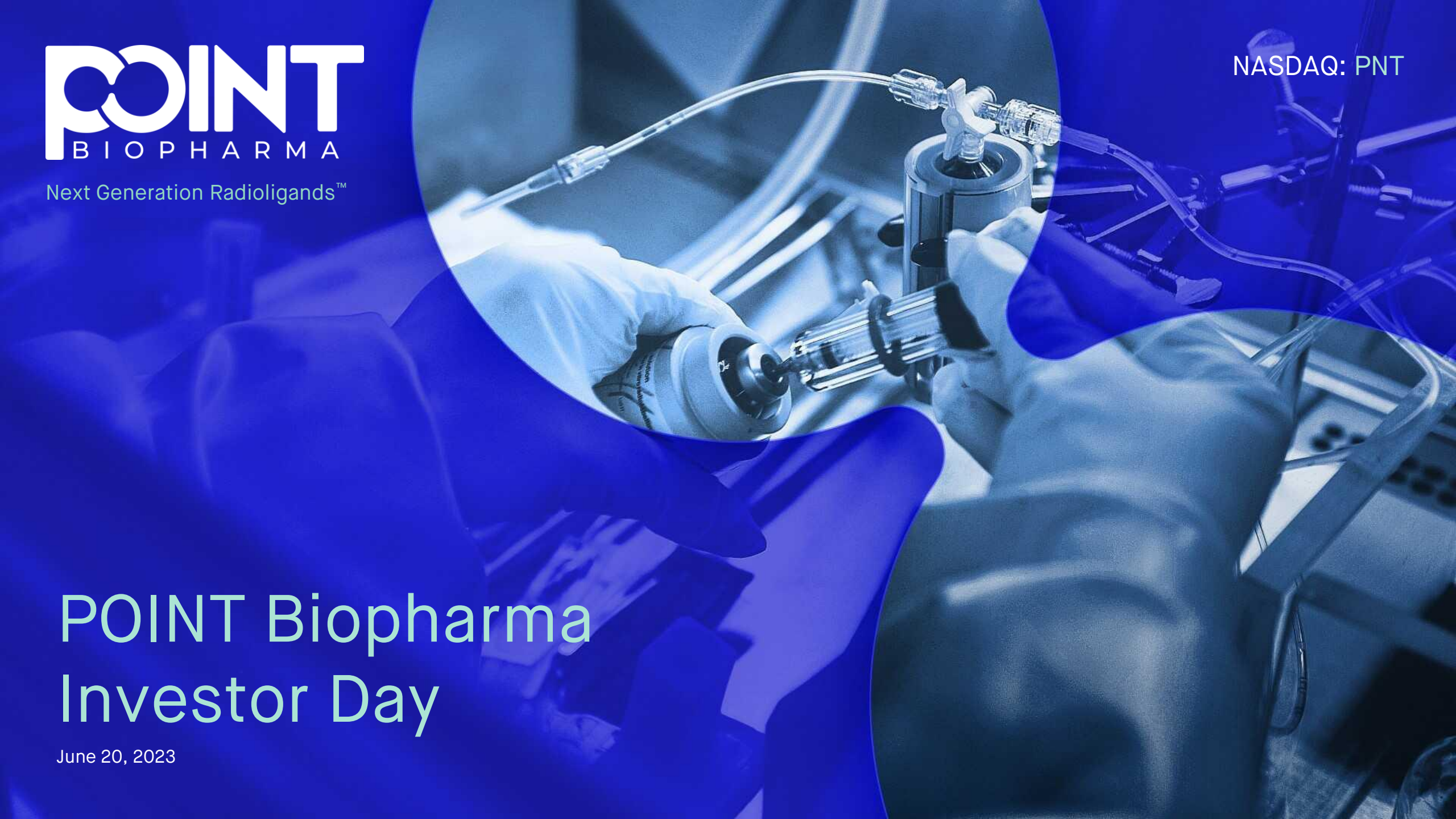
POINT BIOPHARMA

Next Generation Radioligands™

NASDAQ: PNT



POINT Biopharma Investor Day

June 20, 2023

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Housekeeping

- There will be an Analyst Q&A session with Management at the end of today's program
- A replay and today's slides will be available on the Investors page of POINT's website

Welcome to POINT Biopharma's Investor Day (June 2023)

Speakers from POINT Biopharma:

JOE McCANN, Ph.D.
Chief Executive Officer & Co-Founder

NEIL FLESHNER, M.D.
Chief Medical Officer & Co-Founder

JUSTYNA KELLY, M.Sc.
Chief Operating Officer

JESSICA JENSEN, MPH
Executive Vice President, Clinical Development

ROBIN HALLETT, Ph.D.
Senior Vice President, Discovery and Translational Sciences

Agenda

Introduction

Why RLT Now? Why POINT?
Joe McCann, Ph.D.

Part #1
From Neutron To Patient

Isotope Supply Chain
Justyna Kelly, M.Sc.

RLT Manufacturing
Justyna Kelly, M.Sc.

Part #2
Next-Generation Radioligands

Clinically Validated RLT Targets: PSMA
Jessica Jensen, MPH
Robin Hallett, Ph.D.

Developing Novel RLT Targets: FAP
Jessica Jensen, MPH
Robin Hallett, Ph.D.

Part #3
Embracing Radioligands

RLT Treatment Site Access
Neil Fleshner, M.D.

Concluding Remarks
Joe McCann, Ph.D.

Q&A
All

RLT, radioligand therapy; PSMA, prostate specific membrane antigen; FAP, fibroblast activation protein

The Platform For Next-Generation Radioligands

JOE McCANN, Ph.D.
Chief Executive Officer & Co-Founder

POINT Biopharma is advancing radioligands to become a new pillar of cancer treatment

OUR MISSION: Accelerating the discovery, development, and global access to life-changing radiopharmaceuticals

OUR VISION: Transforming lives touched by cancer

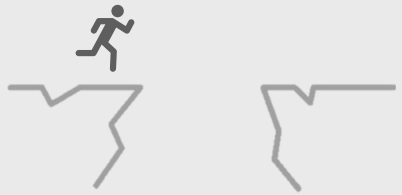
Radiotherapy is proven to treat cancer but lacks precision

Radiopharmaceutical ^{131}I was first approved by FDA in 1951; innovation has been slow since

Only 4 therapeutic radioligands actively marketed in the U.S. today

RLT is a unique drug class that requires unique solutions

Scarce input materials and just-in-time supply chain create barriers to entry



RLT has shown promise in clinical trials, but commercial uptake has historically faltered

POINT is built to accelerate RLT into its rightful position

On the back of decades of combined operational execution in radioligand therapy

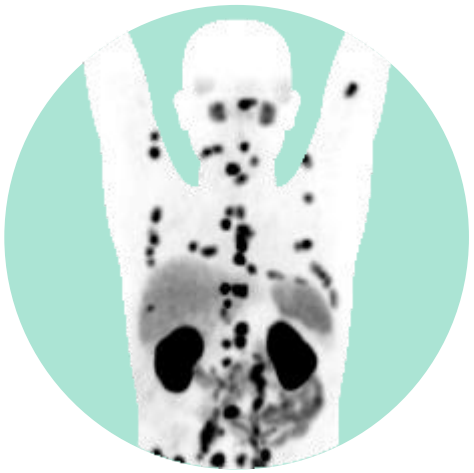
POINT was founded to solve all the complexities of the supply chain, From Neutron To Patient™

RLT, radioligand therapy

Targeted radioligand therapy is an ideal platform for precision oncology

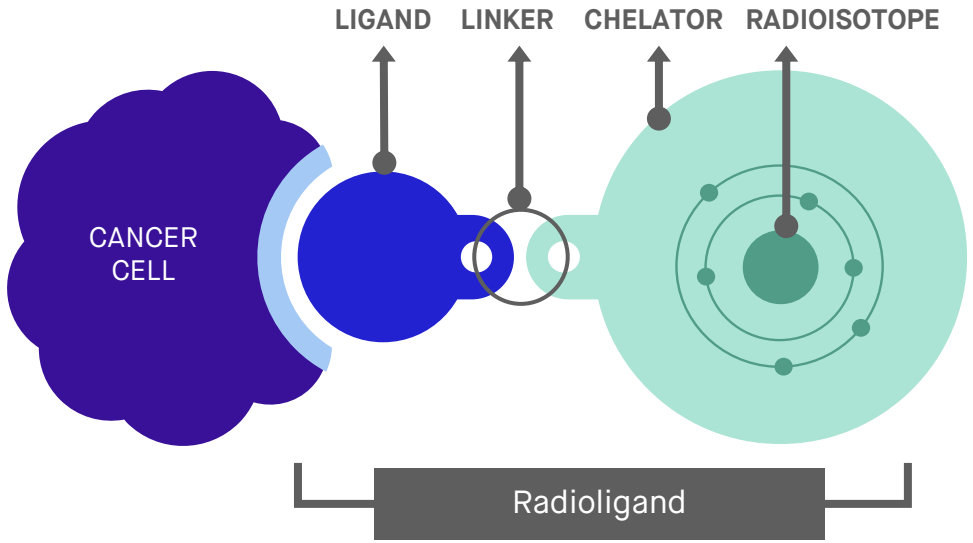
Radioligands enable the precise targeting of cancer by combining a radioisotope, a linker, and a targeting moiety that seeks cancer cells

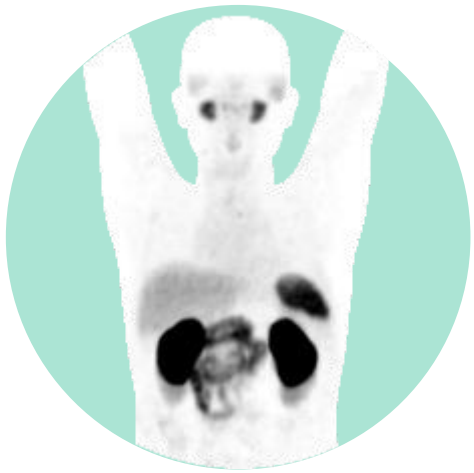
PSMA is overexpressed on prostate cancer cells + A PSMA-specific ligand seeks out cancer cells + The radioisotope emits ionizing radiation = Ionizing radiation kills the tumor cell, while minimizing damage to healthy tissue



PSMA-PET Scan Before Treatment[1]

PSMA = Prostate Specific Membrane Antigen





PSMA-PET Scan After 3 ^{177}Lu-PSMA Treatments[1]

1. Baum et al. J Nucl Med 2016

The radiopharmaceutical industry is overcoming its historical bottlenecks

	Past Issues	Evolving Innovation
Isotope Supply Chain	Government-funded entities are the main source of novel isotope supply chains, creating bottlenecks	New, isotope-specific, private sector commercial suppliers have built businesses to capitalize on the market opportunity
Manufacturing & Production	Drug developers didn't plan for success, supply chains weren't mature, scale and geography mattered	Radiopharmaceutical companies are focusing specifically on manufacturing excellence along with logistics and redundancy
RLT Treatment Site Access	Strong gamma from previous generation isotopes required lead-lined rooms in the basements of hospitals	Next-generation isotopes can be administered in outpatient settings, and next-generation PET scanners have been developed to improve throughput
Drug Development	Limited commercial uptake lowered incentive for heavy investment in R&D	Currently approved RLT for prostate cancer trending towards blockbuster status, >$1.5B invested into RLT companies since Jan 2022

POINT Biopharma has built the platform for **next-generation radioligands™**

As one of the few companies that have demonstrated competency in the discovery, clinical development, and supply of radioligands, POINT is well positioned to be a leader in this exciting emerging modality.

Robust isotope supply chain

Fortified supply chain, safeguarded from disruptions

Radiochemistry & preclinical expertise

Experience engineering optimized combinations of ligands, linkers, and isotopes

Next-generation clinical programs

Currently in the clinic in indications of high unmet need

Commercial scale manufacturing

Internal manufacturing capabilities, ensuring patients needs are consistently met

Our next-generation early-stage pipeline is focused on patient indications of high unmet need

Program	Target	Clinical Candidate	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Commercial Rights
PNT2002	PSMA	^{177}Lu-PNT2002	Metastatic Castration-Resistant Prostate Cancer, Pre-Chemo[1]					LANTHEUS*
PNT2003	SSTR	^{177}Lu-DOTA-TATE	Neuroendocrine Tumors (NETs)[2]					LANTHEUS*
PNT2004	FAP-α	^{177}Lu-PNT6555	Solid Tumors Expressing FAP[3]					POINT BIOPHARMA
PNT2004	FAP-α	^{225}Ac-PNT6555	Solid Tumors Expressing FAP					POINT BIOPHARMA
PNT2001	PSMA	^{225}Ac-PSMA-62	Prostate Cancer					POINT BIOPHARMA

Discovery Programs	
Ligands	Multiple programs are underway assessing the CanSEEK™ platform with novel ligands, as well as other novel small and large molecule candidates
Radioisotopes	Assessment of alpha, beta, and auger emitters to match the right isotope with the specific disease state and target characteristics
Combinations	Combination testing of RLT with existing and novel IO, DDRi, and chemotherapy products for identification of compelling opportunities for clinical testing

** partnered with Lantheus Holdings Inc. for exclusive worldwide rights excluding certain territories of : Japan, South Korea, China (including Hong Kong, Macau and Taiwan), Singapore, and Indonesia*

1. *SPLASH (NCT04647526),* ***2.*** *Trial sponsored by the University Health Network (NCT02743741),* ***3.*** *FRONTIER (NCT05432193) indications include: colorectal, pancreatic, esophageal, melanoma, and soft tissue sarcoma*

POINT is one of only a handful of radioligand therapy companies with demonstrated success in executing a global phase 3 radioligand therapy clinical trial

With only four radioligand therapies approved by the FDA, very few companies have our clinical development expertise

70+
Ethics Committees

180
Health Authority Submissions & Interactions

200+
Site Assessments

62
Site Contracts

41
Vendors

15
Regulatory Filings
2 INDs / **6** CTAs / **3** IBs / **4** IMPDs

65
Radiation Safety Guidelines
7 Country / **3** Provincial / **55** Local

6
Languages

26
Pending and issued patents covering ^{177}Lu-PNT2002 (2 issued)

47
Radiopharmacies

280+
PNT2002 Clinical Doses Supplied from Indianapolis Facility

Key strategic near-term priorities

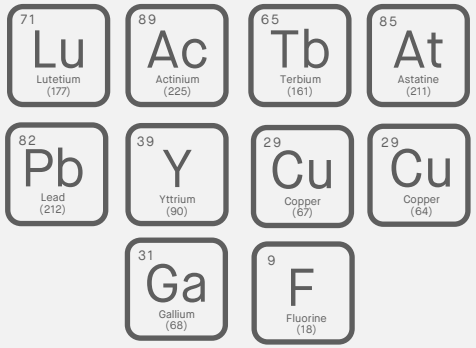
Strategic investment in current and additional programs, new isotopes, and opportunistic partnerships

Programs

Discovery	Preclinical	Phase 1	Phase 2	Phase 3

Expand clinical trials to include novel approaches and continue to increase investment in discovery

Isotopes



Expand isotope "tool chest" to include new, high potential isotopes

Partnerships

Engage in new partnerships and in-licensing opportunities synergistic with POINT's platform

From Neutron To Patient: Supply Chain & Manufacturing

JUSTYNA KELLY, M.Sc.
Chief Operating Officer

Radiopharmaceuticals' history has been troubled with supply chain and manufacturing disruptions

Medscape Friday, May 19, 2023

NEWS & PERSPECTIVE | DRUGS & DISEASES | CME & EDUCATION | ACADEMY | VIDEO

News > Medscape Medical News

Prostate Cancer Drug Shortage Leaves Some With Uncertainty

Patricia McKnight
March 21, 2023

A radioligand treatment approved for certain men with metastatic castration-resistant prostate cancer (CRPC) is in short supply because of manufacturing and delivery issues, according to the US Food and Drug Administration (FDA).

Targeted Oncology

NEWS | CONFERENCES | MEDIA | PUBLICATIONS | CME/CE | RESOURCES

Production of 2 FDA-Approved Radioligand Agents for Prostate Cancer Temporarily Halts

May 9, 2022
Jordyn Sava

Production of lutetium Lu 177 vipivotide tetraxetan and Luthathera have been temporarily suspended due to potential qua issues identified in their manufacturing processes.

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Isotope Supply Chain at Risk from War in Ukraine

Publication date: July 15, 2022

Number: 51

Russia's invasion of Ukraine has brought new urgency to the Department of Energy's efforts to expand U.S. production capacity for critical isotopes, some of which are solely sourced from Russia or rely on precursor materials from the country.

NUCNET

THE INDEPENDENT NUCLEAR NEWS AGENCY

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RADIATION APPLICATIONS

Radioisotopes / Cancer Institute And NRG Highlight Concerns Over Long-Term Lu-177 Supplies

By David Dalton
7 June 2021

Report points to 'lack of central planning' and need for more facilities

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Isotope Shortage Makes Vital Medical Scans Costlier, Riskier

A worldwide shortage of radioactive isotopes that enable life-saving medical scans may have already begun to raise health-care costs and complicate patient care.

Aug. 27, 2010, 12:17 PM EDT / Source: LiveScience

By Jeremy Hsu

A worldwide shortage of radioactive isotopes that
medical scans may have already begun to raise he
complicate patient care.

The medical isotopes represent tiny amounts of s
radioactive substances that get injected into patie
congregate within bone or other tissues, and show up as hot areas in
medical scans. That method enables 20 million medical scans and
other treatments, such as targeting cancer cells for destruction, each
year.

HealthManagement.org
Promoting Management and Leadership

Volume 12, Issue 5/2010 - Crisis Management

Coping with the Unexpected

When Eyjafjallajökull, the Icelandic volcano erupted on March 21st of this year it was surprisingly Europe that was disturbed the most and not Iceland. The spewing cloud of ash caused fewer problems for Iceland in comparison to the havoc it reeked on European air travel. At first thought any effects of volcanic ash on the healthcare sector would be health risks but there was in fact a more pressing problem: nuclear medicine.

The week of the 19th of April saw the use of nuclear medicine screech to a halt in Ireland affecting management and staff and more importantly patients and their families. I spoke to Fionnuala Barker from St. Luke's hospital in Dublin to find out how her department coped with this crisis and what they have learnt from the experience.

So why did nuclear medicine shut down with the airports? Ms. Barker explained that most of the radioactive technetium used for bone scans and day-to-day nuclear medicine is shipped into Ireland from the continent via either France or Holland. Deliveries normally take place over the weekend, having the material ready for patients on Monday. The technetium is usually dispatched from the manufacturers on a Friday evening, arrives in Ireland on the Saturday morning and dispatched to the hospitals over the weekend. As the airports closed on the 17th of April no deliveries could be made.

smaller workload than a larger department. They were able to successfully accommodate patients whose appointments were cancelled within two to three weeks. This would have been a problem for larger departments.

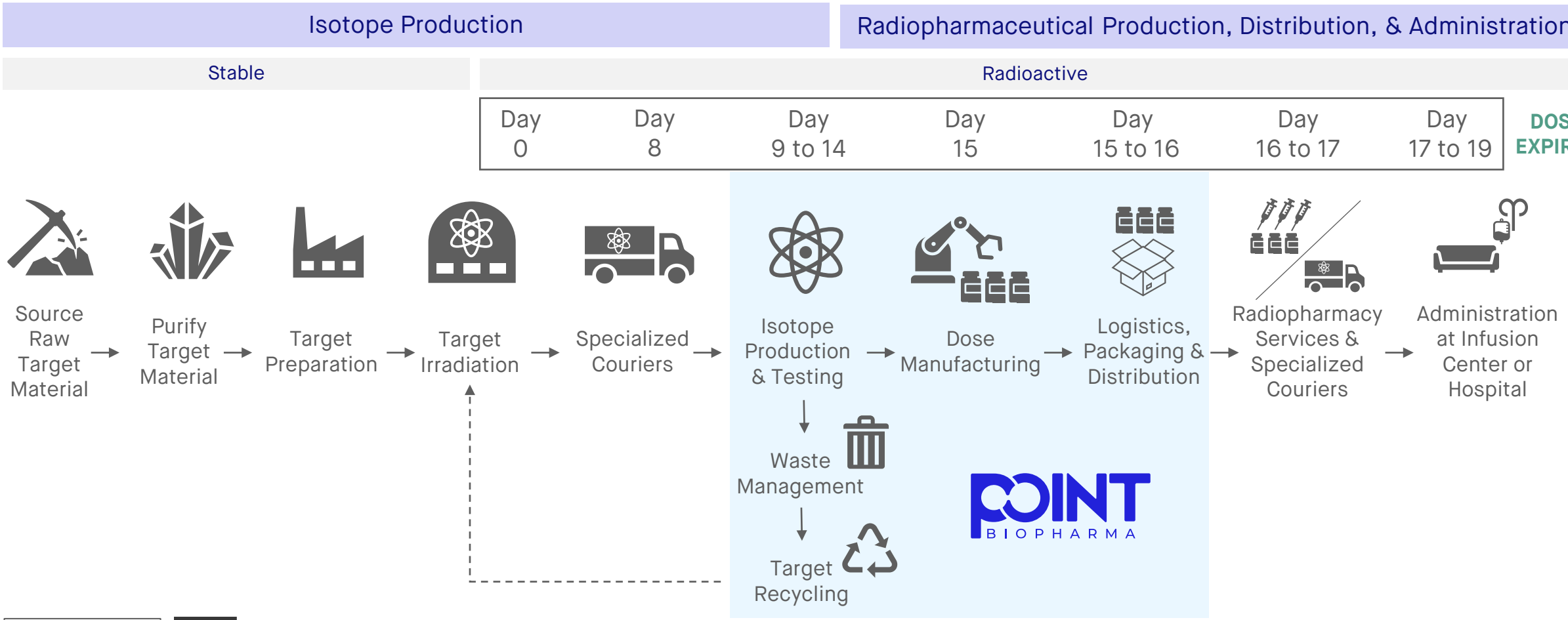
So why did nuclear medicine shut down with the airports? Ms. Barker explained that most of the radioactive technetium used for bone scans and day-to-day nuclear medicine is shipped into Ireland from the continent via either France or Holland. Deliveries normally take place over the weekend, having the material ready for patients on Monday. The technetium is usually dispatched from the manufacturers on a Friday evening, arrives in Ireland on the Saturday morning and dispatched to the hospitals over the weekend. As the airports closed on the 17th of April no deliveries could be made.

NEWS | NUCLEAR IMAGING | FEBRUARY 02, 2022

Update on Unplanned Outage of the HFR Reactor

Mo-99 supply issues continue following HFR shutdown

POINT has established redundancies in a complex, just-in-time supply chain to enable the reliable scale-up and manufacturing of no-carrier-added ^{177}Lu RLT



Announced Partnerships

KINECTRICS

sck cen MURR

sck cen itm isotopia

LANTHEUS

Example shown for n.c.a. ^{177}Lu

Next Generation Radioligands™

Isotope supply is determined by the availability of both target materials and irradiation method

Isotope	71 Lu Lutetium (177)		89 Ac Actinium (225)		82 Pb Lead (212)		29 Cu Copper (67)
Source Raw Target Material	**Ytterbium (Yb)** is natually present in the mineral monazite. Global production is ~50 tonnes per year globally[2].	**Lutetium (Lu)** is naturally present in the mineral monazite.	**Uranium (U)** occurs naturally in several minerals, rocks, and sand. Global production of uranium is about ~41,000 tonnes per year	**Uranium-233** was produced in large quantities in historic nuclear weapons programs through neutron irradiation	**Uranium-232** was produced in large quantities in historic nuclear weapons programs through neutron irradiation, a side product of the thorium fuel cycle		**Zinc (Zn)** is an abundant metal found in several ores, the principal ones being zinc blende and calamine
Target Material (natural abundance)[1]	^{176}**Yb** (13%) is a shelf-stable naturally occurring isotope of Yb	^{176}**Lu** (2.6%) is a naturally occurring isotope of lutetium	^{226}**Ra** (% nm) is a decay product of the natural uranium-238 decay chain	^{229}**Th** (% nm) is isolated from the ^{233}U stockpile leftover from nuclear programs	^{224}**Ra** (% nm) is a short-lived isotope in the decay chain of ^{232}Th and ^{232}U	^{228}**Th** (% nm) is a long-lived isotope in the decay chain of ^{232}Th and ^{232}U and produced from irradiation of ^{226}Ra	^{68}**Zn** (18.5%) is a stable (non-radioactive) naturally occurring isotope of Zinc
Target Preparation	^{176}**Yb** extracted using an electromagnetic separation process	^{176}**Lu** is isolated through radiochemical separation	^{226}**Ra** is isolated through ion exchange	A ^{229}**Th** generator allows chemical separation of ^{225}Ra and ^{225}Ac	^{224}**Ra** is isolated through radiochemical separation	^{228}**Th** is isolated through radiochemical separation	^{68}**Zn** enriched targets are essential to high yields and minimizing impurities
Target Irradiation	Neutron irradiation (reactor)	Neutron irradiation (reactor)	Accelerator	Generator (^{229}Th/^{225}Ac)	Generator (^{224}Ra/^{212}Pb)	Generator (^{228}Th/^{212}Pb)	Accelerator

1. *Royal Society of Chemistry, "Periodic Table"* ***2.*** *Minor Metals Trade Association; nm, not meaningful.*

POINT's Manufacturing and R&D Platform: CORE & PIRI

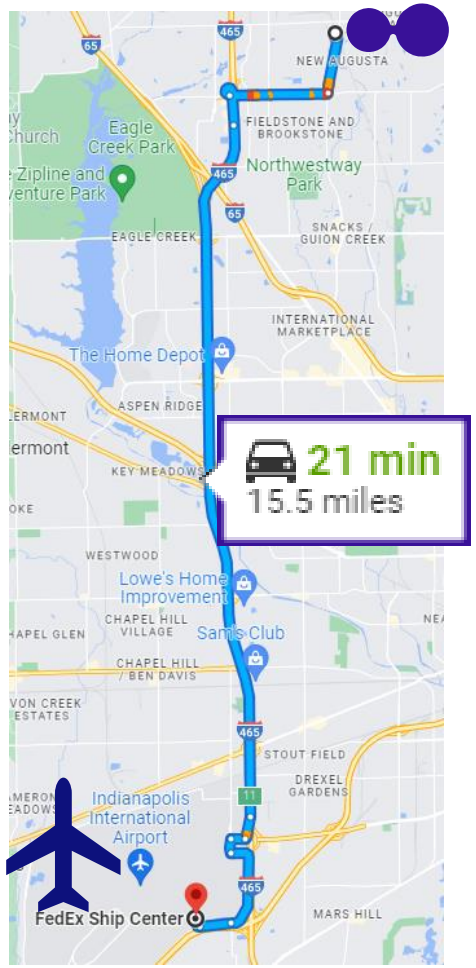
JUSTYNA KELLY, M.Sc.
Chief Operating Officer

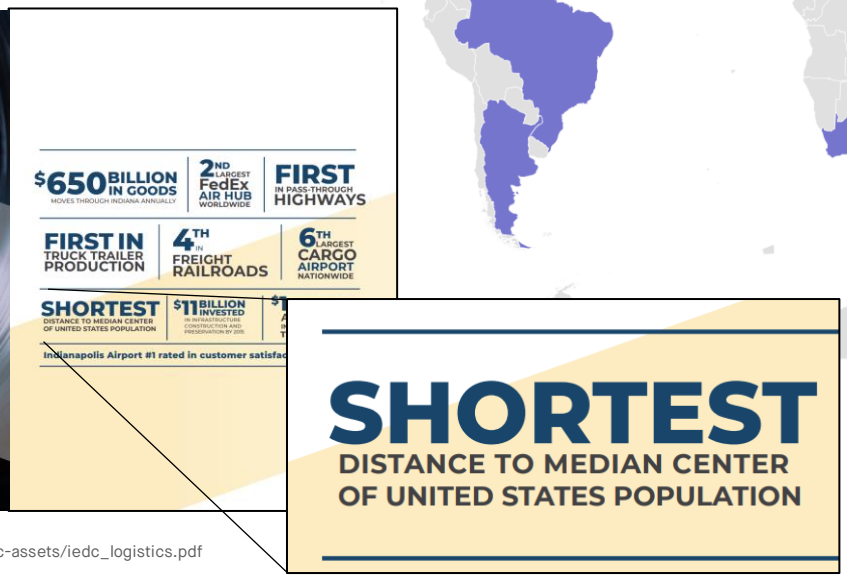
POINT has built the physical infrastructure to develop and scale the next generation of RLT

CORE is POINT's 180,000 ft² commercial manufacturing campus is in Indianapolis, Indiana

Aerial View

The campus' location enables shipment to most of the U.S. population within 12 hours, EU and UK and other major markets within 72 hours





https://www.iedc.in.gov/docs/default-source/iedc-assets/iedc_logistics.pdf

CORE1: Our purpose-built facility is one of the largest of its kind in the world, and scaling in advance of anticipated commercial production of PNT2002 and PNT2003

Building within a building

Modular cleanroom design enables quick access to engineering controls

Modular design minimizes downtime during installations

Modular cleanroom panels enable installation of large hot cells and isolator equipment

Maintain existing GMP operations during buildout

Dedicated air handling units for each production suite allow ongoing buildout of new production lines

Lead lined walls and dedicated sample preparation areas

Promotes radiation safety and minimize radioactive "shine" during manufacturing and testing

Dedicated engineering laboratory space

Development and testing of new manufacturing processes

Waste handling

Large dedicated space for safe storage and decay of radioactive waste

CORE1: Designed for 21 CFR 210, 211, and ICH Q7, Q9, Q10 standards

CORE1: 5,000 ft^2 of lab space, including multiple QC and microbiology laboratories

CORE1: On-site no-carrier-added ^{177}Lu production line decreases likelihood of input-related production delays and lowers cost of goods sold by minimizing isotope loss during transport

CORE2: 100,000 ft^2 building across the street from CORE1, lease executed in March 2023 to provide additional space for future expansion

POINT Institute for Radioligand Innovation (PIRI): POINT's fully operational R&D center, bringing novel programs from discovery to the clinic

POINT™ BIOPHARMA INSTITUTE FOR RADIOLIGAND INNOVATION

State of the art 7,700 ft^2 GMP facility with PETtrace™ 800 cyclotron and hot cells

Currently licensed for alpha, beta, gamma, and positron emitters

Located in Toronto, Canada, in a translational institute & research hospital network (UHN)

PETtrace is a trademark of General Electric Company.

Creating the Next Generation of RLT: Clinically Validated Targets: PSMA

JESSICA JENSEN, MPH
Executive Vice President, Clinical Development

ROBIN HALLETT, Ph.D.
Senior Vice President, Discovery & Translational Sciences

Prostate specific membrane antigen (PSMA) is a clinically validated target with a well-established benefit/risk profile

Unmet needs remain in prostate cancer; metastatic castration-resistant prostate cancer (mCRPC) remains a fatal disease state without a cure

Current PSMA-targeted ligands limit iterative approaches

Limited range of isotopes because of off-tissue absorption

Historically indicated in later stage disease

Next-generation PSMA-RLTs could be designed to:

Have greater tumor-killing effects in mCRPC, or

Potentially prevent patients from succumbing to mCRPC in the first place

Options to lower salivary and renal toxicity

Engineer novel ligands to have greater tumor retention, potentially delivering a lower dose of radioisotope while maintaining efficacy

^{177}Lu-PSMA stops having activity in tumors that express PSMA, where as ^{225}Ac-PSMA has demonstrated clinical activity in these patients

Unmet needs in prostate cancer: patients with biochemical recurrence of prostate cancer after initial surgery or radiation therapy seek to delay or avoid the toxicities of chemical castration

~1/3

Experience biochemical recurrence (BCR) after initial definitive therapy[1,2]

Chemical Castration

Chemical castration via androgen deprivation therapy (ADT), +/- androgen receptor pathway inhibitors (ARPIs), is the standard of care for BCR[3]

Lifelong

ADT for BCR is typically lifelong[3]

↓QoL

ADT for BCR has substantial negative impacts on quality of life (QoL)[4,5]

↓Health

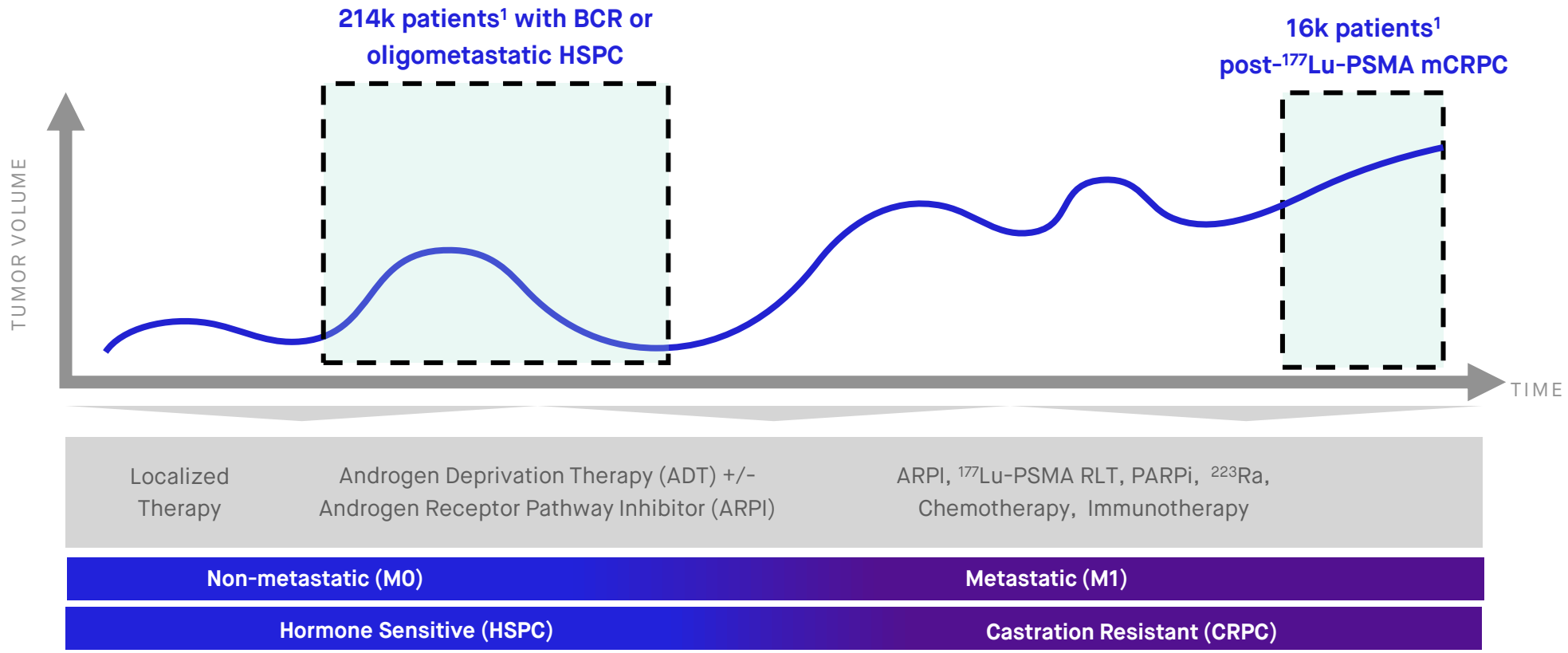
ADT for BCR has serious implications for long-term health[6-13]

Resistance

ADT for BCR ultimately leads to castration resistance

1. Freedland SJ, Branche BL, Howard LE, et al. BJU Int. 2019;124(1):69-75. *2.* Simon NI, Parker C, Hope TA, Paller CJ. Am Soc Clin Oncol Educ Book. 2022;42:1-8. *3.* Schaeffer E, Srinivas S, Antonarakis ES, et al. NCCN Guidelines Insights: Prostate Cancer, Version 1.2021. J Natl Compr Canc Netw. 2021 Feb 2;19(2):134-143. *4.* Cheung AS, de Rooy C, Hoermann R, Lim Joon D, Zajac JD, Grossmann M. Clin Endocrinol (Oxf). 2017;86(3):388-394. *5.* Gay HA, Sanda MG, Liu J, et al. Int J Radiat Oncol Biol Phys. 2017;98(2):304-317. *6.* D'Amico AV, Denham JW, Crook J, et al. J Clin Oncol 2007;25:2420-2425. *7.* Cherrier MM, Rose AL, Higano C. J Urol 2003;170:1808-1811. *8.* Green HJ, Pakenham KI, Headley BC, et al. BJU Int 2002;90:427-432. *9.* Harle LK, Maggio M, Shahani S, Braga-Basaria M, Basaria S. Clin Adv Hematol Oncol 2006;4:687-696. *10.* Higano C, Shields A, Wood N, Brown J, Tangen C. Bone mineral density in patients with prostate cancer without bone metastases treated with intermittent androgen suppression. Urology 2004;64:1182-1186. *11.* Keating NL, O'Malley AJ, Smith MR. J Clin Oncol 2006;24:4448-4456. *12.* Spry NA, Galvao DA, Davies R, et al. BJU Int 2009;104:806-812. *13.* Tsai HK, D'Amico AV, Sadetsky N, Chen MH, Carroll PR. J Natl Cancer Inst. 2007;99(20):1516-1524.

There is significant market potential for a next-generation RLT indicated for treatment of patients with prostate cancer (before or after currently approved RLTs)



1. Management Estimates

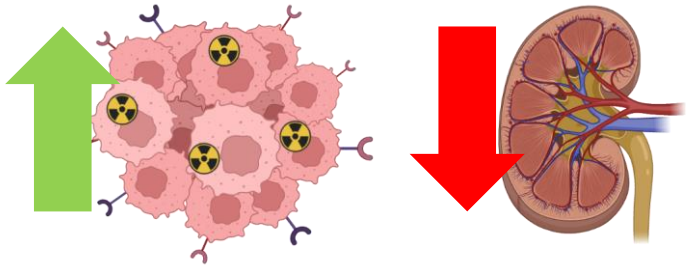
PNT2001 is designed to improve on the profile of first generation PSMA-targeted radioligands

History

Technical University of Munich

- Technology invented by Professor Hans-Jurgen Wester, developer of PSMA-I&T, with the aim of increasing cellular internalization versus first generation compounds (PSMA-617 and PSMA-I&T)
- POINT licensed the family of compounds in late 2019

Screening & Selection



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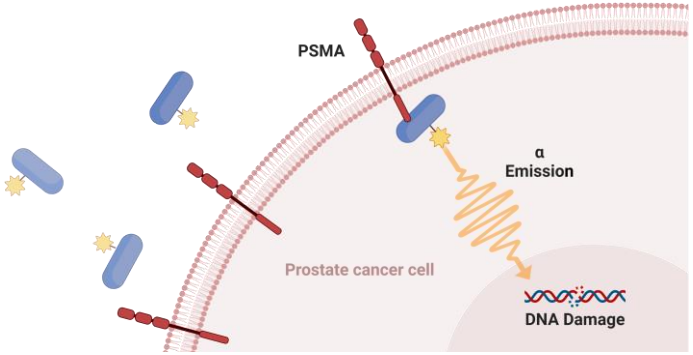
- The lead candidate PSMA-62 demonstrated ~3X increased internalization and tumor uptake and ~50% reduced kidney uptake relative to PSMA-I&T

PSMA-62 Prioritized



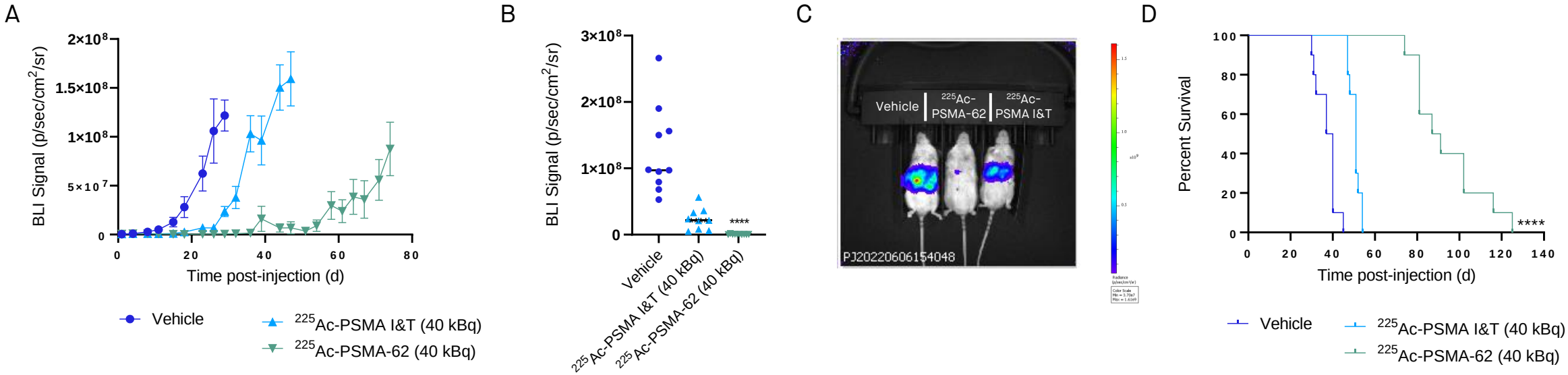
Created using BioRender.com

- The improved cellular internalization of PSMA-62 makes it well suited for the delivery of the short-range, high linear energy transfer, alpha-emitter actinium-225
- Complete non-clinical package planned with expected first patient in Q1 2024

^{225}Ac-PSMA-62 shows robust efficacy as a single dose in a PSMA^{+} metastatic prostate tumor model (C4.2) versus ^{225}Ac-labelled PSMA I&T

Single dose ^{225}Ac-PSMA-62 treated mice showed significant improvement in tumor burden and survival compared to both control and ^{225}Ac-PSMA-I&T.

Intracardiac injection of C4.2 leads to metastatic disease (liver, brain, bone marrow mets) and metastatic burden is monitored using bioluminescence.



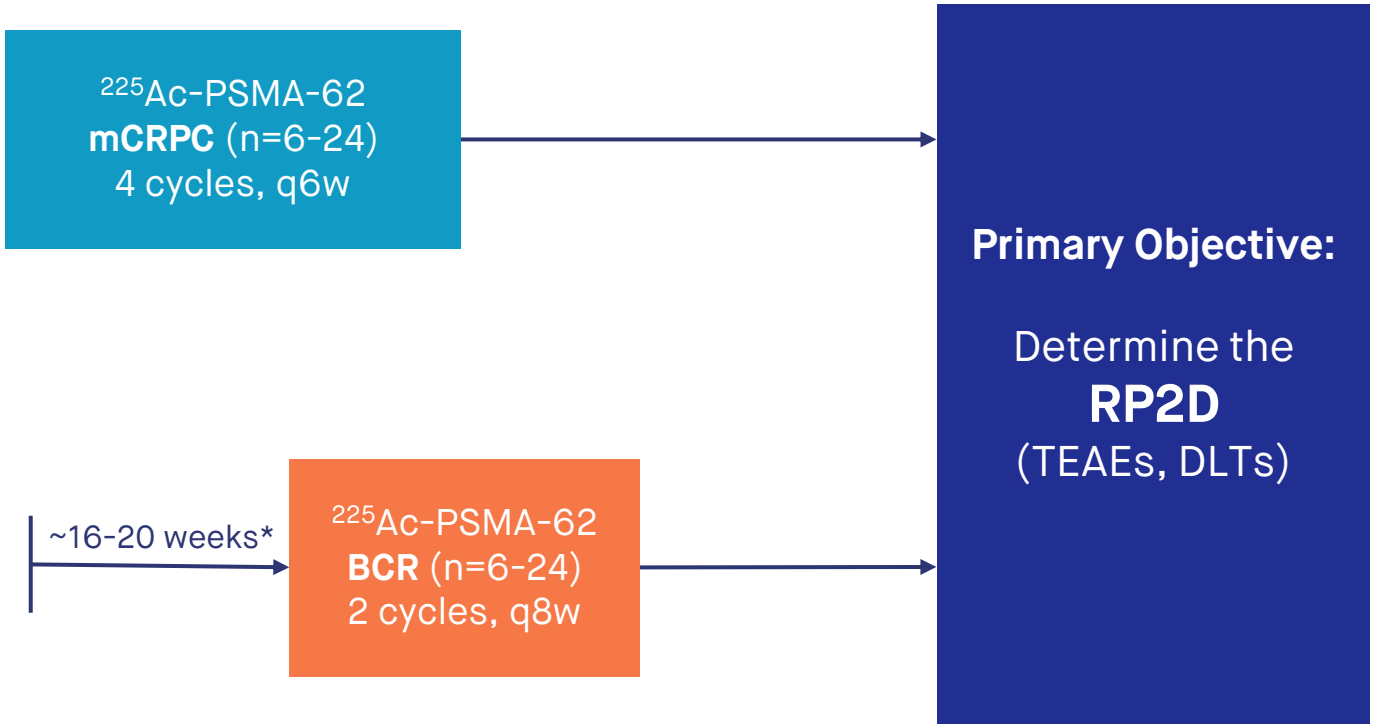
*A single dose of ^{225}Ac-PSMA-62 or ^{225}Ac-PSMA I&T slows tumor growth and improves survival outcomes. NSG mice bearing metastatic C4.2 tumors were treated with vehicle, ^{225}Ac-PSMA-62 (40 kBq), or ^{225}Ac-PSMA I&T (40 kBq). Tumor cells expressed luciferase and could therefore be imaged to assess tumor burden based on the correlative bioluminescence (BLI) signal. Average BLI signal for each group. Graphing stops when the first mouse from a group reaches endpoint. Average BLI signal for each mouse on day 29. Each symbol represents an individual mouse within the group. Representative BLI images on day 29 for each group. Kaplan-Meier survival curves of each group. ****p<0.0001*

Vito A. et al. EP-039. Presented at EANM Congress Oct 2022, Barcelona, Spain.

ACCEL first-in-human study will separately investigate ^{225}Ac-PSMA-62 in both mCRPC and BCR prostate cancer

mCRPC & BCR Bayesian Optimal Interval (BOIN) Dose Escalation

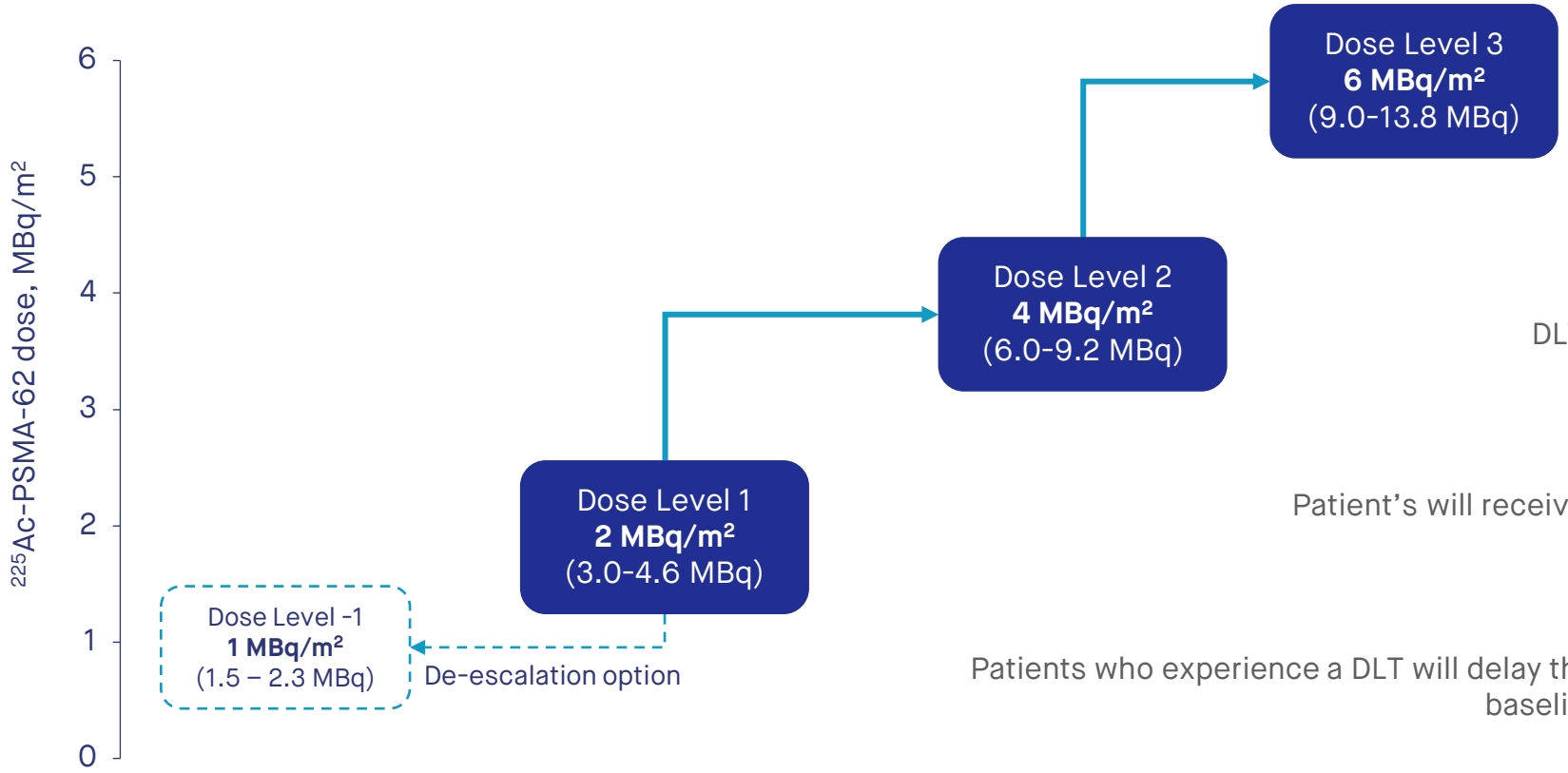
- **mCRPC:** Patients refractory to prior therapy who have exhausted all satisfactory or available approved treatment options. PSMA PET positive.
- **BCR with molecularly defined metastasis:** Patients with biochemical recurrence (BCR) of prostate cancer after surgery or radiation therapy. PSMA PET oligometastatic: 1-5 positive lesions identified outside the prostate bed or remaining gland.



**Enrollment of BCR patients will be opened after initial safety data are generated and reviewed for the mCRPC population (~16-20 weeks). BCR, biochemical recurrence; DLT, dose-limiting toxicity; mCRPC, metastatic castration-resistant prostate cancer; PET, positron emission tomography; PSMA, prostate-specific membrane protein; RP2D, recommended phase 2 dose; TEAE, treatment-emergent adverse event.*

ACCEL dose escalation strategy: reducing suboptimal dosing in prostate cancer

mCRPC & BCR BOIN Dose Escalation



Cohort size will be 3-6 and utilize the BOIN statistical model to guide DEC decisions

DLTs will be assessed during a 4-week observation period post Cycle 1

Patient's will receive ^{225}Ac-PSMA-62 at the same dose level for each cycle, precluding intra-patient dose escalation

Patients who experience a DLT will delay their next cycle until toxicity resolves to Grade 1 or baseline, with subsequent doses reduced by 1 MBq/m^2

BOIN, Bayesian optimal interval; DEC, dose escalation committee; DLT, dose-limiting toxicity; MBq, megabecquerel; PSMA, prostate-specific membrane protein.

ACCEL endpoints will focus on identifying a RP2D taking both safety and PSA-based efficacy into account

Primary Endpoint	Secondary Endpoints	Exploratory Endpoints
RP2D (TEAEs, DLTs)	ORR PSA decline (0%, ≥50%, and ≥90%) bPFS (PCWG3) Changes in lab values, vitals, physical exams Absorbed dose estimates in normal organs Salivary Gland PRO	ctDNA Circulating immune cell changes Absorbed dose estimates in tumor lesions Correlation between PSMA-avidity and ORR

bPFS, biochemical progression-free survival; ctDNA, circulating tumor DNA; DLT, dose-limiting toxicity; ORR, objective response rate; PCWG3, prostate cancer working group 3; PRO, patient reported outcome; PSA, prostate-specific antigen; PSMA, prostate-specific membrane protein; RP2D, recommended phase 2 dose; TEAEs, treatment-emergent adverse events.

Creating the Next Generation of RLT: Novel Targets: Fibroblast Activation Protein In The Tumor Microenvironment

JESSICA JENSEN, MPH
Executive Vice President, Clinical Development

ROBIN HALLETT, Ph.D.
Senior Vice President, Discovery & Translational Sciences

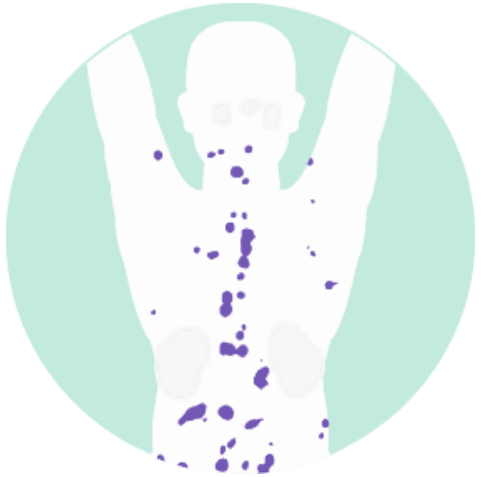
An ideal radioligand targets tumors quickly with high specificity while sparing healthy tissue, minimizing side effects

The amount of DNA damage a radioisotope causes is determined by:

- The isotope's physical properties
- Its proximity to the tissue
- The amount of time it spends in proximity to the tissue

The ideal radioligand:

- Can be used with imaging isotopes to select patients with high probability of response (theranostic principle)
- Delivers large radiation dose to tumor cells and spares normal tissue
- Allows selection of therapeutic isotope best matched to ligand and patient characteristics



An ideal radioligand therefore "sticks" to tumors, but flushes out of healthy tissue quickly, enabling the radioisotope to inflict maximum damage to the tumor but little to no damage elsewhere.

Key questions to be answered when looking at new targets

Where does the ligand go? And how long it stays there?

Does the new target expression profile drive correct biodistribution of radiation?

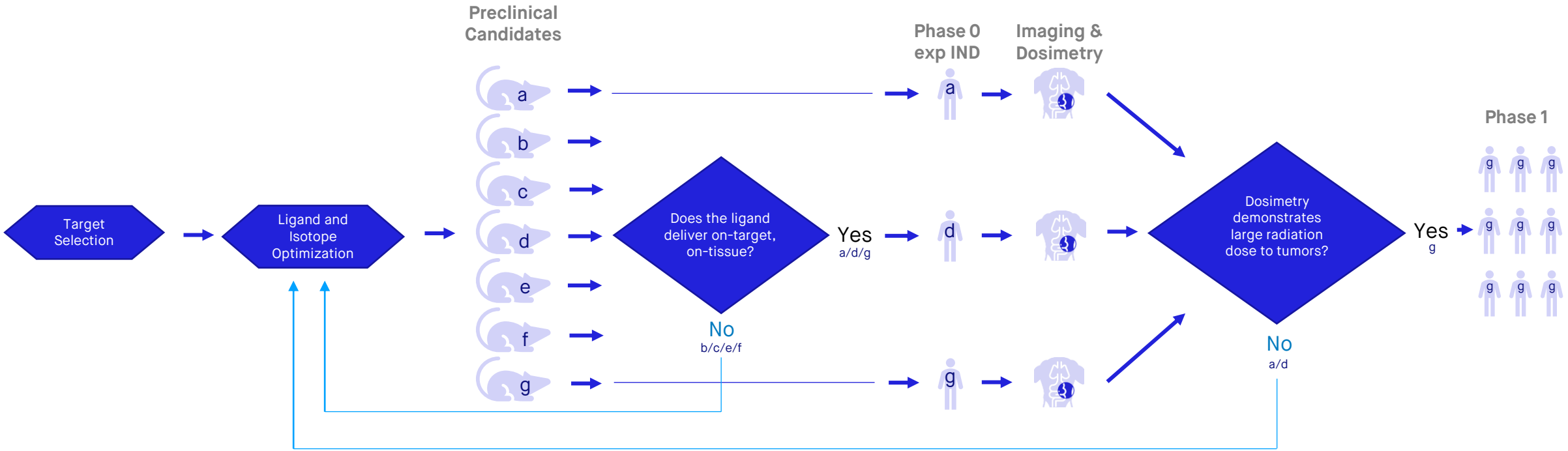
Do the ligand properties match to patient populations and isotope selection?

What combination approaches might be available?

Imaging and dosimetry can be used to accelerate new RLTs into human proof-of-concept studies, accelerating the drug development feedback loop

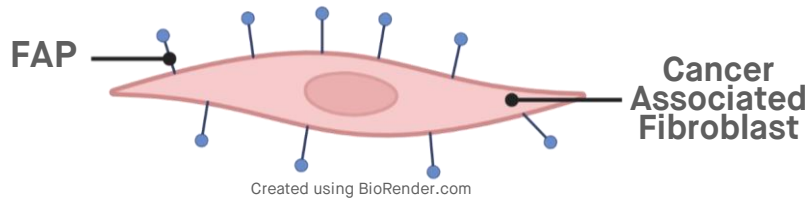
Radiation emissions can be used to produce images to estimate efficacy and safety of new radioligands: where the ligand goes, how much radiation could be delivered, and for how long.

Imaging data can therefore be used to efficiently screen multiple preclinical candidates in parallel.



exp IND, exploratory IND.

Fibroblast activation protein (FAP-α) is a compelling pan-cancer target for imaging and therapy

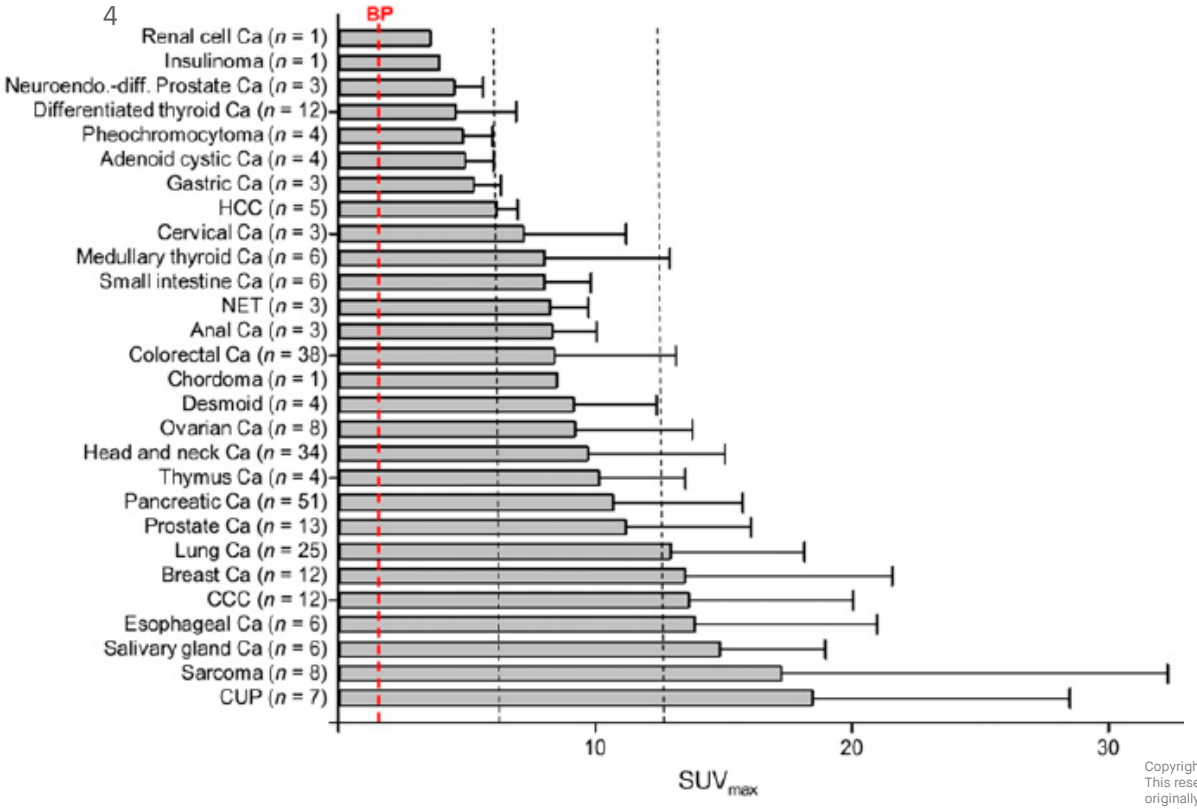


Fibroblast activation protein-α (FAP) is normally expressed during embryonic development, but is expressed at very low levels in healthy, adult tissues.[1]

FAP is highly overexpressed on CAFs[2]

- Found in >90% of epithelial tumors[3]
- Imaging studies have shown the presence of FAP in virtually all major tumor types[4]

Therefore, FAP-targeted radiation may represent a nearly universal approach for the imaging and therapy of cancer.



1. *Niedermeyer J. et al. 2001. Int J Dev.* ***2.*** *Jacob M. et al. 2012. Curr. Mol. Med.* ***3.*** *Mhawech-Fauceglia P. et al. 2015. Cancer Microenviron* ***4.*** *Kratochwil C. et al. 2019. J. Nucl. Med.*

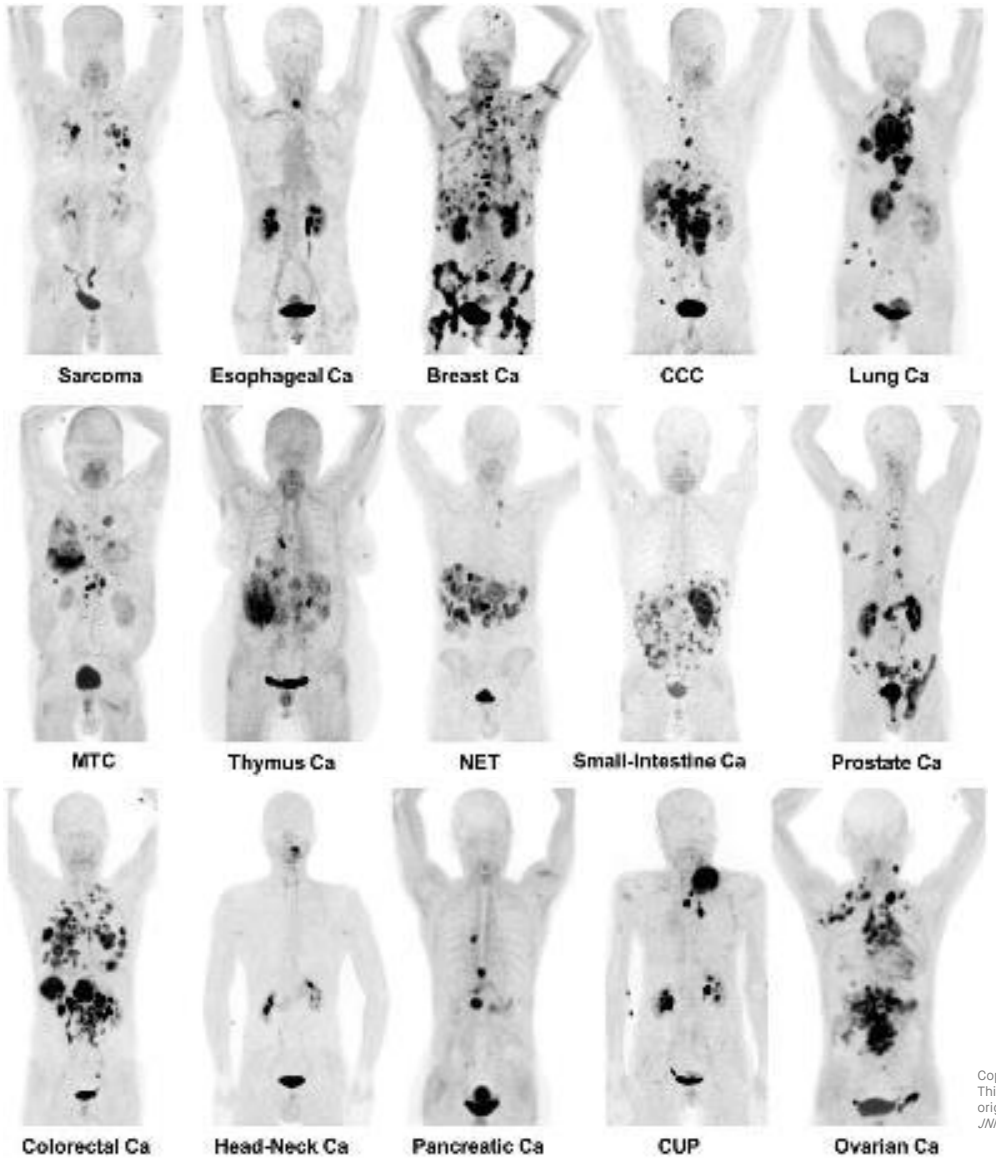
Proof of concept: FAP imaging in the clinic

A theranostic approach to targeting FAP allows for precision imaging and therapy of FAP-positive tumors.

Successful FAP-based radioligands will require:

- High affinity for the target (FAP)
- Low affinity for closely related molecules (ie. DPPIV, PREP)
- Long retention time in tumor tissue
- Rapid clearance from healthy tissue

FAP inhibitor imaging agents have demonstrated compelling tumor targeting across many tumor indications (shown on right).



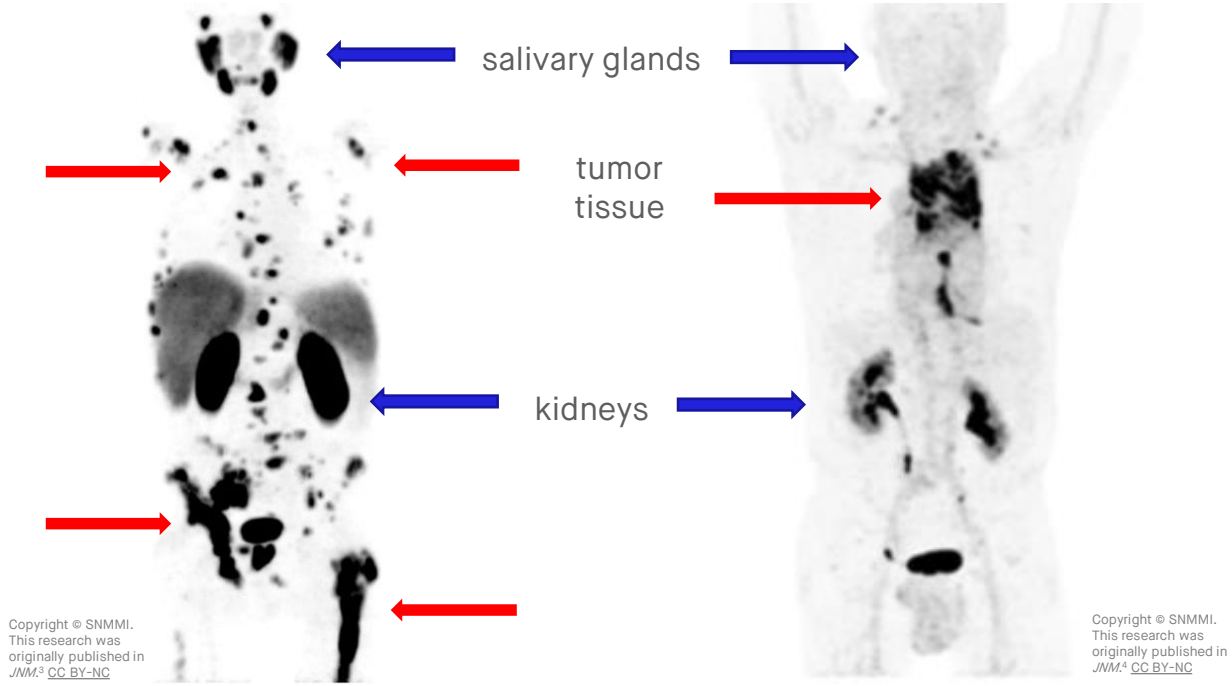
1

1. *Kratochwil et al. J Nucl Med 2019; 60:801–805*

FAP-based RLT is expected to deliver reduced radiation to normal tissues leading to larger therapeutic windows

FAP is not expressed in kidney tubules,[1,2] therefore kidney exposure is limited to excretion only.

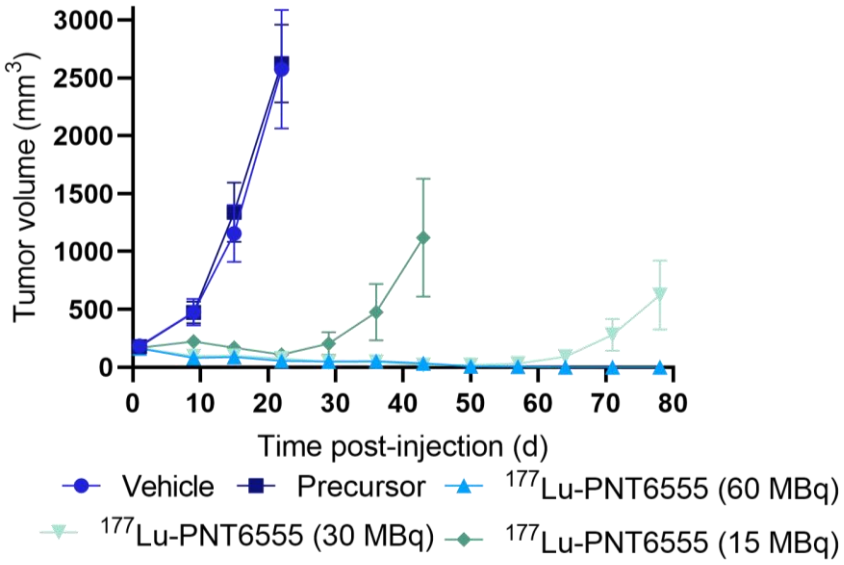
FAP is not expressed in salivary glands.[1,2]



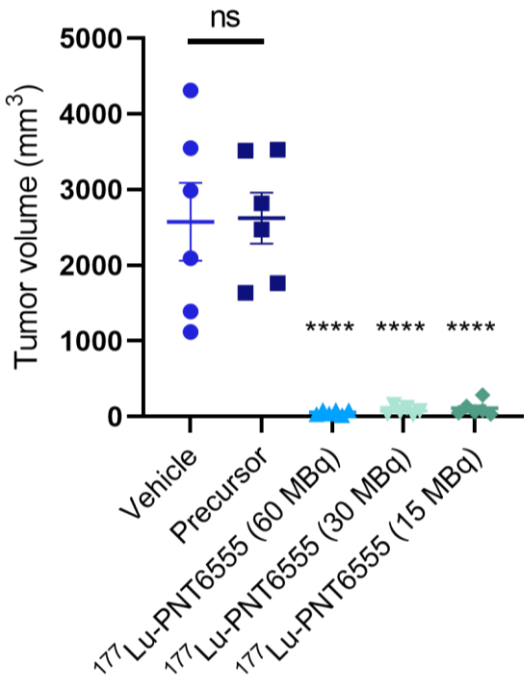
1. Rettig WJ, et al. Proc Natl Acad Sci USA. 1988;85(9):3110-3114. 2. Dolznig H, et al. Cancer Immun. 2005;5:10. 3. Kratochwil C, Giesel FL, Stefanova M, et al. PSMA-Targeted Radionuclide Therapy of Metastatic Castration-Resistant Prostate Cancer with 177Lu-Labeled PSMA-617. J Nucl Med. 2016;57(8):1170-1176. doi:10.2967/jnumed.115.171397 4. Loktev A, Lindner T, Mier W, et al. A Tumor-Imaging Method Targeting Cancer-Associated Fibroblasts. J Nucl Med. 2018;59(9):1423-1429. doi:10.2967/jnumed.118.210435

^{177}Lu-PNT6555 shows compelling anti-tumor activity, with mice experiencing long-term survival

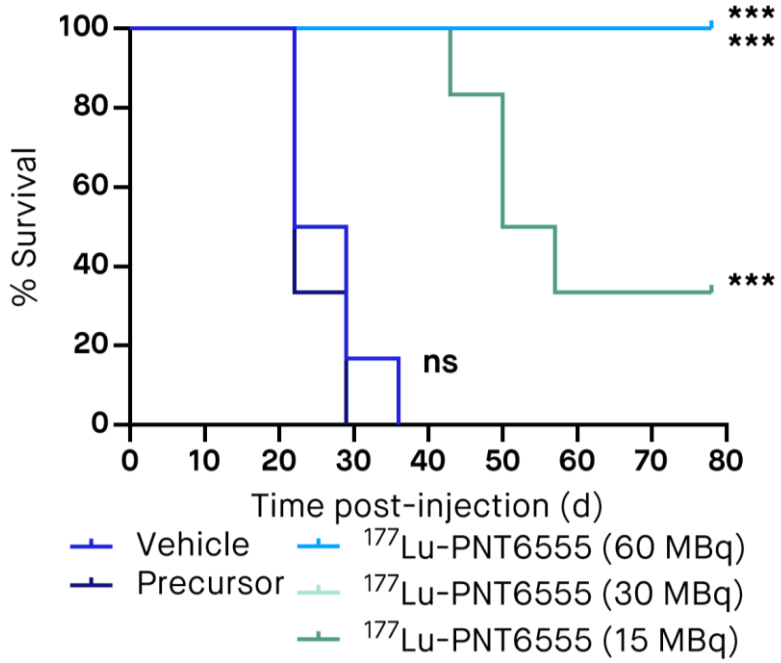
Tumor Volumes



Tumor Volumes on Day 22



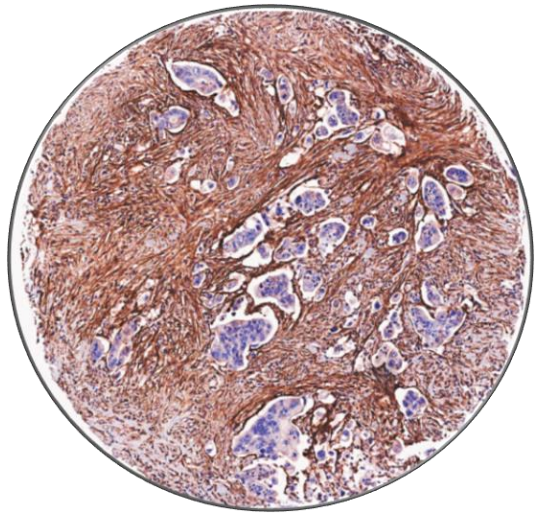
Kaplan-Meier Survival Curves



*HEK-mFAP model, n=6/group, single dose treatment in mice with tumors (~200mm^3), ns=not significant, *p<0.05, **p<0.01, ***p<0.001, **** p<0.0001. Hallet R, et al. Pre-clinical characterization of the novel fibroblast activation protein (FAP) targeting ligand PNT6555 for the imaging and therapy of cancer. Presented at SNMMI Annual Meeting April 2022; Vancouver, BC, Canada.*

Three key areas of exploration

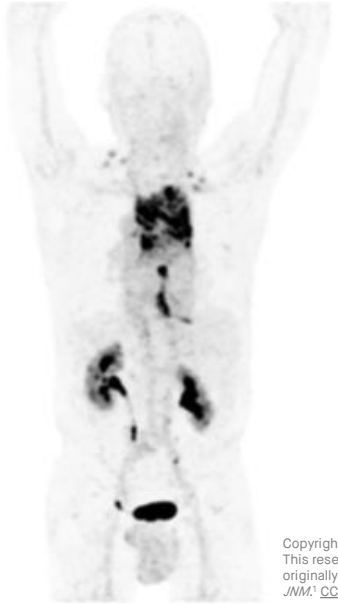
FAP Expression



Variation across tumor types and patients

Changes in expression over time

Interpretation of FAP Imaging



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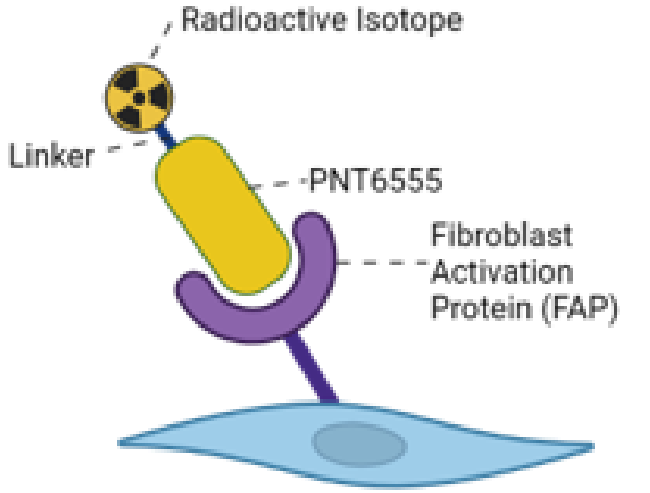
Comparison with FDG

Defining entry criteria

Optimizing FAP RLT Design & Treatment Regimen



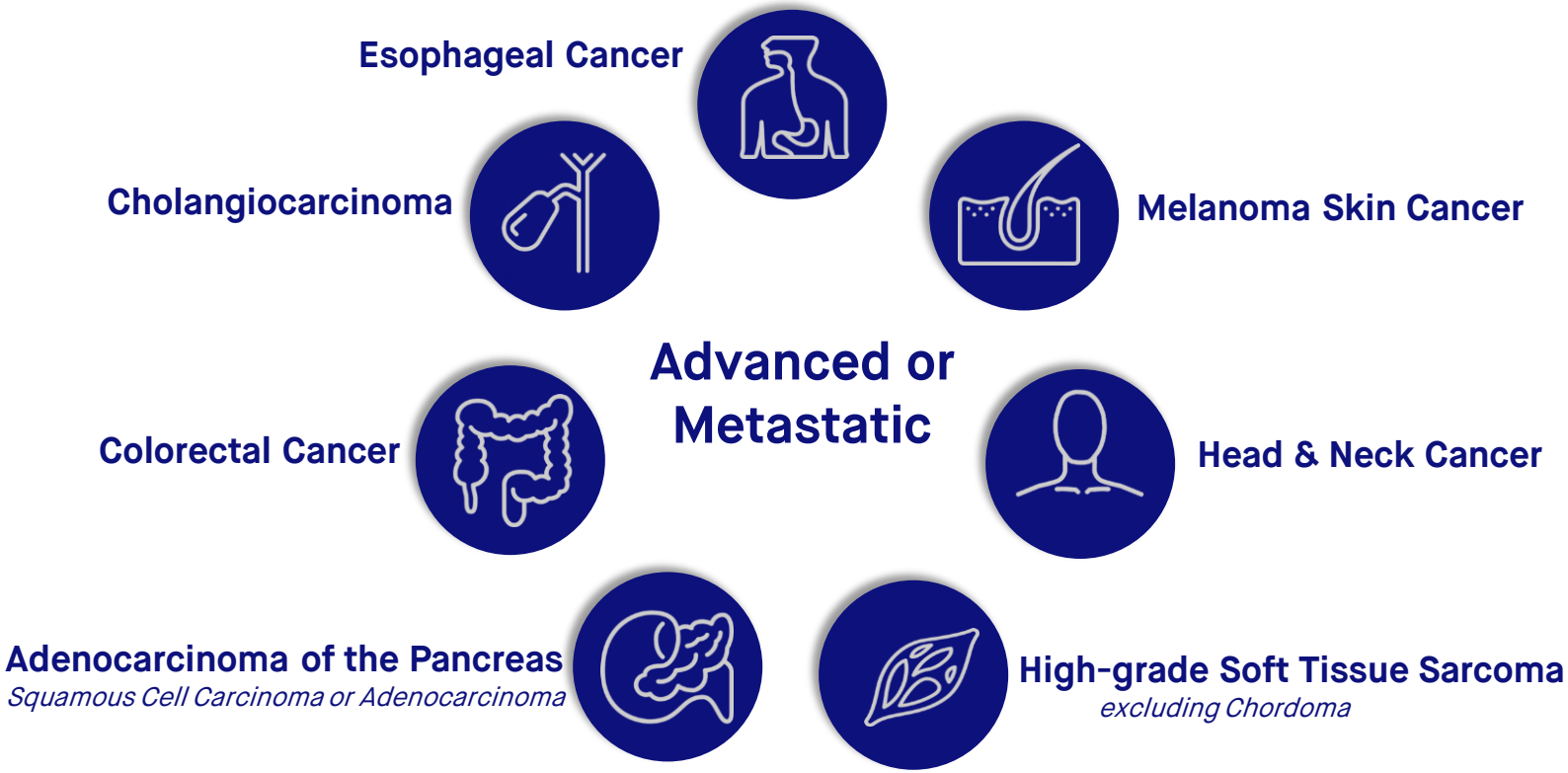
Created using BioRender.com

Defining optimal dosing from PK and normal tissue effects

Maximizing tumor dose through isotope selection

1. *Loktev A, Lindner T, Mier W, et al. A Tumor-Imaging Method Targeting Cancer-Associated Fibroblasts. J Nucl Med. 2018;59(9):1423-1429. doi:10.2967/jnumed.118.210435*

FRONTIER: **F**APi **R**adioligand **O**pe**N**-label, phase 1 study to evaluate safety, **T**olerability and dos**I**metry of ^{177}Lu-PNT6555—A dose **E**scalation study for t**R**eatment of patients with select solid tumors



FRONTIER: **F**APi **R**adioligand **O**pe**N**-label, phase 1 study to evaluate safety, **T**olerability and dos**I**metry of ^{177}Lu-PNT6555—A dose **E**scalation study for t**R**eatment of patients with select solid tumors.

Imaging & Therapy

^{68}Ga-PNT6555

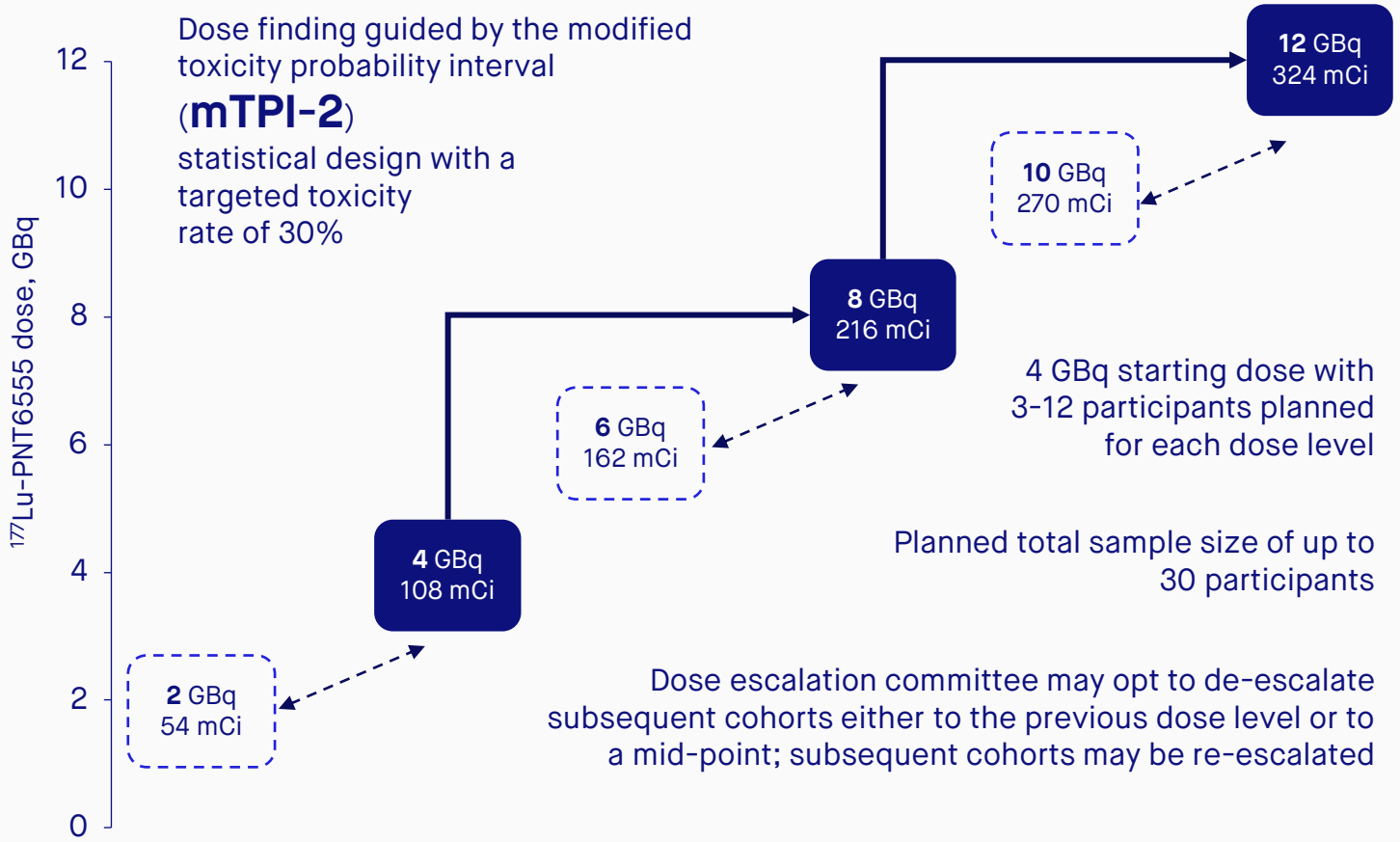
120 - 220 MBq
(3.2 - 5.9 mCi)

≥50% of lesions with SUV$_{max}$ ≥1.5x liver SUV$_{mean}$

^{177}Lu-PNT6555

Once every 6 weeks for up to
6 cycles

Dose Escalation



DLT, dose limiting toxicity; GBq, gigabecquerel; MBq, megabecquerel; mCi, millicurie.

FRONTIER: FAPi **R**adioligand **O**pe**N**-label, phase 1 study to evaluate safety, **T**olerability and dos**I**metry of ^{177}Lu-PNT6555—A dose **E**scalation study for t**R**eatment of patients with select solid tumors.

Primary Objective

RP2D for ^{177}Lu**-PNT6555**

Determine the recommended phase II dose (RP2D) for ^{177}Lu-PNT6555

Exploratory Objectives

^{177}Lu**-PNT6555**

- Tumor response
- Biomarker changes
- Tumor immune response
- Tumor dosimetry

Secondary Objectives

^{68}Ga**-PNT6555**

Safety and tolerability

Biodistribution and radiation dosimetry to normal organs

Qualitative tumor lesion detection

Quantitative tumor lesion uptake

^{177}Lu**-PNT6555**

Safety and tolerability

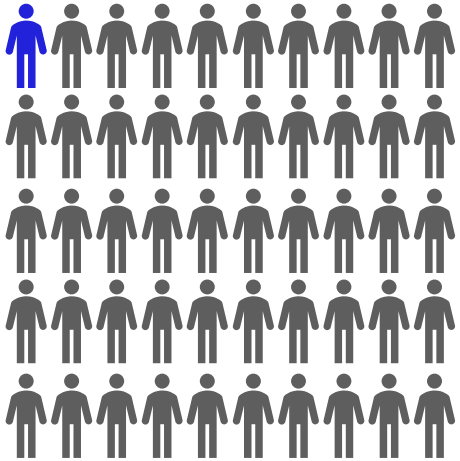
Biodistribution and radiation dosimetry to normal organs

Current Status: Enrollment to dose level cohort 3 (12 GBq) began in May 2023 with data anticipated 1H 2024

RLT Treatment Site Access

NEIL FLESHNER, M.D.
Chief Medical Officer & Co-Founder

Radiopharmaceuticals and radioligands are complex molecules that are used in nuclear medicine to diagnose and treat diseases in thousands of procedures each day around the world



1 in 50 people requires diagnostic nuclear medicine each year in developed countries[1]

10,000

>10,000 hospitals worldwide use radioisotopes in medicine[1]

20 million

>20 million nuclear medicine procedures per year in the U.S., and ~90% of these are for diagnosis[1]

1. World Nuclear Association, "Radioisotopes in Medicine"

Diagnostic imaging infrastructure is well established, while RLT treatment site access has significant growth potential

	SPECT (Single Photon Emission Computed Tomography)	PET (Positron Emission Tomography)	PET/CT (Positron Emission Tomography/Computed Tomography)
Initial Procedure	Injection of a radiotracer into the patient's bloodstream		
U.S. Install Base	~13,000 SPECT scanners[1]	~2,500 PET scanners[3, 4]	
U.S. Annual Procedures	>18 million SPECT scans[2]	~2 million PET scans[3, 4]	
Emission	Gamma (γ)	Positron (e^+)	Positron (e^+)
3D Image Resolution	Medium	High	Highest
Utility	Functional	Functional	Functional & Anatomical

1. Axis Imaging News 2. Cardinal Health 3. Strategic Market Research LLP, May 2022, 4. Phillips

By leveraging the same ligand, RLT can also drive expansion of molecular imaging

New radioligands optimized for the delivery of therapeutic isotopes can also be used for traditional molecular imaging uses, such as patient staging, selection, guided surgery, and radiotherapy

Staging & Recurrence

RLT Patient Selection

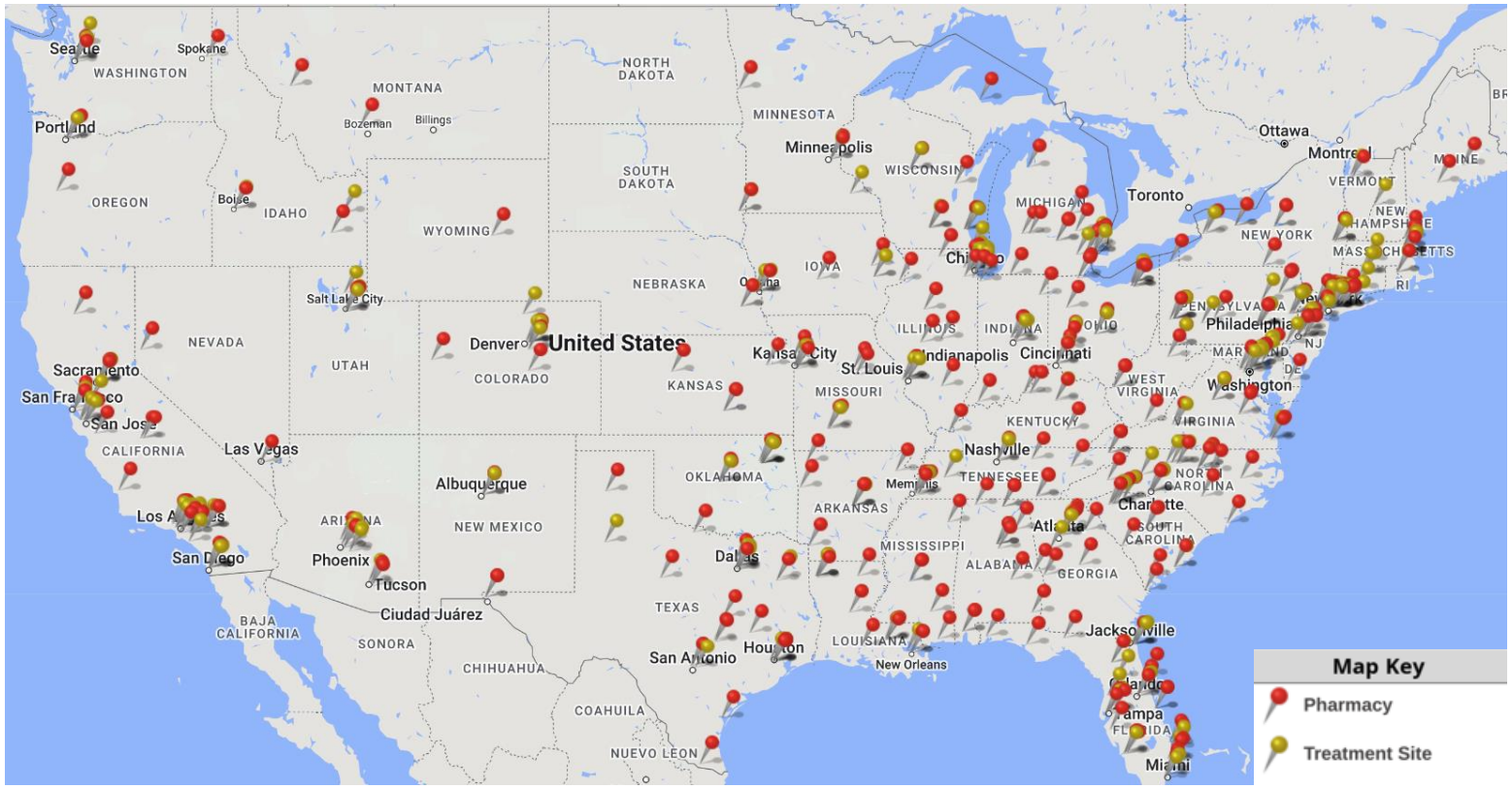
Guided Surgery

Guided Radiotherapy

^{177}Lu and other new isotopes can be administered outside of hospitals, making them easily accessible with the growing network of both radiopharmacies and treatment centers in the U.S.

Infusion access is broad and expanding, with sites for modern radiopharmaceuticals increasing access for patients with prostate cancer and neuroendocrine tumors.

Strong radiopharmacy network makes reaching patients at treatment convenient and practical coast to coast.



Establishing redundancy and multi-sourcing are best practices in nuclear medicine departments

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ARCHIVED - Lessons learned from the shutdown of the Chalk River reactor

Generators

It is not uncommon for larger hospitals and independent radiopharmacies to have contracts with both generator manufacturers. However, smaller hospitals and facilities have little choice but to contract with one manufacturer to control costs.

Recommendations

3.6 Explore options and opportunities to diversify generator supply sources within Canada.

3.7 Evaluate mechanisms that would allow Health Canada to "fast track" generator products that are currently not approved by Health Canada but may be of use in emergency situations should be evaluated.

3.8 Hospitals and radiopharmacies should secure generators from more than one supplier. This may require facilities in smaller centres to develop regional purchasing strategies. Nuclear medicine facilities contracting for supply with central radiopharmacies should stipulate that the radiopharmacy will obtain generators from more than one supplier.

3.9 Health Canada, as the regulatory authority that ensures generators are safe for transfer between facilities, and the provincial and territorial governments, as the bodies responsible for health care delivery, should develop a strategy to maximize generator productivity including

- shipping partly spent generators to more remote regions from central large facilities (as was done in Alberta during the recent crisis) for use in the event of a supply disruption
- developing a plan to monitor and use generators past their expiry dates.

The Supply of Medical Isotopes

AN ECONOMIC DIAGNOSIS AND POSSIBLE SOLUTIONS

OECD NEA Nuclear Energy Agency

Technetium Generators are delivered at least weekly

Generators are highly regulated products; they must be produced according to the conditions of their medical licence as well as under strict regulated controls for handling radioactive material. Generator manufacturers typically source bulk Mo-99 from a number of processor organisations to provide operational flexibility and to have back-up options in the event of supply problems. Not all processors can produce and supply material every week of the year. The problems experienced in the 2009-2010 period of Mo-99 supply crisis led to increased multi-sourcing by generator manufacturers and multi-sourcing subsequently became more common throughout the supply chain.

Multi-sourcing is important for security of supply, but brings additional costs; medical licences must be maintained for each separate supplier, even if that supplier is only used infrequently. The addition of a new

1. *Health Canada* ***2.*** *Organisation for Economic Co-operation and Development*

Simplifying administration and improving waste management are important to increasing access and reducing burden on hospitals and outpatient centers

Radiopharmaceuticals are governed by both the FDA and the NRC.[1]

Clear visibility on supply chain is needed, as production of radionuclides goes into the NDA application.[2]

Licensing, waste disposal, and long-lived impurities all affect the operations of the hospital or clinic.[2]

U.S. FOOD & DRUG ADMINISTRATION

Home / Drugs / News & Events for Human Drugs / FDA-NRC Workshop Enhancing Development of Novel Technologies: Radiopharmaceuticals and Radiological Devices - 10/14/2020 - 10/14/2020

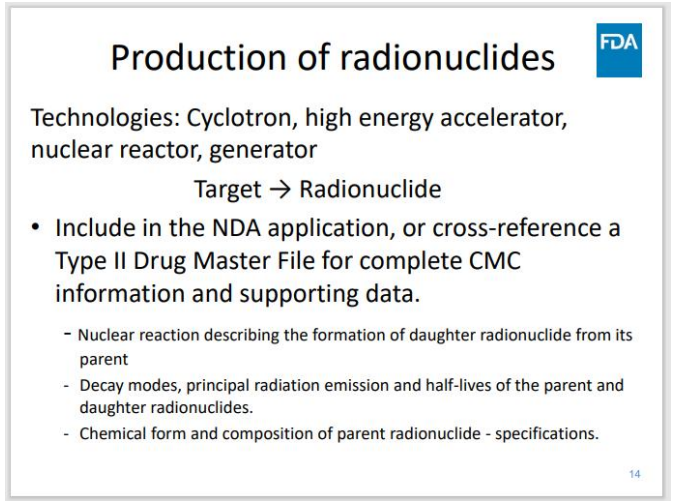
WORKSHOP

FDA-NRC Workshop Enhancing Development of Novel Technologies: Radiopharmaceuticals and Radiological Devices

OCTOBER 14, 2020

Topics

- Overview of Regulatory Process for Marketing and Licensing of Radiopharmaceutical Devices
- Novel Radiopharmaceuticals: physical standards development, product quality considerations, supply and demand
- Safety and Efficacy Considerations for Radiopharmaceutical Products
- The Evolving Landscape—Radiological Devices
- Clinical Trial Design Considerations for Radiopharmaceuticals



Production of radionuclides

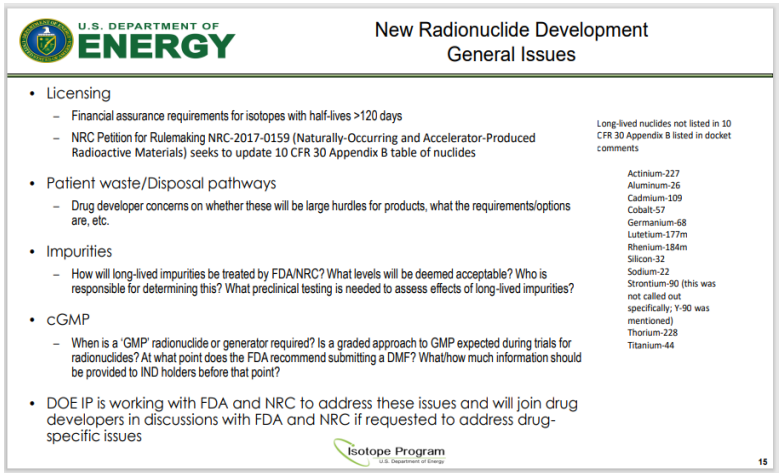
FDA

Technologies: Cyclotron, high energy accelerator, nuclear reactor, generator

Target → Radionuclide

- Include in the NDA application, or cross-reference a Type II Drug Master File for complete CMC information and supporting data.
  - Nuclear reaction describing the formation of daughter radionuclide from its parent
  - Decay modes, principal radiation emission and half-lives of the parent and daughter radionuclides.
  - Chemical form and composition of parent radionuclide - specifications.

14



U.S. DEPARTMENT OF ENERGY

New Radionuclide Development General Issues

- Licensing
  - Financial assurance requirements for isotopes with half-lives >120 days
  - NRC Petition for Rulemaking NRC-2017-0159 (Naturally-Occurring and Accelerator-Produced Radioactive Materials) seeks to update 10 CFR 30 Appendix B table of nuclides
- Patient waste/Disposal pathways
  - Drug developer concerns on whether these will be large hurdles for products, what the requirements/options are, etc.
- Impurities
  - How will long-lived impurities be treated by FDA/NRC? What levels will be deemed acceptable? Who is responsible for determining this? What preclinical testing is needed to assess effects of long-lived impurities?
- cGMP
  - When is a 'GMP' radionuclide or generator required? Is a graded approach to GMP expected during trials for radionuclides? At what point does the FDA recommend submitting a DMF? What/how much information should be provided to IND holders before that point?
- DOE IP is working with FDA and NRC to address these issues and will join drug developers in discussions with FDA and NRC if requested to address drug-specific issues

Long-lived nuclides not listed in 10 CFR 30 Appendix B listed in docket comments

Actinium-227
Aluminum-26
Cadmium-109
Cobalt-57
Germanium-68
Lutetium-177m
Rhenium-184m
Silicon-32
Sodium-22
Strontium-90 (this was not called out specifically; Y-90 was mentioned)
Thorium-228
Titanium-44

Isotope Program
U.S. Department of Energy

15

1. *FDA-NRC Workshop Enhancing Development of Novel Technologies: Radiopharmaceuticals and Radiological Devices, October 2020* ***2.*** *U.S. Department of Energy DOE Isotope Program Production of Radioisotopes for Medical Applications, October 2020*

Concluding Remarks

JOE McCANN, Ph.D.

Chief Executive Officer & Co-Founder

Key Takeaway:
POINT has a highly differentiated platform that positions us to lead this exciting modality

1. The **market potential for radioligand therapy (RLT) is growing significantly**, driven by new targets and increased accessibility.

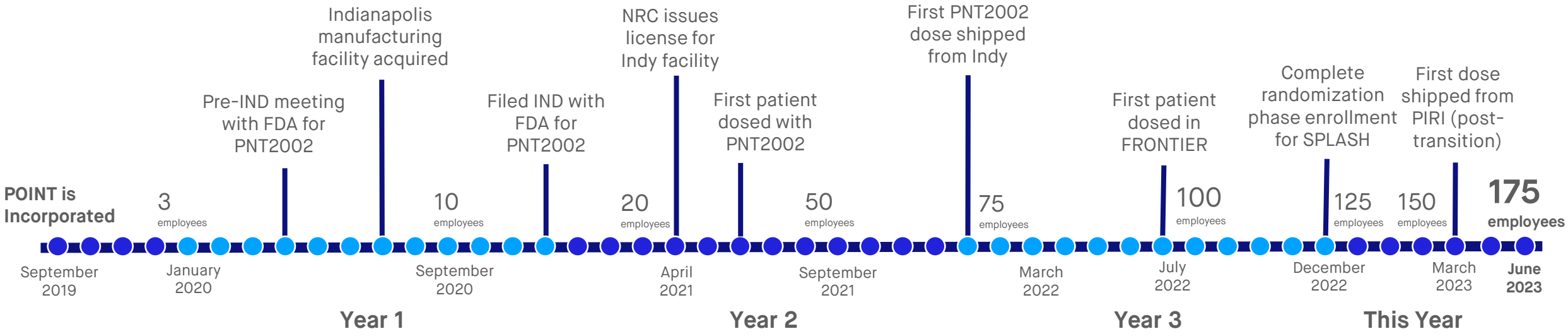
2. Early investment in manufacturing and supply chain positions POINT as **one of the few vertically-integrated, large-scale, commercial-ready** therapeutic radioligand companies.

3. POINT has **demonstrated success** in both the development of novel radioligands and the clinical development of late-stage programs.

4. POINT is actively leveraging its unique capabilities and internal expertise in radioligand development to **develop potentially best-in-class agents in large indications with high unmet need**.

POINT's track record of rapid execution is driven by the collective RLT-specific operational experience of our management team

We are one of the only therapeutic radiopharmaceutical companies in the world manufacturing our own radioligands in our own manufacturing facility for our own Phase 3 trial



Meaningful near-term value creation milestones with a long-term goal of introducing **five new programs in humans** by the end of 2028

Program	Clinical Candidate	Indication	Timing (Est.)	Milestone
PNT2002	^{177}Lu-PNT2002	mCRPC	**2H 2023**	Top line data
PNT2001	^{225}Ac-PSMA-62	Prostate cancer	**Q4 2023**	Health authority submission
PNT2001	^{225}Ac-PSMA-62	Prostate cancer	**Q1 2024**	First patient in phase 1
Discovery Program A	Undisclosed	Undisclosed	**1H 2024**	Disclose new development candidate
PNT2004	^{177}Lu-PNT6555	Solid tumors expressing FAP	**1H 2024**	Phase 1 data
PNT2001	^{225}Ac-PSMA-62	Prostate cancer	**EOY 2024**	Clinical data update
Discovery Program B	Undisclosed	Undisclosed	**EOY 2024**	Disclose new development candidate
Manufacturing & Isotope Supply		**Location**	**Timing (Est.)**	**Milestone**
In-house n.c.a ^{177}Lu production		Indianapolis Campus	**EOY 2023**	Online

Balance Sheet	**$519M** in cash, cash equivalents, and investments, as of Mar 31, 2023
Projected Runway	Cash runway into 2026
Capital Structure	**105.6M** Common Shares + **8.5M** Options

Q&A

Welcome to POINT Biopharma's Investor Day (June 2023)

Speakers from POINT Biopharma:

JOE McCANN, Ph.D.
Chief Executive Officer & Co-Founder

NEIL FLESHNER, M.D.
Chief Medical Officer & Co-Founder

JUSTYNA KELLY, M.Sc.
Chief Operating Officer

JESSICA JENSEN, MPH
Executive Vice President, Clinical Development

ROBIN HALLETT, Ph.D.
Senior Vice President, Discovery and Translational Sciences

Thank You