with Tagrisso treatment

Preclinical models show ENV105 can overcome resistance and shrink tumors

ENV105 could not only reverse resistance but make Tagrisso work better to enable complete responses

Accruing Phase I study of patients resistant to Tagrisso or partial responders with persistent circulating tumor cell DNA



PHASE 1 TRIAL FOR EGFR-DRIVEN LUNG CANCER: Osimertinib (Tagrisso) + ENV105

Patients that have become resistant to Tagrisso

Patients that are incompletely treated with Tagrisso (persistent ctDNA)



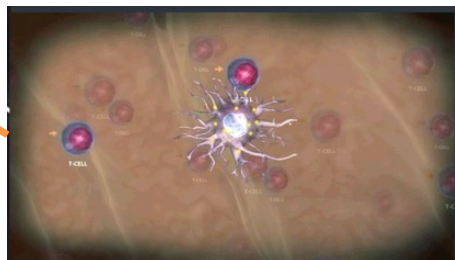
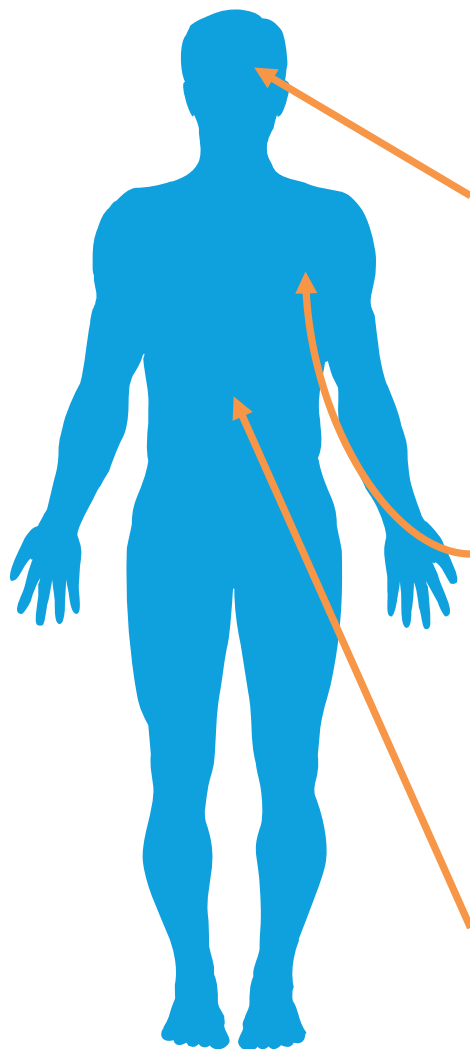
PRIMARY ENDPOINT: Determine safety and effective dose of ENV105 in patients with EGFR lung cancer

SECONDARY ENDPOINT: Identify biomarkers for patients most responsive to ENV105

KROS DRUG CANDIDATES

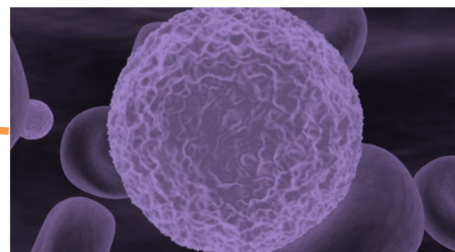
OVERCOMING IMMUNE SUPPRESSION

Immunotherapy is a \$118b market with only a 17% response rate.



THE PROBLEM:

Cancer is comprised of billions of growing cells. However, our immune system seldom generates enough T cells to kill all the cancer cells.

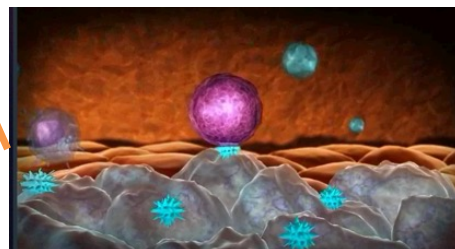


THE SOLUTION: KROS drug candidates allows regulation of the immune response by increasing T cells or by generating T cells outside of the immunosuppressed patient's body.

KROS 101 Using our novel mechanism through GITR ligand, increases the number of T cells and renders them more effective at killing cancer cells.

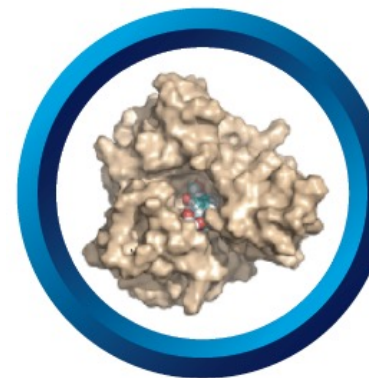
KROS 201 Generates T cells outside of the body and delivers to cancer stem cells.

KROS 401 Converts pro-tumor macrophages into cancer-killing macrophages.



KROS 101: GITR (glucocorticoid-induced tumor necrosis factor receptor) ligand is a powerful checkpoint that increases the T cell response against cancer.

Kairos Pharma developed a small molecule that increases T cell numbers and anti-tumor killing activity by acting as a GITR agonist.



Kairos identified structure of GITR ligand through X ray crystallography.

KROS-101 pictured here in the center of the GITR protein

OTHER DRUGS TARGETING GITR RECEPTOR

COMPANY	DRUG	ACTIVITY
Kairos Pharma	KROS101	• Targets the GITR ligand (the signal for the receptor) enabling expansive growth of T cells • Small molecule has shorter half-life allows for more fine tuning of dose to limit side effects • Having both agonist (KROS101) and antagonist (KROS102) molecules allows reversal of side effects
AstraZeneca	MEDI1873	• Hexameric GITR ligand fusion protein does not enable significant T cell response
Merck	MK4166	• Agonist antibody has significant toxicity including autoimmune gastritis

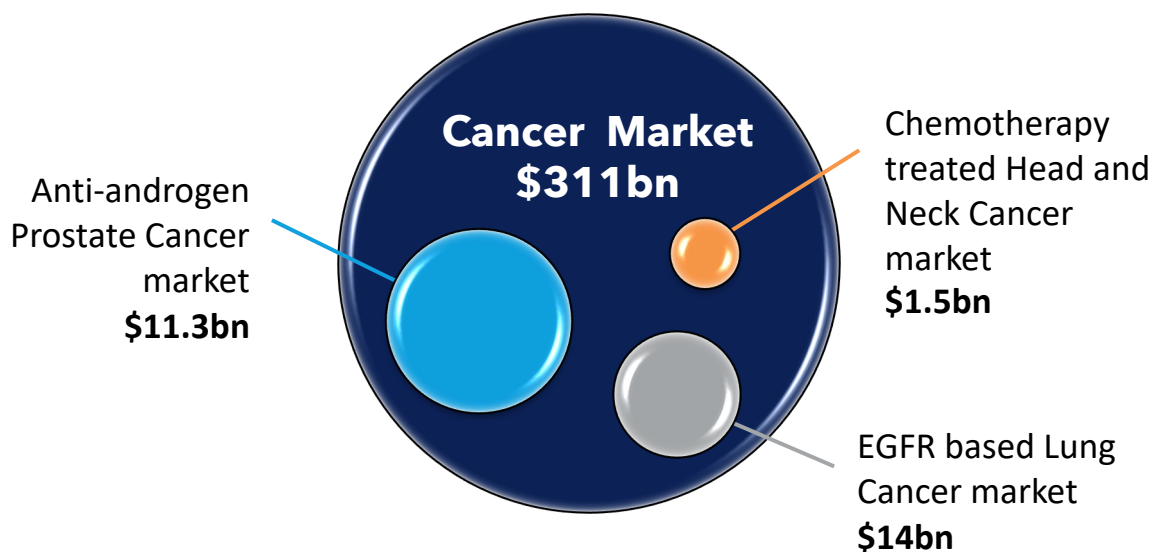
ENV105 MARKET OPPORTUNITY BY DISEASE - 2024

- Anti-androgen therapy prostate cancer market of **\$11.3 billion¹**. *Apalutamide* (Eylea) \$3B in 2024 sales)
- EGFR based lung cancer therapy market of **\$14 billion²**. *Tagrisso* generated total revenue of \$6.6 billion in 2024.
- Chemotherapy treated head & neck cancer market is estimated at approximately **\$1.5 billion²**.

NOTES:

1. Grandview Research
2. Researchandmarkets.com

ENV105 MARKET OPPORTUNITY BY DISEASE



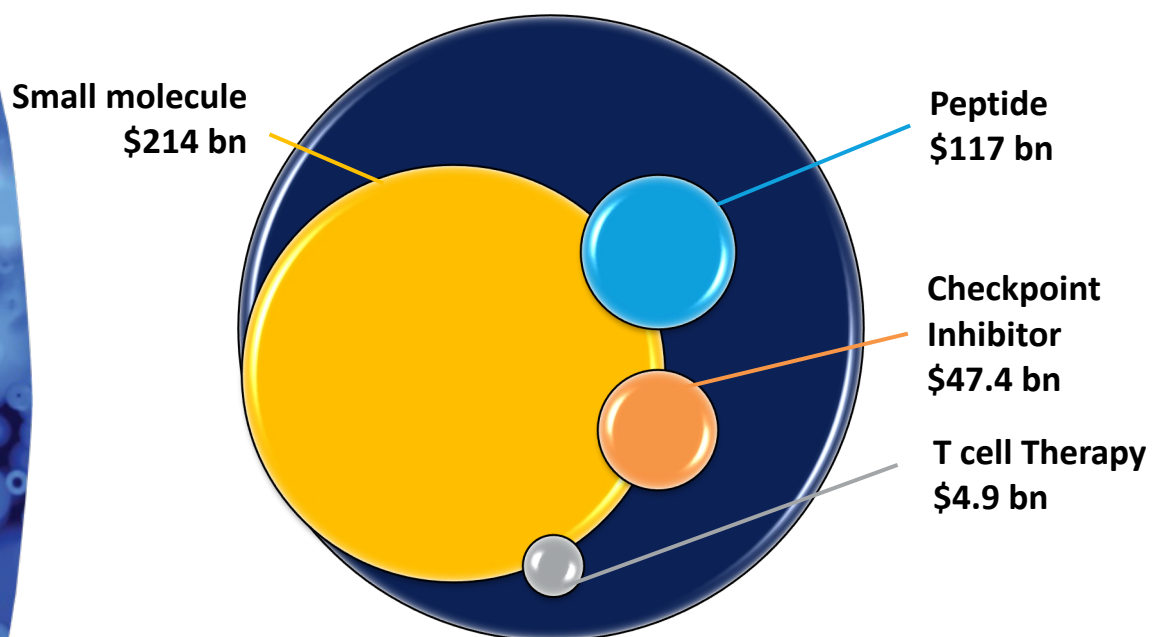
Immuno-Oncology Market

Global immunotherapy market valued at \$226 B in 2024, with CAGR of 12% from 2025-2030.²

MARKET DRIVERS

- Increasing patient pool and higher mortality rate are augmenting the need for cancer immunotherapy globally.
- Increasing number of approvals for new immunotherapeutic drugs is driving the global oncology market.

KROS MARKET OPPORTUNITY BY DRUG TYPE



KROS MARKET OPPORTUNITY BY DRUG CANDIDATE

KROS 101 & 102	Global immune checkpoint inhibitor market size was \$47.4 billion in 2024, growing with a CAGR of \$16.7% ¹ .
KROS 201	Global T cell therapy market was \$4.9 billion in 2021, growing to \$20.8 billion by 2030 resulting in a CAGR of 20.4% ² .
KROS 301	Global small-molecule cancer therapies market was \$214 billion in 2024, growing with a CAGR of 5.6% ³ .
KROS 401	Global peptide therapeutics market was estimated at \$117 billion in 2024 ³ .

NOTES:

1. Global Market Insights
2. Grandview Research
3. Grandview Research

IP extends to 2040



Key IP generated from Murali,
Bhowmick and Yu labs



Published patents
executed internationally



Exclusive, worldwide rights to IP
licensed from Cedars Sinai
Medical Center

Pub #	KROS101 PCT/US2019/045478	KROS201 PCT/US2020/045570	KROS301 PCT/US2015/050906	KROS401 PCT/US2016/035318	ENV105 PCT/US2017/037558
Title	Compositions And Methods For Treating Cancer And Autoimmune Diseases	Method Of Generating Activated T Cells For Cancer Therapy	Compositions And Methods For Treating Fibrosis	Methods And Use Of Compounds That Bind To RELA Of NF-KB	Sensitization Of Tumors To Therapies Through Endoglin Antagonism



John S. Yu, MD
CEO & CHAIRMAN

Professor of Neurosurgery, Director Surgical Neuro-Oncology at Cedars-Sinai Medical Center

- BAS from Stanford, MD from Harvard Medical School and MIT
- Numerous immunotherapies and nanotechnologies from his NIH funded laboratory
- Developed 8 new investigational drugs with the FDA and has led numerous clinical trials
- Most recently CEO and Chairman of AcTcell, and Director of Enviro Therapeutics
- Immunology Fellowship at the Institute Pasteur, Paris, Neurosurgery Residency at Massachusetts General Hospital/Harvard Medical School



Doug Samuelson
CHIEF FINANCIAL OFFICER

- 25+ year finance and accounting professional
- Former CFO of .Wellness Center USA
- Former Director of Accounting of Second Sight Medical Products, Inc.
- Former Chief Financial Officer of AdvaVet, Inc. and Chief Financial Officer of Solis Tek, Inc.
- CPA in State of California



Ramchandran Murali, Ph.D
VP, RESEARCH AND DEVELOPMENT

Professor, Biomedical Sciences and Research in Immunology at Penn/Cedars-Sinai Medical Center.

- Leading expert in X-ray crystallography, biophysical, biochemical, and immunology fields, having made significant advances in molecular engineering and cell surface receptors by developing pharmacological agents which include new paradigms in structure-based peptidomimetics drug discovery
- Developed numerous technologies that reverse key mechanisms of immune suppression of cancer. Previous technologies from Penn licensed by Ception (bought by Teva) and Nidus.

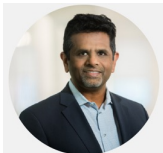


Neil Bhowmick, Ph.D
CHIEF SCIENTIFIC OFFICER & PRESIDENT, ENVIRO THERAPEUTICS

Professor of the Department of Medicine and Director of the Cancer Biology Program at Cedars-Sinai Medical Center

- Fellowship at Vanderbilt University Medical Center Research Director, Oppenheimer Urologic Reference Laboratory (OURLab)
- Holds 6 patents for biomarker detection platforms and stromal targeted therapeutics (inclusive of ENV105 and ENV205)
- Consultant at Xencor Inc. (NASDAQ: XNCR) and Tracon Pharma (NASDAQ: TCON)
- NCI/NIH funded for over 15 years and cited over 11,700 times





Rahul Singhvi, Sc.D.

Chemical engineering from MIT. MBA from the Wharton School of the University of Pennsylvania, where he graduated as a Palmer Scholar.

- Global leader in the Life Sciences industry and is cofounder of the biomanufacturing company, Resilience (National Resilience, Inc.).
- Former Operating Partner at Flagship Pioneering, where he founded and operated companies launched from Flagship's innovation foundry, Flagship labs.
- Former Chief Operating Officer of Takeda's Vaccine Business Unit where he led worldwide vaccine CMC manufacturing.
- Former President and CEO of Novavax, Inc. where he transformed the company from a specialty pharmaceutical business into a vaccine development company.
- Career began at Merck & Co in 1994, where he held several positions in R&D and manufacturing.
- Serves on the Board of Trustees of the Keck Graduate Institute, and on the Board of Directors for Codexis (Nasdaq:CDXS), and Garuda Therapeutics (private).



Hyun W. Bae, MD

BS in Biomechanics from Columbia, MD cum laude from Yale, former NIH Howard Hughes Research Fellow Bethesda, MD.

- Professor of Surgery in Orthopaedic Surgery at CSMC, Director of Education and clinical partner of the Orthopaedic Stem Cell and Tissue Engineering Laboratory
- 10+ years experience in drug development, PI for 3-4 FDA-approved randomized clinical trials with over 30 clinical studies, 60+ published scientific papers, 5 review articles and 30 patents
- Chief Medical Officer and Director of Prosidyan, Scientific Advisory Board Member of Mesoblast, Tissuegene, Spine Biopharma and Engage Surgical



Michael Keyoung, MD, Ph.D

MD and Ph.D. in Neuroscience and Neurology from Cornell and Sloan Kettering (MSKCC), UCSF Health, Biomedical Fellow at Rockefeller and MSKCC

- Senior ME, Head of N.A. for CBC Group, a healthcare-dedicated PE firm with over US\$9 Billion AUM
- 20+ year career as a physician, executive and institutional investor in US, Europe and Asia advising Eli Lilly, Bausch & Lomb, and Samsung Electronics/Biologics on Asian expansion, global drug development and commercial/partnership strategies
- Former CEO of Genexine (KOSDAQ: 095700 w/ \$1 Billion MC), led clinical development in Europe and Asia, raised \$100M and created partnerships with Merck, Fosun Pharma, Tasly Pharma and Kalbe Pharma valued at over \$250M
- Former President of Catalyst Biosciences, (NASDAQ: CBIO) a clinical stage hemophilia and ophthalmology company partnered with Pfizer, MedImmune and Isu Abxis
- Previous Board Chair of AffaMed Therapeutics and Director of Graybug Vision and InxMed
- Board member of Hugel Inc. (kosdaq: 145020.KQ)





- Clinical stage company with an antibody that impacts a central mechanism of **CANCER DRUG RESISTANCE**
- Extensive pipeline targets **IMMUNE SUPPRESSION**
- Enrolling in phase 1 and 2 trials with interim efficacy data in 2025
- Strategic relationship with Cedars-Sinai Medical Center (ranked #2 in the nation) provides access to medical expertise, drives clinical trial efficiency and accelerates therapeutic innovations
- Small company with technology that could impact large pharma therapeutics in widespread cancers

INNOVATIVE CANCER THERAPEUTICS

New technologies reverse key mechanisms of cancer drug resistance and immune suppression



**KAIROS
PHARMA**

INVESTOR RELATIONS

Louie Toma

MANAGING DIRECTOR

CoreIR

louie@coreir.com

NYSE American: KAPA

kairospharma.com