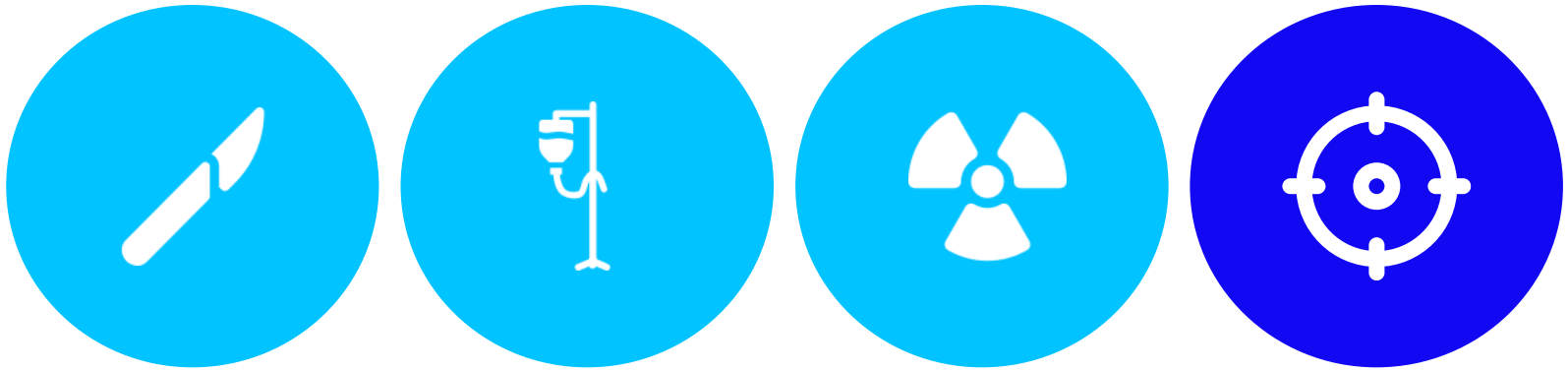
PRECIRIX

precision radiopharmaceuticals

Targeted therapies have revolutionized oncology

Then

Now



150+

approvals in 28 types of cancer since 1997

Frontiers in Pharmacology

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Evolution of targeted therapies for cancer

1990 — 2000 — 2010 — 2020 → Market value by 2025

Immune Checkpoint Inhibitors

3. pembrolizumab (Keytruda), 2014
2. nivolumab (Opdivo), 2014
1. ipilimumab (Yervoy), 2011

$56 B

Small Molecules Inhibitors

3. erlotinib (Tarceva), 2004
2. gefitinib (Iressa), 2001
1. imatinib (Gleevec), 2001

$66 B

Monoclonal Antibodies

3. cetuximab (Erbitux), 2004
2. trastuzumab (Herceptin), 1998
1. rituximab (Rituxan), 1997

$71 B

Allied Market Research, Globe Newswire, Market Data Forecast

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Not there yet

Current limitations of targeted cancer therapies

resistance

side effects

subset populations

Image: National Cancer Institute

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Welcome to

Precision Radiopharmaceuticals

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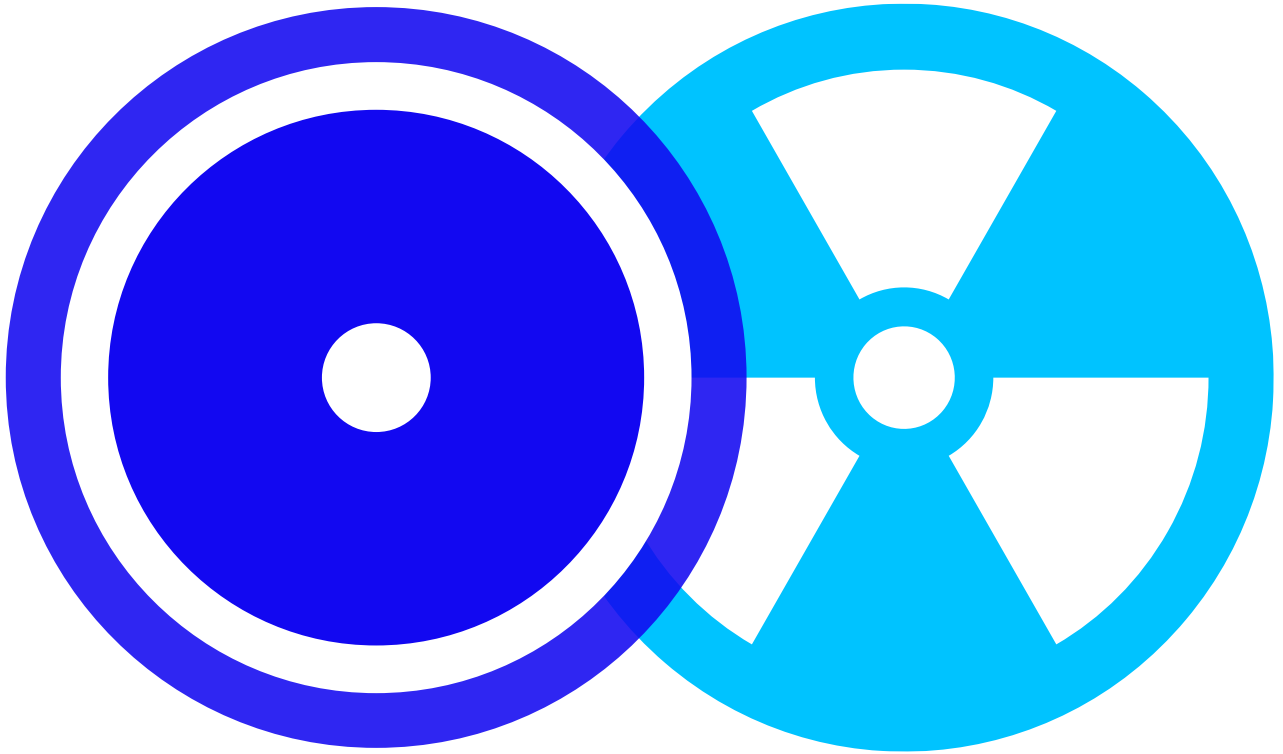
Precirix precision radiopharmaceuticals

single domain Ab



radioisotope

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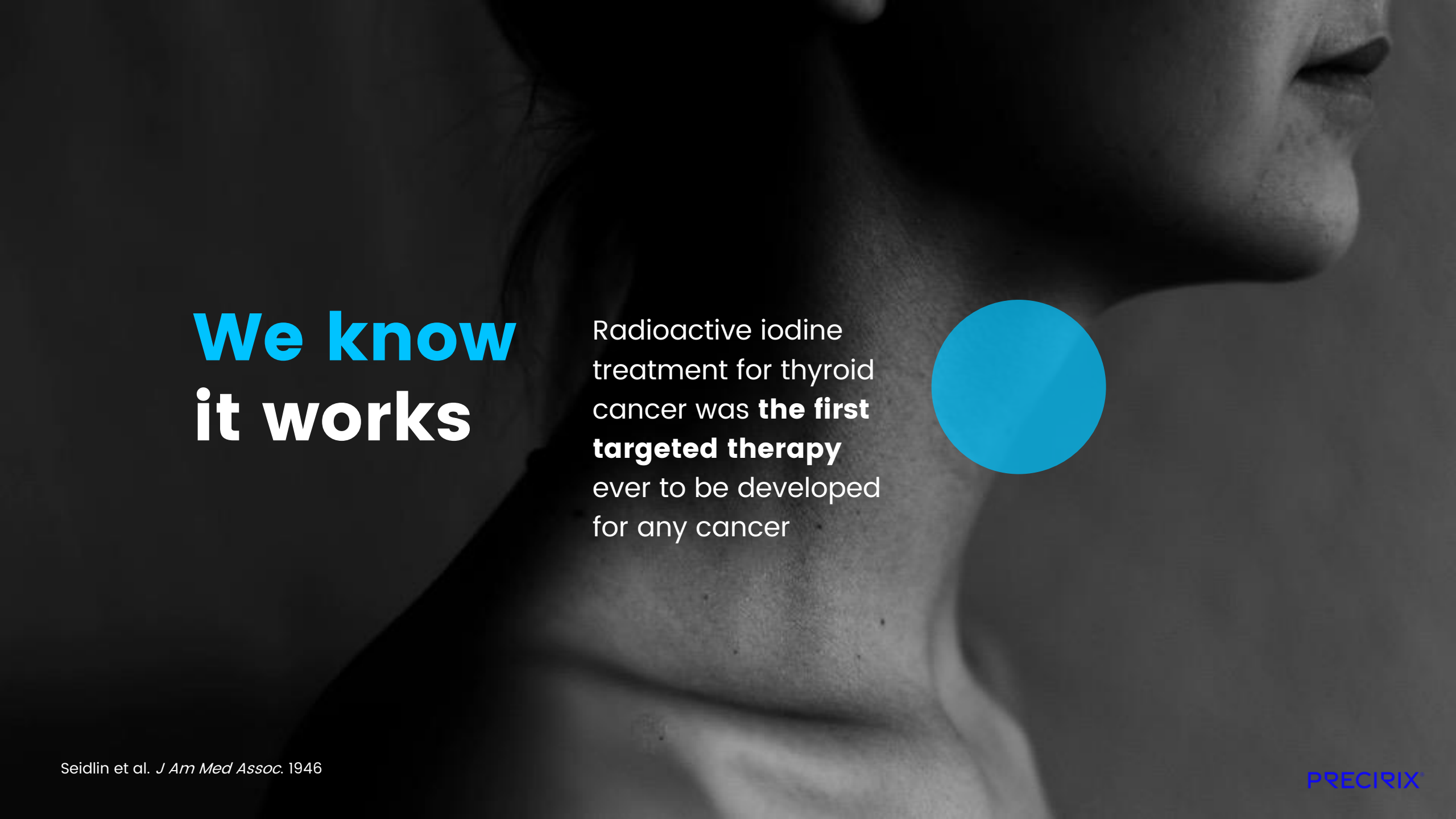

We know it works

Radioactive iodine treatment for thyroid cancer was **the first targeted therapy** ever to be developed for any cancer

Seidlin et al. *J Am Med Assoc*. 1946

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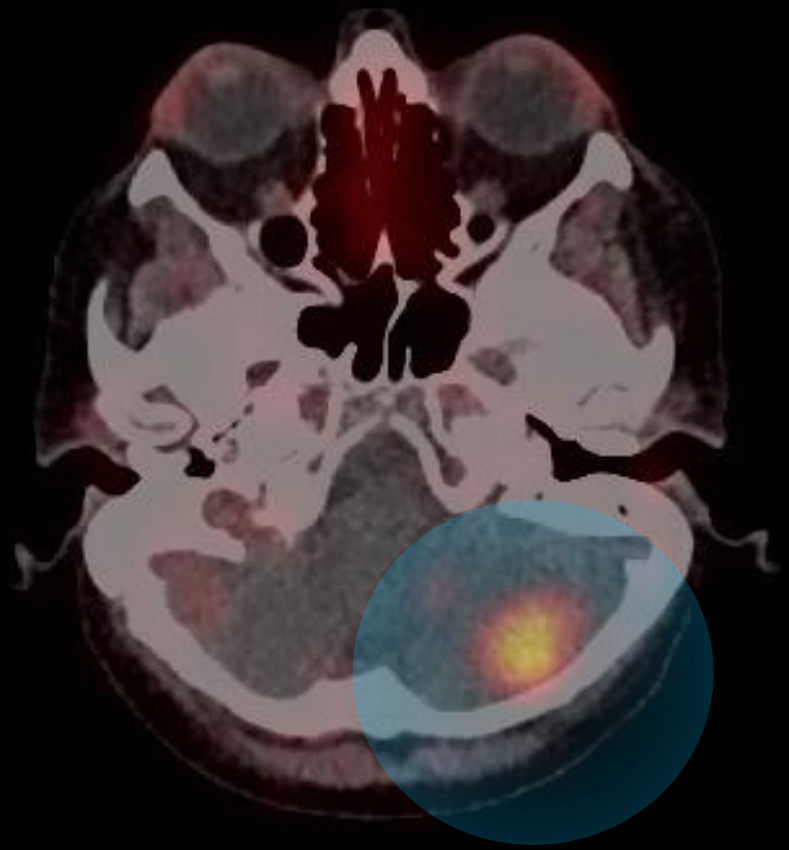

NCT03331601 (Keyaerts et al. UZ Brussel, VUB)

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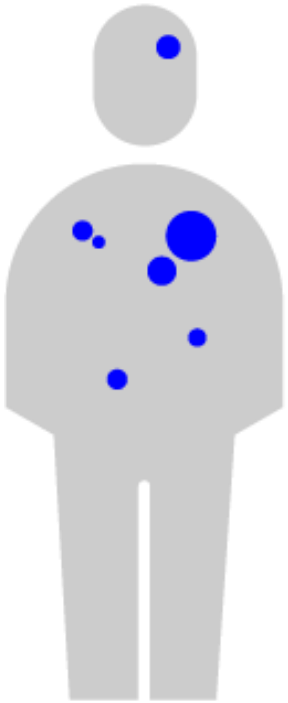
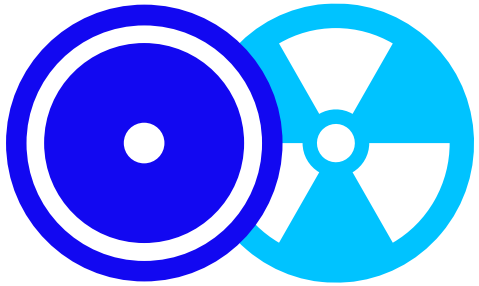
It's a **platform**

Unique





Radioisotope kills through DNA breaks

Direct cell killing and bystander effects

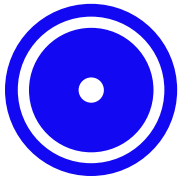
Single domain antibody targets the cancer

On target in minutes after IV infusion anywhere in the body

Deep tumor penetration and prolonged tumor retention

Rapid renal clearance of unbound product

Flexible



Multiple targets

cancer cells
specific epitopes
tumor microenvironment

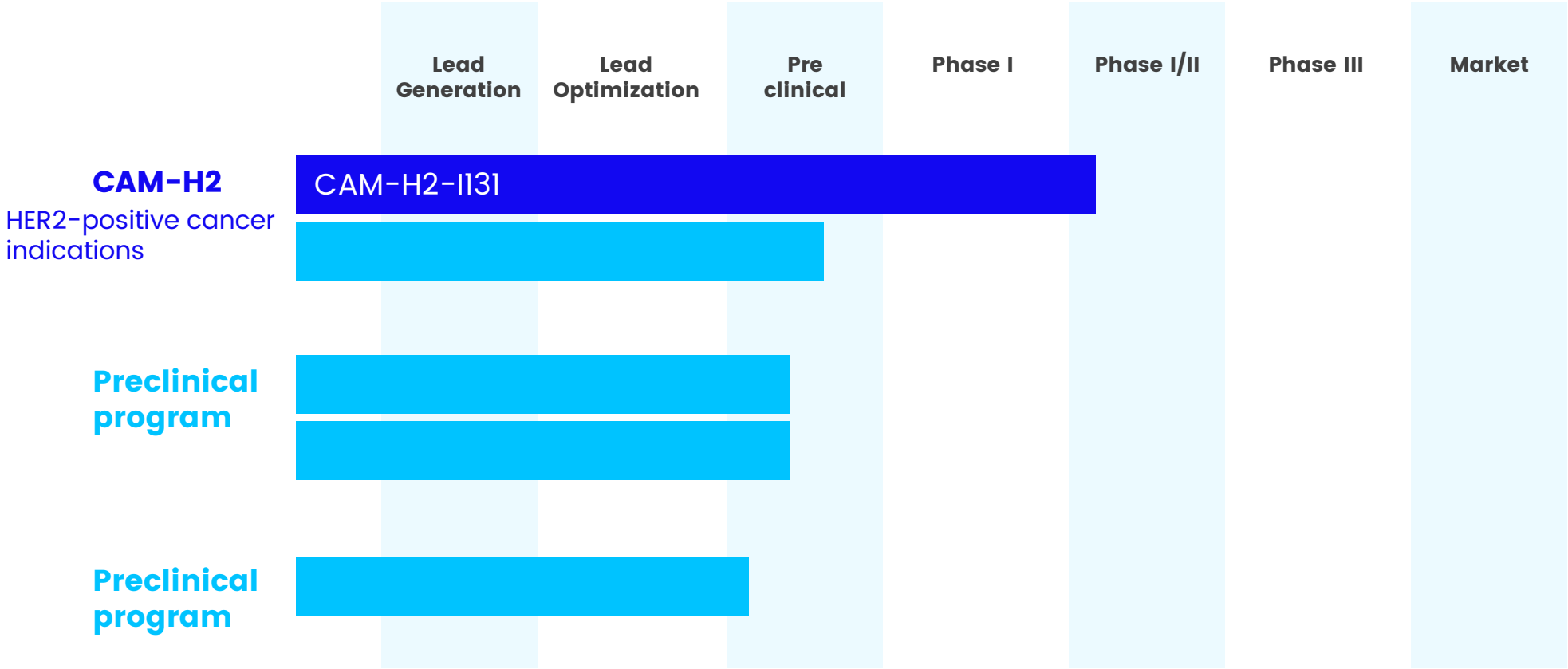
Different isotopes

alpha emitters
beta emitters

Various applications

therapeutic
patient selection
combination therapy

Broad



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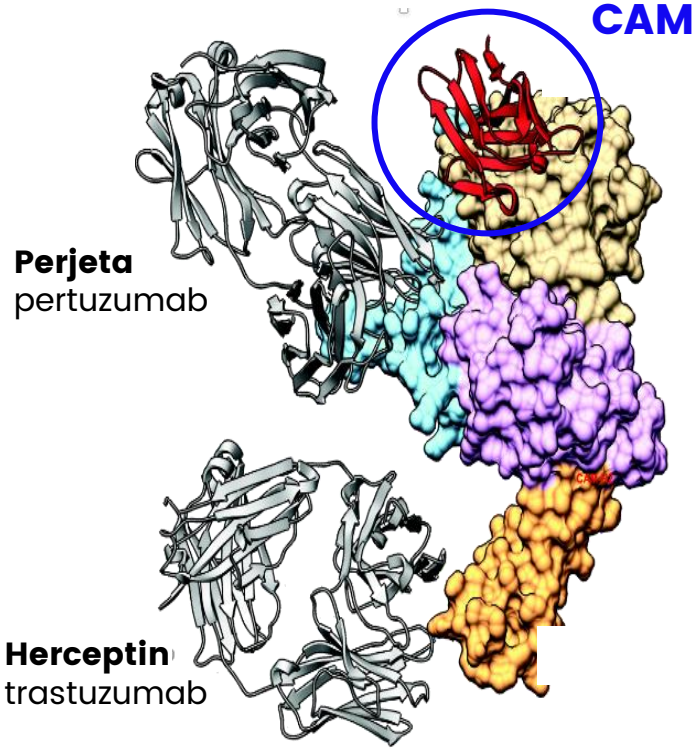
It’s
real

HER2

CAM-H2 clinical candidate



Resistance to HER2 therapy is an issue for approved drugs, CAM-H2 targets a different epitope and brings a new mechanism of action

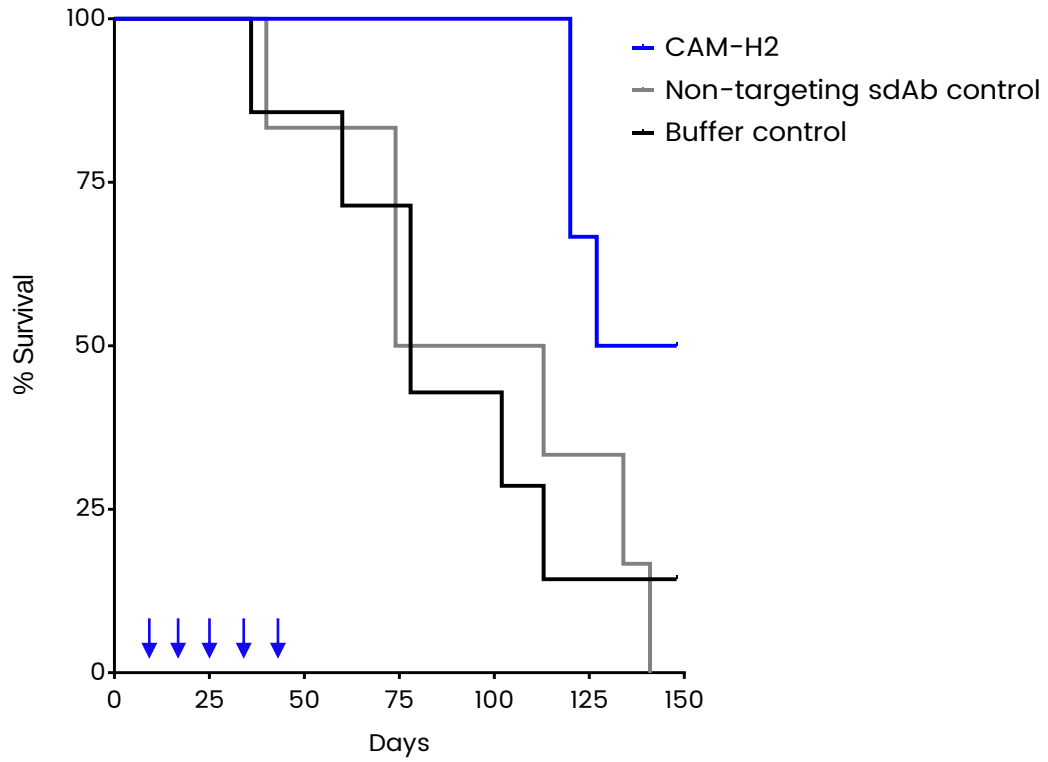
Intra-tumoral HER2 heterogeneity is associated with poor survival, CAM-H2 has crossfire effect that can target heterogeneous HER2-positive tumors

Tissue penetration is an issue for approved mAbs, CAM-H2 penetrates cancer tissues within minutes, including brain lesions

Strong preclinical data

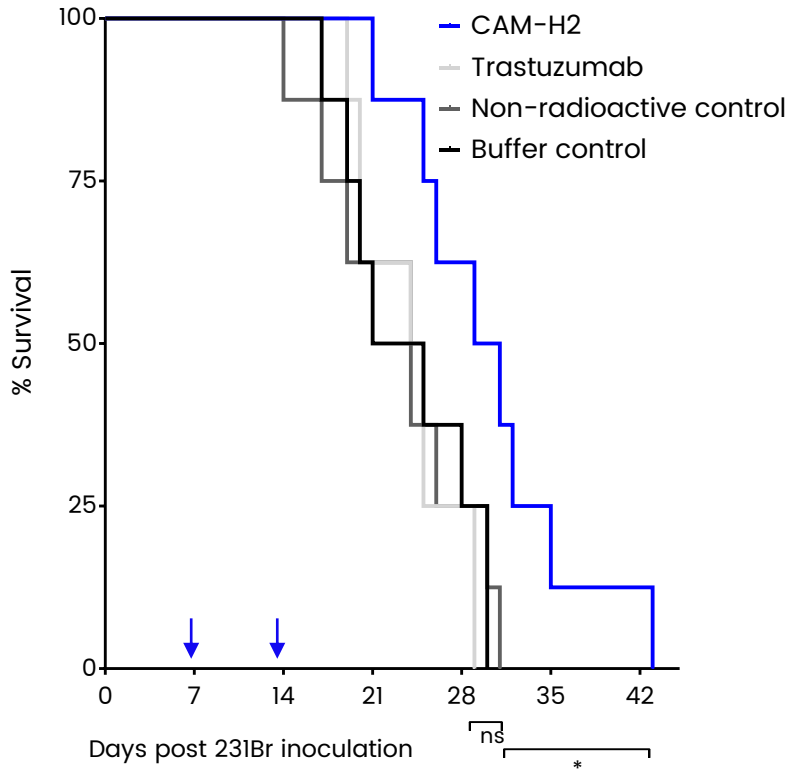
CAM-H2-I131 improves survival in breast cancer and brain metastasis models

BT474/M1 xenografts



D'Huyvetter M et al., 2017, *Clin Cancer Res*

Intracranial 231Br tumors



Puttemans et al., 2020, *Cancers*

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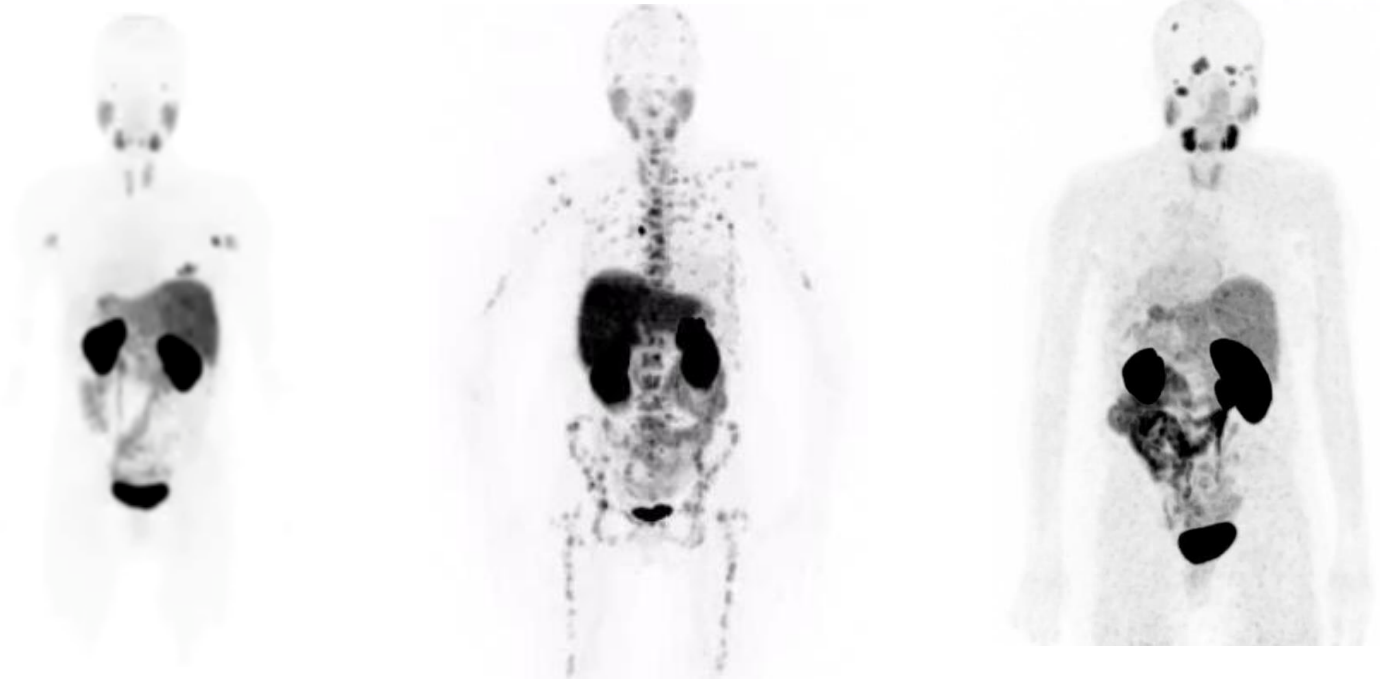
PET imaging analogue supports development

Gallium-68 labeled CAM-H2 in HER2-positive breast cancer

Primary | **Metastatic** | **Brain**



Keyaerts et al. (VUB Brussels)

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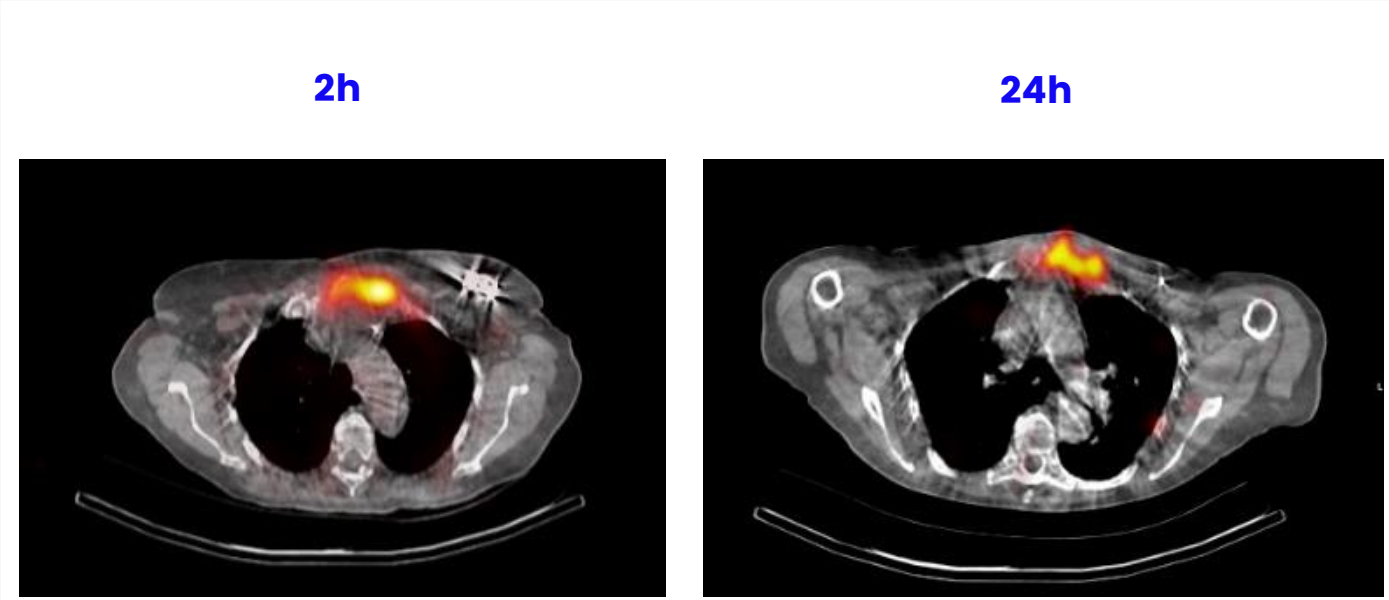
Successful Phase I study

CAM-H2-I131
6 healthy subjects, 3 patients
biomarker dose

No drug-related adverse events
Short biological half-life (7.7 hours)
Kidney is the dose-limiting organ
No accumulation in other organs
Confirmed cancer targeting



NCT02683083

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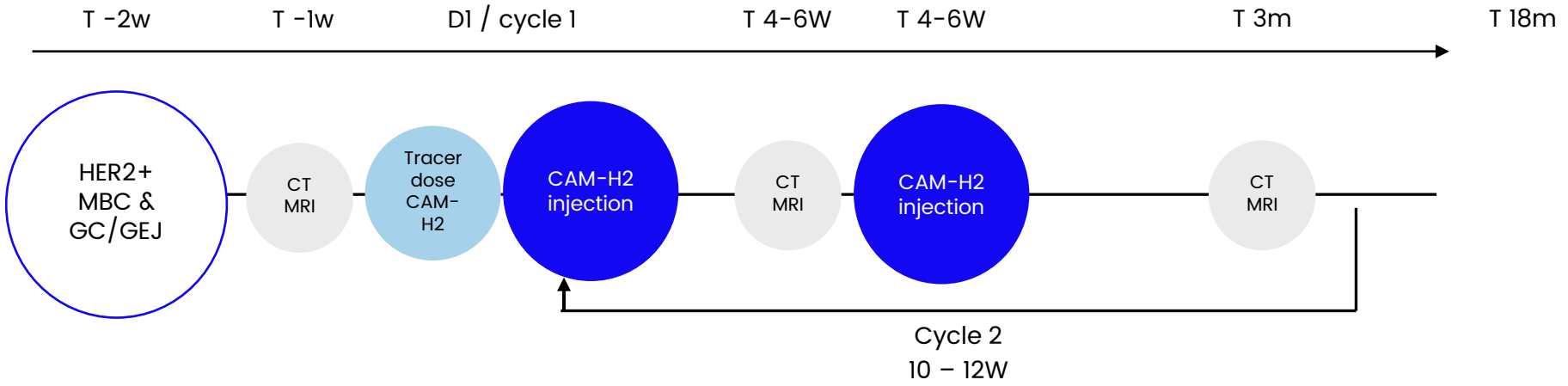
Phase I/II study ongoing



Multi-center, international trial (North America + Europe)

Dose Escalation Phase – Open label 3+3 design

3 cohorts = 1st cycle: 2 IV injections of 50/100/150 mCi each, 4-6 wks apart

2nd cycle: 10-12 wks apart

Dose Expansion Phase
Patient inclusion depending on positive CAM-H2 scan at tracer dose
Expansion cohort at optimal dose over 50 patients

Brain mets patients eligible throughout the study, enriched in Dose Expansion

Primary endpoints
Safety, tolerability and dosimetry
Objective response rate
Clinical benefit rate

Key secondary endpoints
Progression-free survival
Duration of response

NCT04467515

PRECIRIX®

It’s **Precirix**

Unique combination of complementary talents

Ruth Devenyns
CEO

25+ yrs healthcare investment banking and VC

Ogeda CFO until acquisition by Astellas, 2017

Master in Applied Economics

KBC ogeda korys

Tony Lahoutte
CSO

15+ yrs in Nuclear Med Research

Scientific Founder Precirix

MD, PhD in Nuclear Medicine

VUB VRIJE UNIVERSITEIT BRUSSEL · Universitair Ziekenhuis Brussel

Ruggero Della Bitta
CMO

25+ yrs oncology drug development

Prior VP Product Development Oncology, Roche/Genentech

MD, Internal Med & Hematology

Roche Genentech · MERCK SERONO · IQVIA

Matthias Friebe
CTO

20+ yrs radiotherapy, SPECT- and PET-probe development

Prior VP Drug Discovery Radiochemistry Bayer

Co-founder Piramal Imaging

PhD in Chemistry

Piramal · Bayer HealthCare · SCHERING

PRECIRIX®

Strong in-house skills

- sdAb discovery
- Radiochemistry
- Preclinical testing
- CMC
- Clinical development
- Corporate

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IP Portfolio

HER2 - Therapy

WO 2016/016021

Protection of a sdAb targeting HER2 linked to radionuclide, and its use for treatment of cancer expressing HER2

Patent granted in US (US 9,855,348), Japan, S. Korea, Canada, Australia, Mexico, China

Patent pending in Europe, Hong Kong, Brazil.

HER2 – Theranostic

WO 2017/013026

Protection of a method wherein a sdAb targeting HER2 linked to a radionuclide is used as a theranostic (diagnostic, then therapy), for the treatment of cancer expressing HER2

Patent pending in US, Europe, China, Brazil, Mexico, S. Korea, Japan, Canada, Australia, Hong Kong.

Pre-clinical targets

CMC

First filings in 2020

Work in progress

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Clinical-stage oncology company developing precision radiopharmaceuticals

Rich preclinical pipeline and discovery platform

IND approved to start Phase I/II with lead compound