

# The Dawn of a New Era for Prostate Cancer Patients: The Role of PSMA and Artificial Intelligence in Diagnostics and Therapy

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October 2019

**Progenics**  
Pharmaceuticals®  
*Find Fight and Follow®*



# Our Mission

## FIND FIGHT AND FOLLOW®

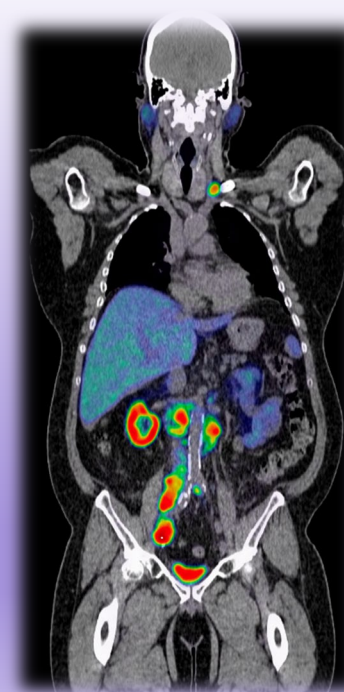
### Leading Development of Radiopharmaceuticals to Detect and Treat Cancer

#### HSA iobenguane I 131 for Ultra Orphan neuroendocrine tumors (NET)

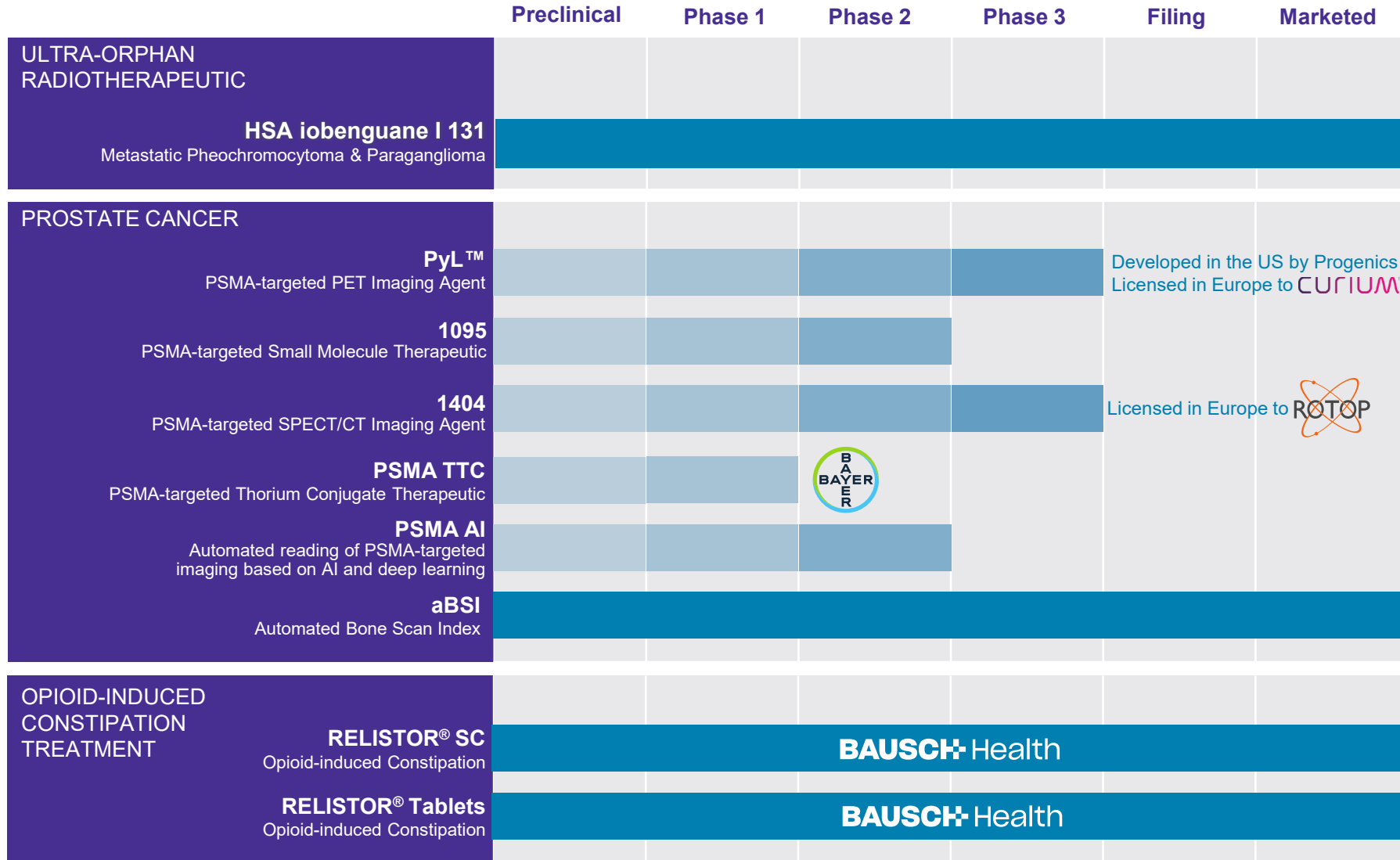
Treatment for adults and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy

#### Prostate-specific membrane antigen (PSMA) – Portfolio for Prostate Cancer

Imaging and therapeutics agents designed to improve diagnosis, treatment and monitoring of prostate cancer

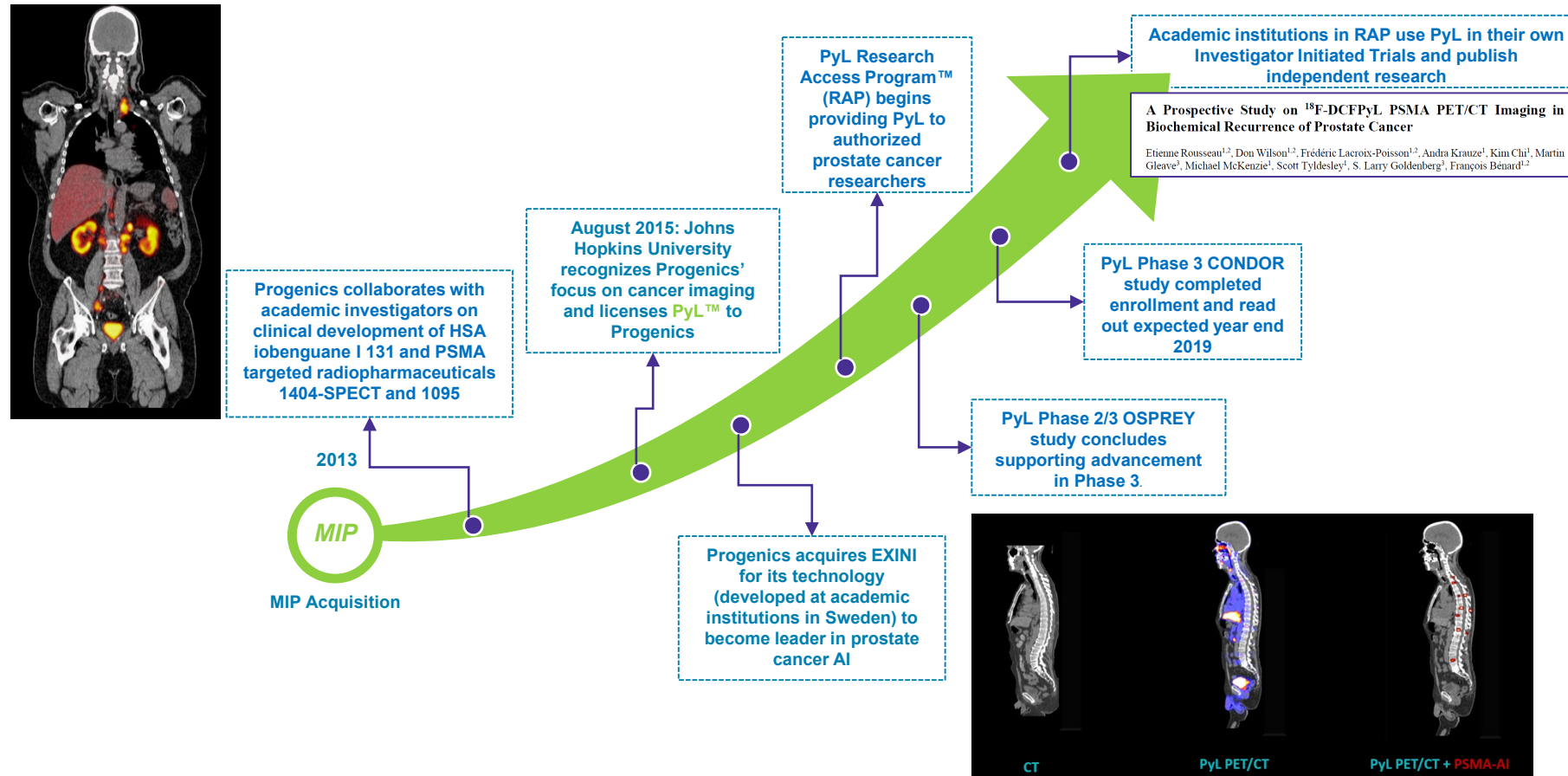


# Robust Product Pipeline



# PSMA-Targeted Pipeline

# Progenics' advancement of PSMA imaging program has been powered by Academic Collaboration



# PyL™: PSMA-targeted PET/CT Agent

*“Physicians indicated that imaging results improved decision-making in **89.1%** and changed management plans in **87.3%**.”*

Rousseau, E. et al, JNM 2019

- Enables visualization of both bone and soft tissue metastases
- Highly specific to prostate cancer cells, not confounded by degenerative or inflammatory conditions
- Very high standardized uptake values (SUV) even in small lesions
- Identified more lesions than conventional imaging

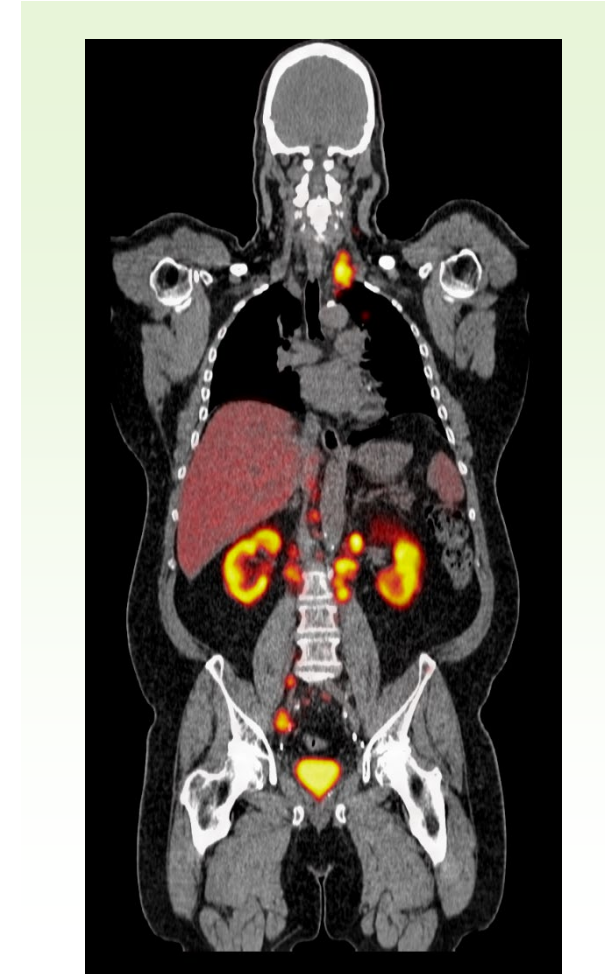
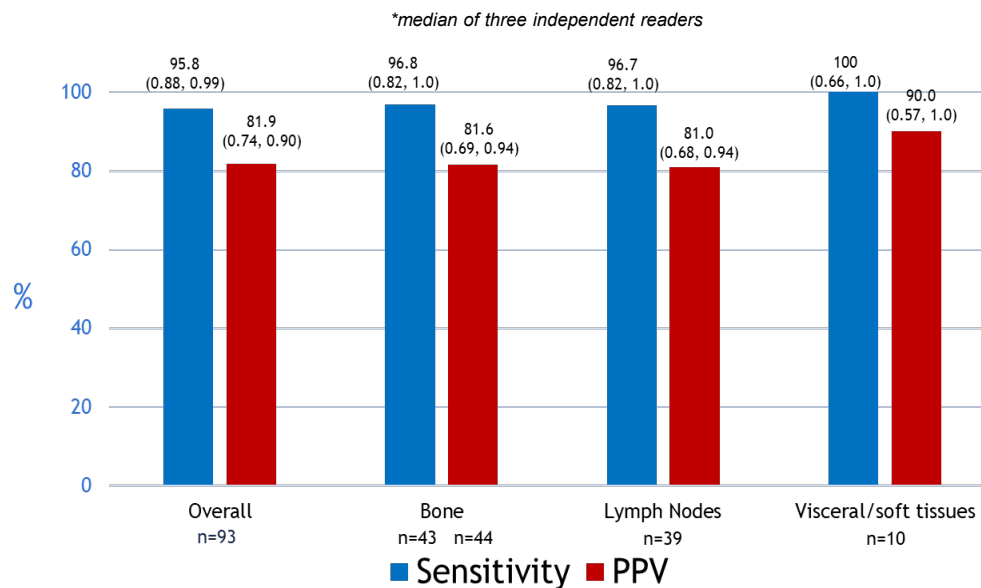
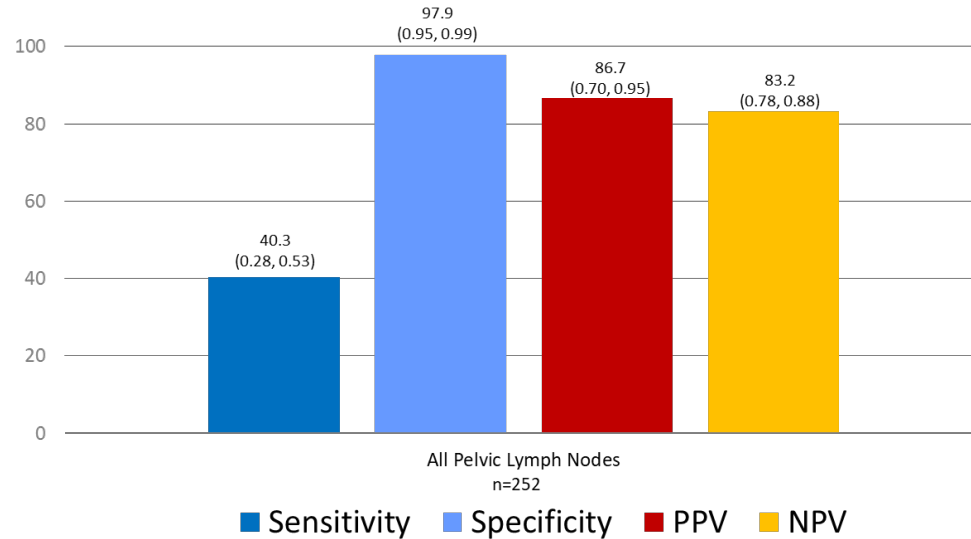


Image from OSPREY Study

# PyL OSPREY trial results support advancement into Phase 3



- Demonstrated high sensitivity in detecting distant metastatic prostate cancer lesions
- Demonstrated high specificity in confirming the absence of pelvic lymph node disease
- Associated strong positive predictive values (PPV) and negative predictive value (NPV) of PyL imaging

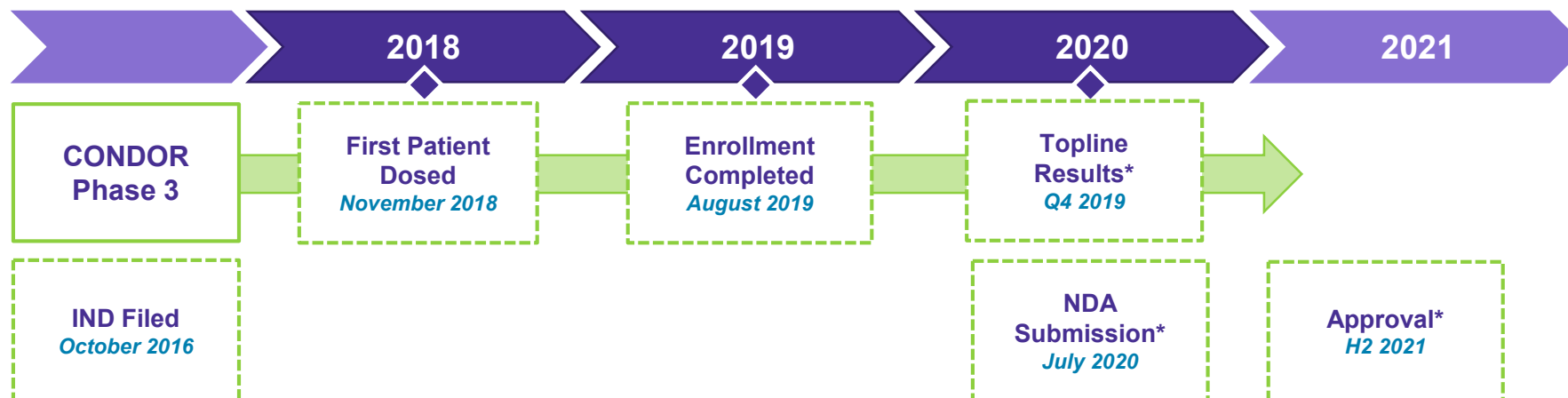
# PyL OSPREY Results Supported Advancement into Pivotal Phase 3 CONDOR Trial

**Objective:** To evaluate the diagnostic performance & clinical impact of 18F-DCFPyL PET/CT imaging in patients with suspected biochemical recurrence (BCR) of prostate cancer

**Primary Endpoint:** Correct Localization Rate (CLR), defined as percentage of subjects with a one-to-one correspondence between localization of at least one lesion identified on 18F-DCFPyL PET/CT and the composite truth standard.

14 sites in the US and Canada | Total subjects: N=208

## PyL Development Timeline



Enrollment completed August 2019; Topline data expected by YE 2019

\* Indicates anticipated events based on the company's expectations.



**PyL™**

**PSMA-targeted PET/CT Agent**

**12**

ongoing investigator-initiated trials (IIT)  
supported by Progenics Pharmaceuticals as  
part of the  
**Progenics PyL Research Access  
Program™**

To initiate an IIT using PyL for PET imaging,

**Submit a proposal or inquiry  
at [PyLAccess@Progenics.com](mailto:PyLAccess@Progenics.com)**

# KOLs Drive Development of PyL

## Leveraging investigator-sponsored studies to expand and advance PyL development

### Stanford University School of Medicine

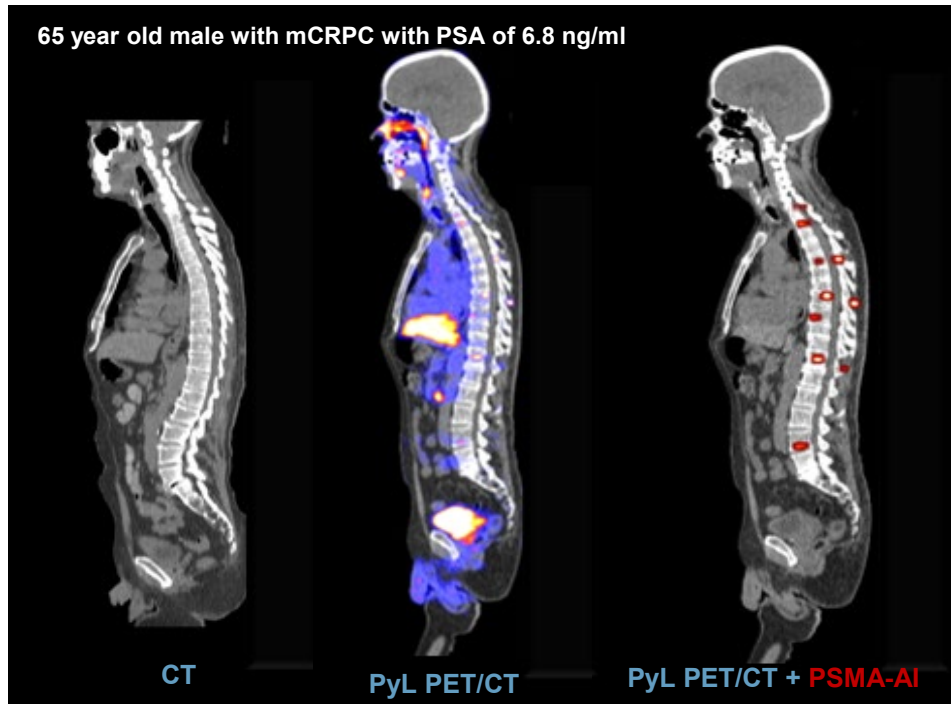
- This 50-patient study reported that PyL imaging localized disease in the majority of patients, including those with **very low PSA levels**
- PyL imaging had an impact on clinical management **in 65% of the patients**, including 25% who had negative findings with conventional imaging<sup>1</sup>

### *The Journal of Nuclear Medicine*

- Data from a Prospectively Designed Independent Trial of 130 Patients showed that PyL upstaged and downstaged disease in 65.5% of patients, improved physician decision-making in **89.1% of patients**, and changed management plans in 87.3% of patients<sup>2</sup>

# PSMA Artificial Intelligence (AI) may provide faster, more accurate image analysis compared to a human reader alone

## Demonstrated clinical utility of PSMA AI



### – Prospectively planned retrospective analysis of PSMA images

- Automated analysis performed using deep convolutional neural network algorithms
- PSMA-targeted imaging data sourced from previous trials

### – Statistically significant improvement achieved over manual assessment

- Increased diagnostic accuracy, precision, speed, and reproducibility
- Results to be presented at scientific conference in June 2020

In August, we received 510(k) clearance from the FDA to market our cloud-based version of Automated Bone Scan Index (aBSI) product in the U.S

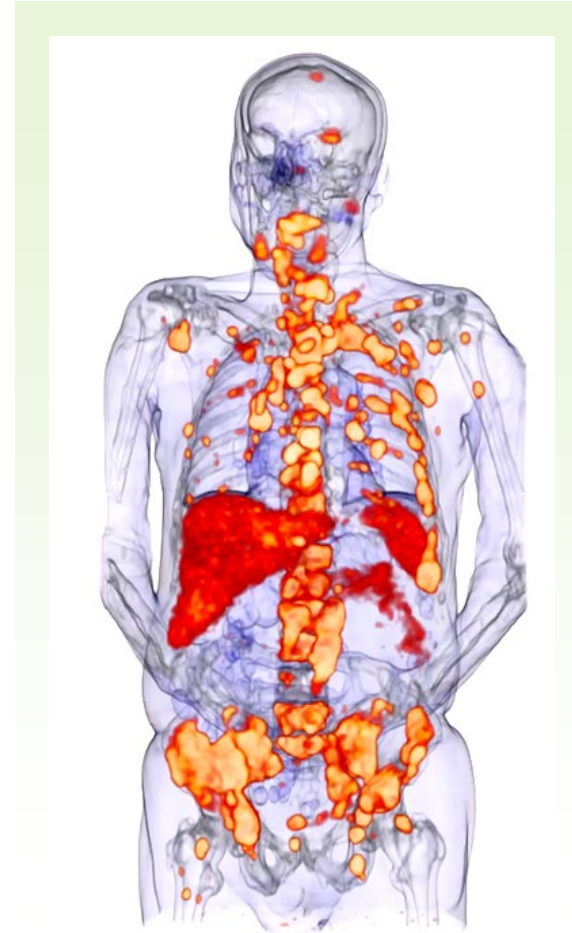
# 1095: PSMA targeted small molecule theranostic for prostate cancer

## – 1095 delivers a targeted radiation dose to prostate cancer utilizing I-131

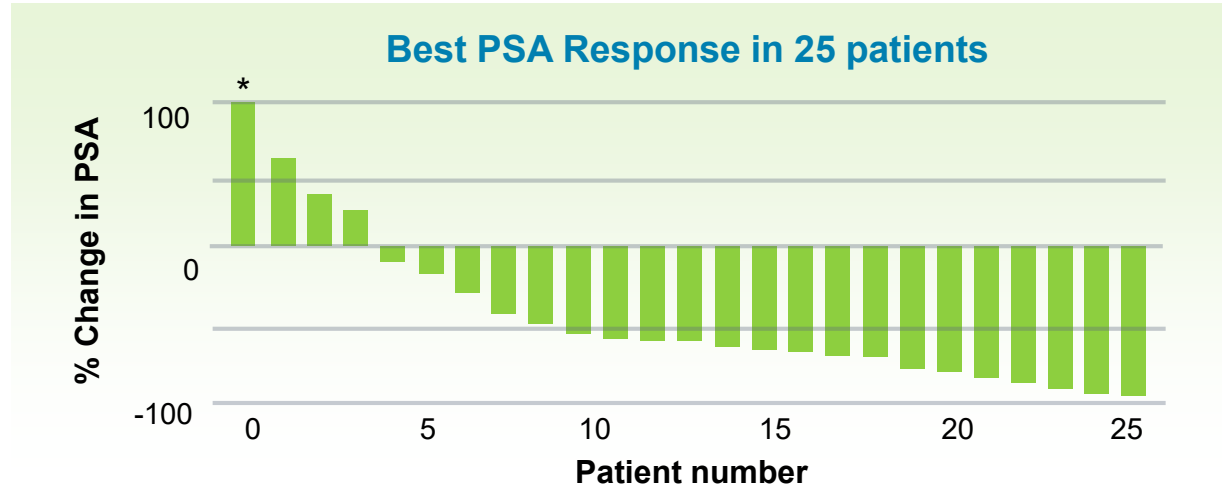
- I-131 has a longer range and higher energy
- Iodine has been used widely in other cancer therapeutics, is broadly available with a ready supply, and has a known safety profile

## – Unmet need well-established

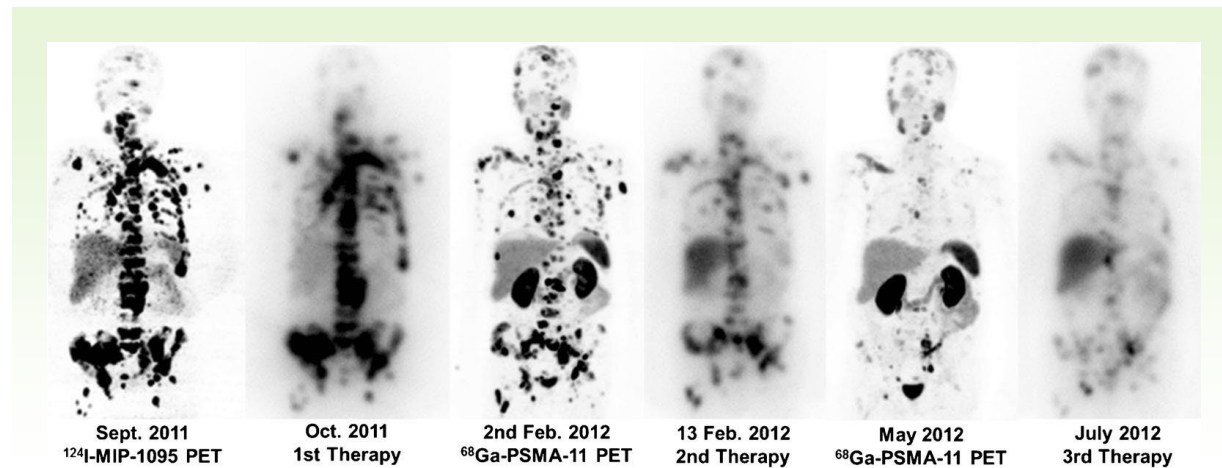
- High medical need for targeted drug with different MoA; attractive to patients and HCPs
- Nearly all patients fail NAADs\*
- Growing patient population unwilling or unable to receive chemotherapy



# 1095 was shown to markedly reduce prostate-specific antigen levels



German compassionate use setting in advanced prostate cancer in a heavily pretreated group of 25 evaluable patients



**70%** of patients had a  $\geq 50\%$  PSA decline after the first therapeutic dose

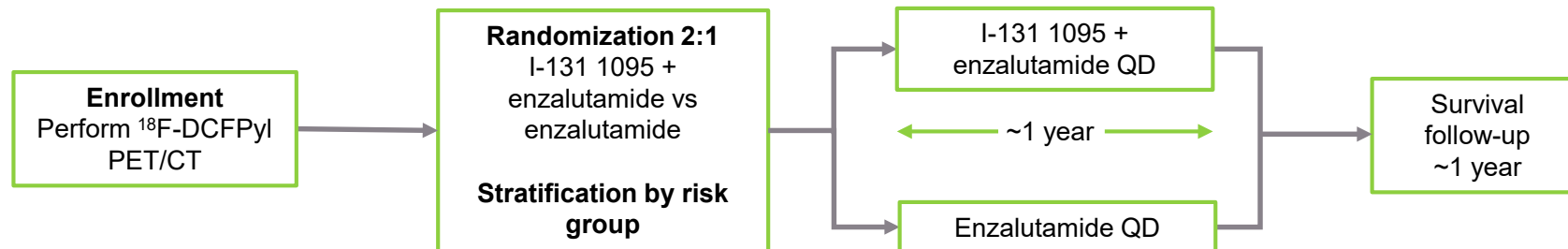
References: 1. Zechmann et al. *Eur J Nucl Med Mol Imaging*, 2014.; 2. Afshar-Oromieh et al. *Eur J Nucl Med Mol Imaging*, 2017.

# 1095: Multicenter Phase 2 trial initiated

**Objective:** Evaluating 1095 plus enzalutamide in metastatic castration-resistant prostate cancer (mCRPC) patients who are PSMA-avid, chemotherapy-naïve, and progressed on abiraterone

**Primary Endpoint:** PSA response rate according to Prostate Cancer Clinical Trials Working Group 3 (PCWG3) criteria

~15 sites in the US and Canada | Total planned subjects: N~120



## 1095 Development Timeline



Based on the early data in this open label study, we will evaluate initiating a pivotal trial of 1095 in 2020

\* Indicates anticipated events based on the company's expectations.

# Leading development of targeted radiopharmaceuticals to detect and treat cancer

- PyL
  - Robust PPV, specificity and NPV in high risk and metastatic settings suggest its high clinical utility to confidently guide physicians on pelvic lymph node and distant metastases to better inform on treatment decisions
  - Potential to serve as a reliable diagnostic imaging agent for the staging of men with high risk disease
  - BCR patients being further studied in an ongoing prospective, phase 3, multi-center, multi-reader trial (CONDOR; NCT03739684)
- PSMA AI
  - Leverage PSMA Targeted Imaging data to develop algorithms for the automatic detection and quantification of prostate cancer images
- 1095
  - Initiated Phase 2 Trial in mCRPC patients who are PSMA-avid, chemotherapy-naïve, and progressed on abiraterone



# Thank You