

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 8-K

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CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: June 1, 2014  
(Date of earliest event reported)

**CELLECTAR BIOSCIENCES, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**333-119366**  
(Commission  
File Number)

**04-3321804**  
(IRS Employer  
Identification Number)

**3301 Agriculture Drive**  
**Madison, WI 53716**  
(Address of principal executive offices)

**(608) 441-8120**  
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**ITEM 8.01      OTHER ITEMS**

On June 1, 2014 and June 2, 2014 presentations relating to our technology were made at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting. The presentations are attached as Exhibit 99.1 and 99.2 and are incorporated herein by reference.

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**ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS**

(d) Exhibits

Number	Title
99.1	Presentation entitled "A phase 1 study of phospholipid ether [131I]-CLR1404 in patients with advanced solid tumors (Abstract #130053; Poster #20)"
99.2	Presentation entitled "A novel "diapeutic" molecular imaging agent for combined oncologic diagnosis and therapy in a broad spectrum of human cancers: Preliminary clinical experience with CLR1404 (Abstract #11000)"

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: June 4, 2014

**CELLECTAR BIOSCIENCES, INC.**

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Vice President and Chief Financial Officer

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**EXHIBIT INDEX**

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## Background

Preclinical data suggest that tumor cells of many types selectively accumulate and retain phospholipid ethers. To capitalize on this, a radiolabeled phospholipid ether [<sup>131</sup>I]-CLR1404 was developed with the goal of improving tumor imaging specificity and as a novel approach to therapy. Preclinical experiments with [<sup>131</sup>I]-CLR1404 (Figure 1) in mouse models demonstrated safety and efficacy. Imaging trials with different radioisotopes coupled to CLR-1404 have demonstrated a high degree of tumor specificity. Results from a dosimetric phase 1a study demonstrated the ability to image tumor uptake at a dose of 10 mCi/m<sup>2</sup>. (Image 1)

We conducted a phase 1 study of escalating doses of [<sup>131</sup>I]-CLR1404 in patients with advanced solid tumors. The primary objective of this study was to determine a recommended dose of [<sup>131</sup>I]-CLR1404 for treating advanced solid malignancies. The secondary objectives were to expand the safety and pharmacokinetic profile, determine anti-tumor activity, and obtain tumor imaging with [<sup>131</sup>I]-CLR1404.

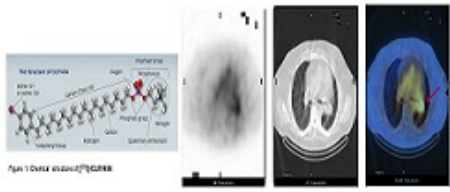


Figure 1: Chemical structure of CLR1404

Image 1: SPECT, CT and fused SPECT/CT of a patient with advanced cancer prior to receiving CLR1404

## Materials/Methods

Patients with advanced solid tumors, measurable disease by RECIST 1.1, ECOG performance status 0-2 and adequate bone marrow, cardiac, renal and hepatic function were eligible. Patients were first given a dosimetric dose of [<sup>131</sup>I]-CLR1404 followed by a treatment dose 4-2 weeks later in an algorithmic escalation design starting at 12.5 mCi/m<sup>2</sup>. Toxicity follow up included weekly laboratory and clinical assessment. Patients had SPECT scans to assess [<sup>131</sup>I]-CLR1404 biodistribution. Imaging followup to assess response was performed at 8 weeks.

Toxicity follow up included q 7 day laboratory and clinical assessment. Patients had single photon emission computed tomography (SPECT) scans to assess [<sup>131</sup>I]-CLR1404 biodistribution. Imaging follow up was performed at treatment day 56 with CT.

## Results

Twelve patients were enrolled at 3 open centers. Two patients withdrew from study before receiving drug; 10 patients received protocol therapy and were used for the safety analysis (Table 1). Myelosuppression was common and dose-related, with the highest-grade toxicities occurring 4-6 weeks post-infusion, and resolving within 2 weeks with growth factor support. The per-protocol dose-limiting toxicities (DLT) related to drug were grade 4 thrombocytopenia and grade 4 neutropenia at 37.5mCi/m<sup>2</sup> (2/2 pts). For further safety analysis, an intermediate dose level was opened at 31.25 mCi/m<sup>2</sup>; 2/4 patients suffered DLTs. No DLTs were seen at 12.5 mCi/m<sup>2</sup> or 25 mCi/m<sup>2</sup>. Other common toxicities included low-grade fatigue, and a dose-dependent, asymptomatic elevation in GGT. (Table 2)

Response assessments demonstrated 4 patients with stable disease (SD). Patients with stable disease included a patient with heavily pretreated ovarian cancer (2 systemic chemotherapies, 1 intraperitoneal chemotherapy), one patient with triple-negative breast cancer, and two patients with castrate-resistant prostate cancer with SD for 2-6 months. There were no complete or partial responses by RECIST 1.1.

SPECT imaging confirmed selective [<sup>131</sup>I]-CLR1404 accumulation in known tumors of a variety of histologic subtypes. Solid intraparenchymal tumors were able to be visualized, and a pleural effusion was SPECT-avid in a patient with metastatic triple negative breast cancer (see images 2-6).

Table 1: Patient Demographics/Toxicities (N=10)

Characteristic	N
Median age	55 (Range 40-70)
Gender	Male=5 Female=5
Tumor type	Colonial=3 Breast=2 Prostate=2 Sarcoma=1 Ovarian=1
Lines of systemic cytotoxic therapy	3 lines=3 2 lines=2 1 line=0 0 lines=2
ECOG PS	0-1 1-1 2-0
Race	White=9 Asian=1

Table 2: Toxicities in the study (N=10) (N=10)

Dose (mCi/m <sup>2</sup> )	Toxicity	Grade 1	Grade 2	Grade 3	Grade 4
12.5 mCi/m <sup>2</sup>	Thrombocytopenia	2	0	0	0
	Leukopenia/Neutropenia	1	0	0	0
25 mCi/m <sup>2</sup>	Fatigue	2	0	0	0
	Thrombocytopenia	2	0	0	0
37.5 mCi/m <sup>2</sup>	Leukopenia/Neutropenia	1	1	0	0
	Anemia	0	1	0	0
	Elevated GGT	0	1	0	0
	Fatigue	2	0	0	0
	Thrombocytopenia	0	1	1*	0
	Leukopenia/Neutropenia	0	0	2*	0
31.25 mCi/m <sup>2</sup>	Anemia	0	2	0	0
	Elevated GGT	0	2	0	0
	Fatigue	1	0	0	0
31.25 mCi/m <sup>2</sup>	Thrombocytopenia	0	2	1*	0
	Leukopenia/Neutropenia	1	2	1*	0
	Anemia	1	1	0	0
31.25 mCi/m <sup>2</sup>	Fatigue	2	0	0	0

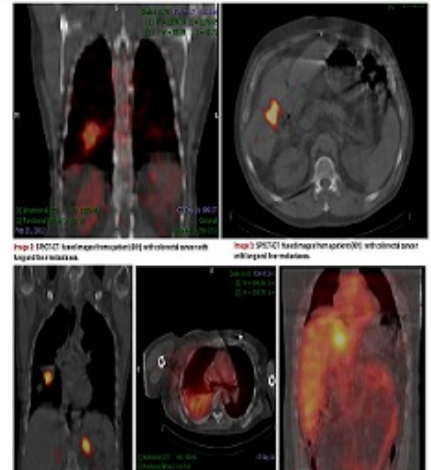


Image 2: SPECT/CT head/neck/thorax/abdomen/pelvis with no visible uptake in metastatic triple negative breast cancer

Image 3: SPECT/CT head/neck/thorax/abdomen/pelvis with no visible uptake in metastatic triple negative breast cancer

Image 4: SPECT/CT head/neck/thorax/abdomen/pelvis with no visible uptake in metastatic triple negative breast cancer

Image 5: SPECT/CT head/neck/thorax/abdomen/pelvis with no visible uptake in metastatic triple negative breast cancer

## Conclusions

At a dose of 31.25 mCi/m<sup>2</sup>, dose-limiting toxicities were thrombocytopenia and neutropenia. Studies exploring the mechanism(s) of action of [<sup>131</sup>I]-CLR1404 toxicity are ongoing to minimize myelosuppression. Disease-specific phase II protocols will further explore the toxicity profile of the compound and are also underway to identify patients most likely to benefit from [<sup>131</sup>I]-CLR1404.

In this study, there was a suggestion of [<sup>131</sup>I]-CLR1404 anti-tumor activity (4 pts with SD) in a heavily pretreated population that merits further study. Future studies may examine different response evaluation, as assessing response by RECIST 1.1 in a compound for which the primary method of action is delivery of ionizing radiation has its limitations.

From the standpoint of tumor imaging, there was sustained uptake in tumors by SPECT. Tumor uptake and delayed excretion of phospholipid ether demonstrates the potential diagnostic and therapeutic capability of this compound.

**Funding source:** Funding provided by Cellular Bioimaging, Inc.

# **A Novel “Diapeutic” Molecular Agent for Combined Oncologic Diagnosis and Therapy in a Broad Spectrum of Human Cancers:**

## **Preliminary Clinical Experience with CLR1404**

Pickhardt PJ, Lee MH, Longino M, Pinchuk A, Banach M, Grudzinsk J, Titz B, Jaskowiak C, Traynor AM, Kuo JS, Weichert JP, Hall LT

From the Departments of Radiology, Medical Physics, Internal Medicine, Neurological Surgery, and Carbone Cancer Center, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, USA; and Collectar Biosciences, Madison, Wisconsin, USA.

PRESENTED AT THE 2014 ASCO ANNUAL MEETING. PRESENTED DATA IS THE PROPERTY OF THE AUTHOR.





# Disclosure of Potential COI

The following co-authors either have or recently had a financial relationship with the following commercial organizations:

- PJ Pickhardt: Viatronix, Braintree, Mindways, VirtuoCTC, Collectar
- M Longino, A Pinchuk, M Banach, J Grudzinski, B Titz, C Jaskowiak: Collectar
- JP Weichert is Founder & Chief Science Officer of Collectar

Funding for the imaging studies were supported by the NCI (R01-158800), UW Institute for Clinical and Translational Research pilot grant (9U54TR000021), and Collectar Biosciences

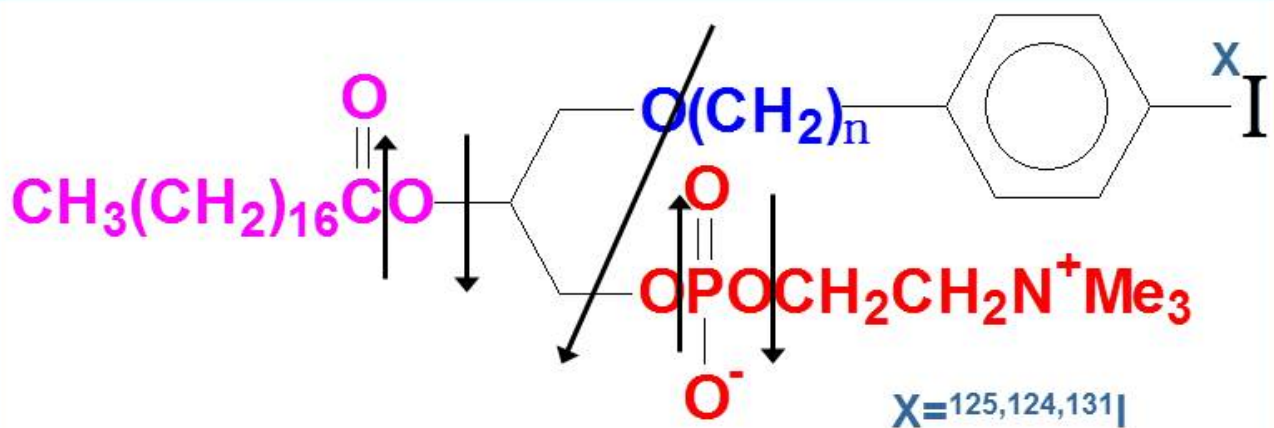
Presented by: Perry J. Pickhardt, MD

PRESENTED AT:



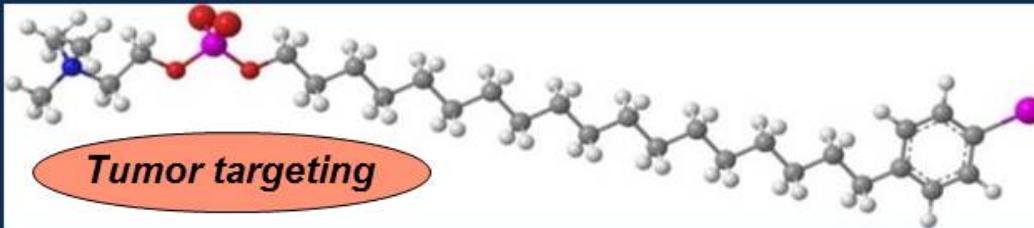


# Background



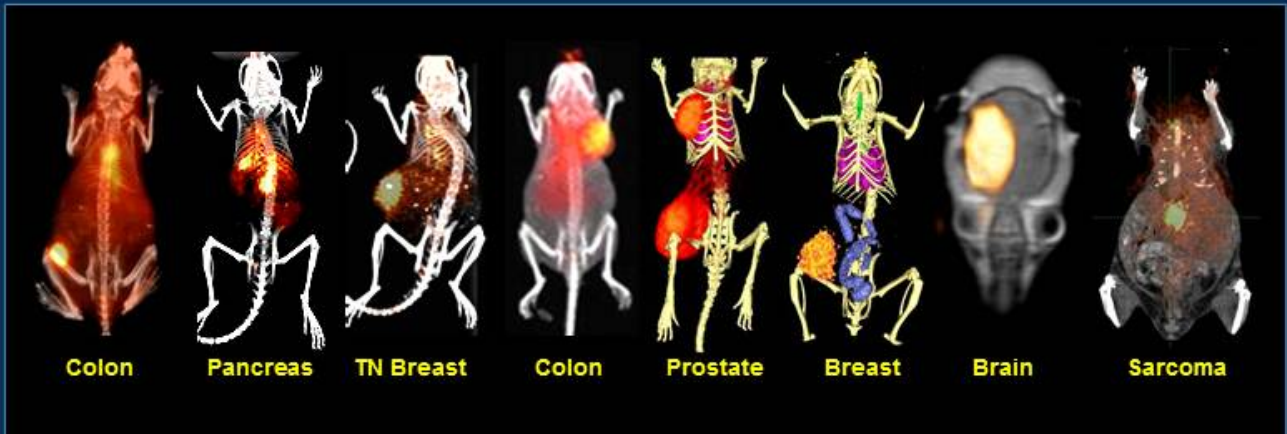
- **CLR1404** – an alkylphosphocholine analog
- Capitalizes on over-abundance of phospholipid ethers present in most cancer cells

# Background



- Tumor-targeting not affected by iodine label
- PET tumor imaging with  $^{124}\text{I}$ -CLR1404
- Molecular radiotherapy with  $^{131}\text{I}$ -CLR1404
- Potential for both imaging diagnosis and therapy = “**diapeutic**” (same agent)
  - Distinct from a “theranostic” approach

# Background



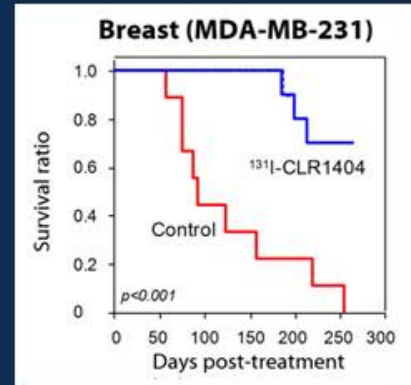
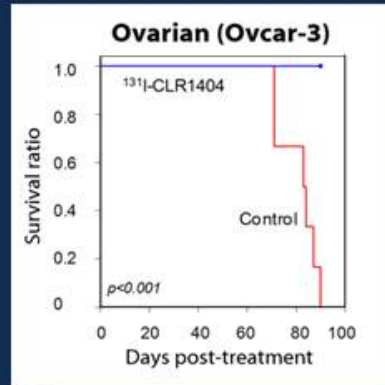
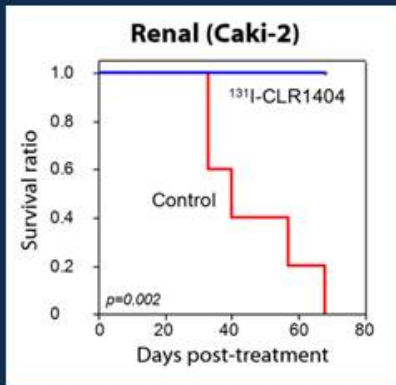
- Prolonged tumor-selective retention in >60 in vivo rodent and human cancer models & cancer stem cell models (“universal”)
- No retention w/in benign or inflamed tissue

Presented by: Perry J. Pickhardt, MD

PRESENTED AT:



# Background



- Significant tumor growth reduction and survival benefit from a single injection of  $^{131}\text{I}$ -CLR1404 in a wide range of human tumor xenograft models
- Weichert JP et al. *Sci Trans Med* (in press)



# Purpose

Report our initial experience with CLR1404 for localization and imaging in a broad spectrum of cancers in early human trials

- **PET/CT imaging with  $^{124}\text{I}$ -CLR1404**
  - Oncologic imaging; compare with  $^{18}\text{F}$ FDG PET
- **SPECT/CT imaging with  $^{131}\text{I}$ -CLR1404**
  - Therapeutic form of this “diapeutic” agent

# Methods

- IRB-approved prospective imaging protocols
- All patients gave signed informed consent
- Early phase trials with  $^{124}\text{I}$ -CLR1404 PET and subtherapeutic  $^{131}\text{I}$ -CLR1404 SPECT
- **Main inclusion criterion:** biopsy-proven refractory advanced solid malignancy
  - Separate trial of primary brain tumors excluded

# Methods

- **$^{124}\text{I}$ -CLR1404 PET/CT scans:**
  - 64-detector-row PET/CT scanner (Discovery VCT, GE Healthcare, Waukesha, WI)
  - Serial imaging out to 5-10 days following the injection of up to 5 mCi of  $^{124}\text{I}$ -CLR1404
  - 2D acquisition mode
  - No correction employed for the  $^{124}\text{I}$  cascade gammas
  - Low-dose non-contrast MDCT for attenuation correction and lesion localization using 140 kV<sub>p</sub> and tube current modulation (70 mA average)



# Methods

- **$^{131}\text{I}$ -CLR1404 SPECT/CT scans:**
  - Serial imaging (Infinia/Hawkeye, GE Healthcare) out 21 days
  - Phase I dosimetry trial not designed to show therapeutic benefit
  - Non-contrast low-dose CT was performed using 140 kV<sub>p</sub> and 2.5 mA

# Methods

- **Review of imaging studies:**
  - All PET/CT and SPECT/CT studies were reviewed on PACS workstation (McKesson) with fusion software (Mirada XD3)
  - Correlation with concurrent  $^{18}\text{F}$ FDG PET/CT in most cases
  - Additional relevant cross-sectional imaging studies were also reviewed

# Initial Findings

**Study Cohort:** 22 patients with metastatic cancer

- Mean age, 60.4 years; 12M, 10F
- Complex prior treatment histories
- **Tumor types:** bronchogenic carcinoma (n=7), colorectal cancer (n=4), prostate cancer (n=3), triple-negative breast cancer (n=2), esophageal cancer (n=2), head & neck squamous cell carcinoma (n=2), pancreatic cancer (n=1), and melanoma (n=1)

# Initial Findings

$^{124}\text{I}$ -CLR1404 PET/CT in 14 patients and  
 $^{131}\text{I}$ -CLR1404 SPECT/CT in 9 patients

- Preferential uptake of  $^{124}\text{I}$ - and  $^{131}\text{I}$ -CLR1404 within metastatic foci with all cancer subtypes
- Persistent retention within metastatic sites, coupled with progressive washout of background activity, favored delayed imaging (6-21 days after single injection).

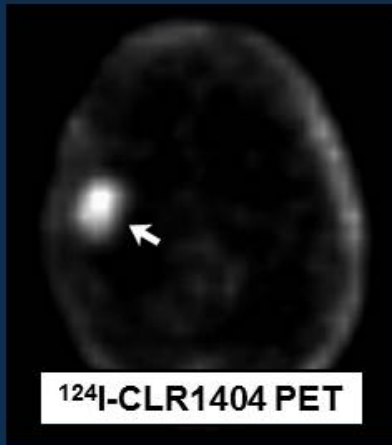


# Initial Findings

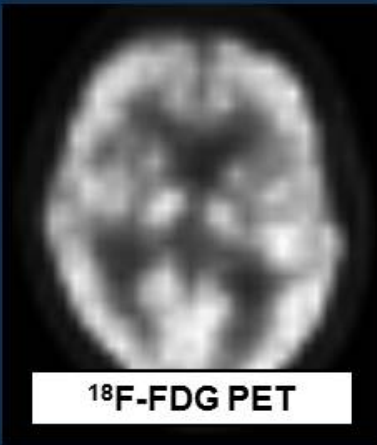
$^{124}\text{I}$ -CLR1404 PET/CT in 14 patients and

$^{131}\text{I}$ -CLR1404 SPECT/CT in 9 patients

- CLR1404 uptake was evident in pulmonary, nodal, skeletal, hepatic, CNS, and other sites of active metastatic disease
- Potential advantages in oncologic imaging over FDG PET included both fewer false-negatives and fewer post-treatment false-positives



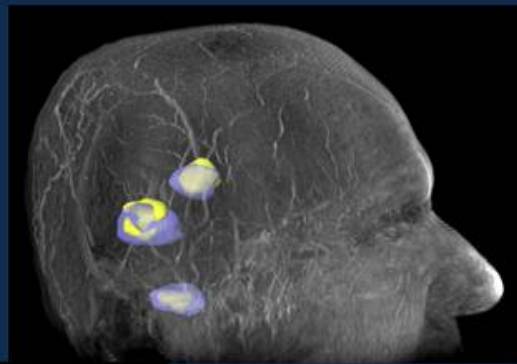
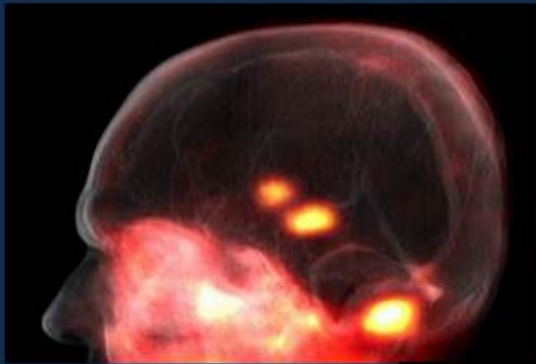
**<sup>124</sup>I-CLR1404 PET**



**<sup>18</sup>F-FDG PET**



**Post-Contrast MR**

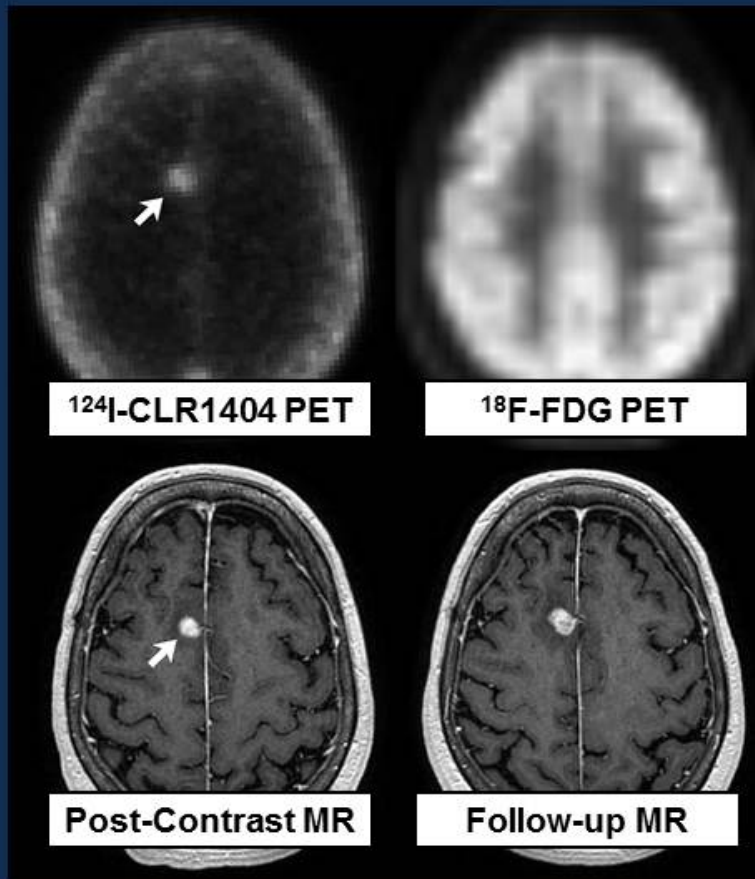


**<sup>124</sup>I-CLR1404 PET**

**70M with bronchogenic carcinoma**

PRESENTED AT:





**60F with recurrent malignant melanoma**

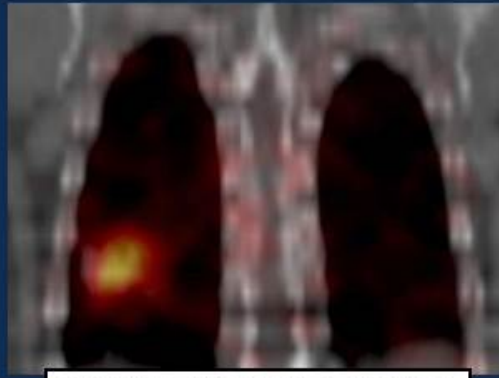
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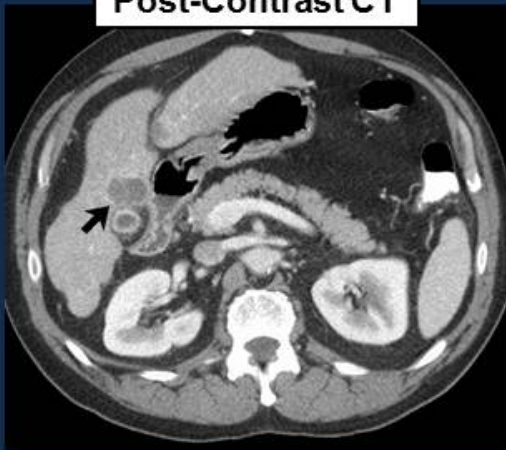




Post-Contrast CT



<sup>131</sup>I-CLR1404 SPECT/CT



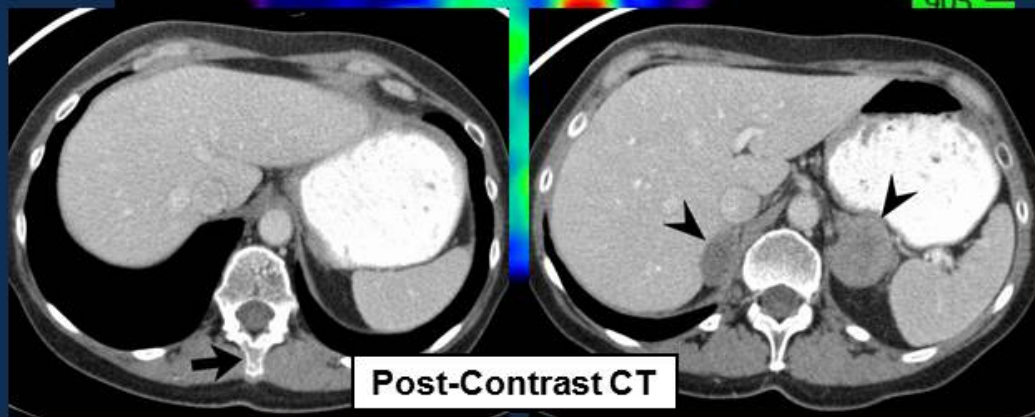
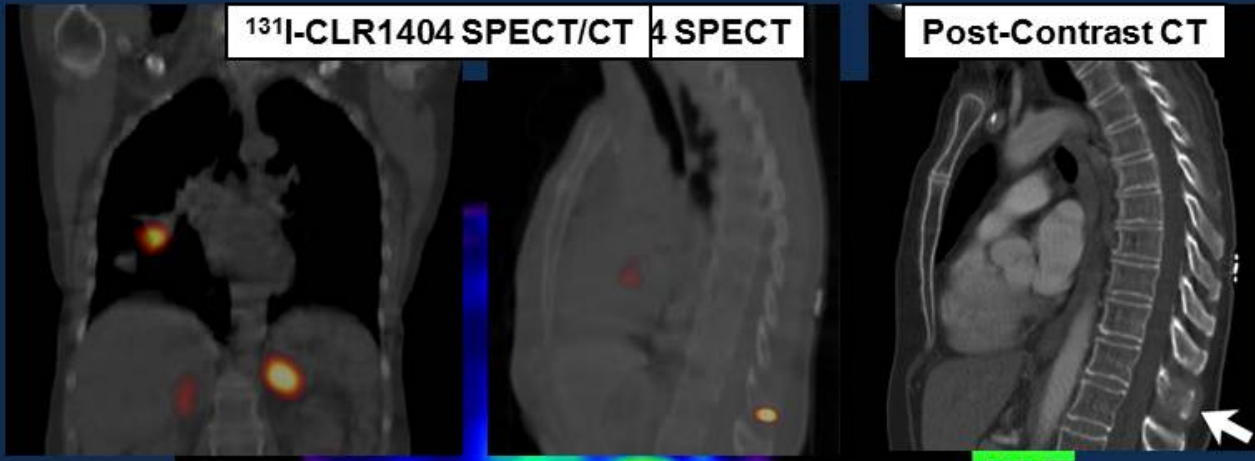
48M with colorectal carcinoma

PRESENTED AT:



**<sup>131</sup>I-CLR1404 SPECT/CT 4 SPECT**

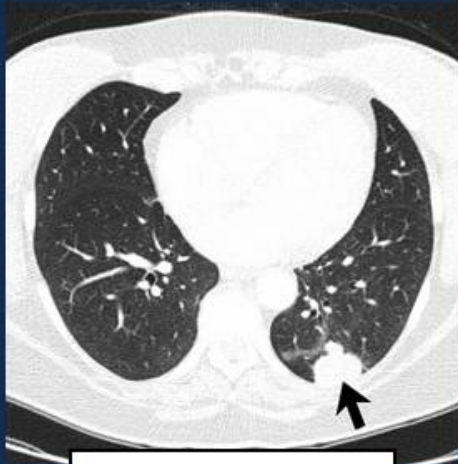
**Post-Contrast CT**



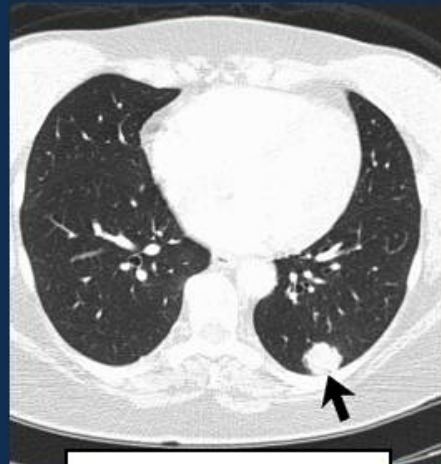
**57F with colorectal carcinoma**

PRESENTED AT:





Post-Contrast CT



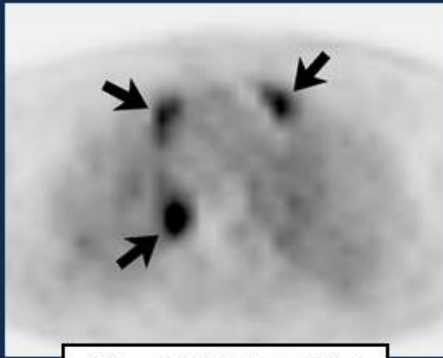
Follow-up CT



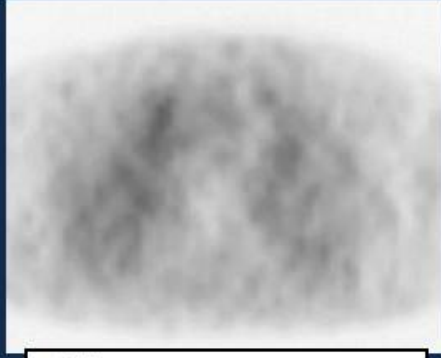
58F with triple-negative breast carcinoma

PRESENTED AT:

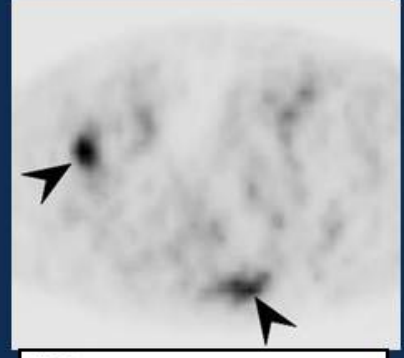




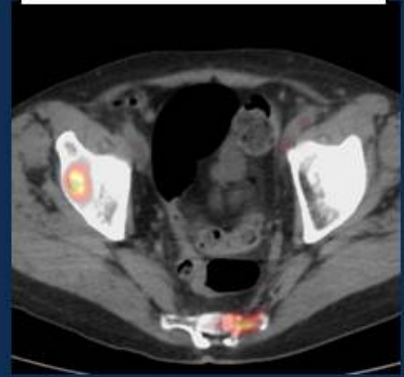
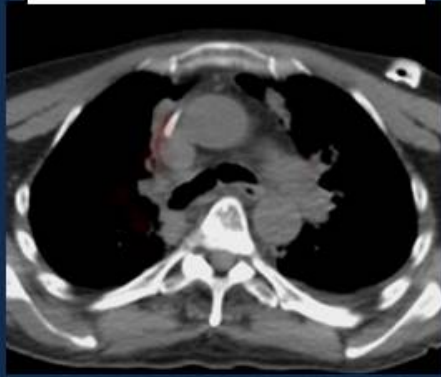
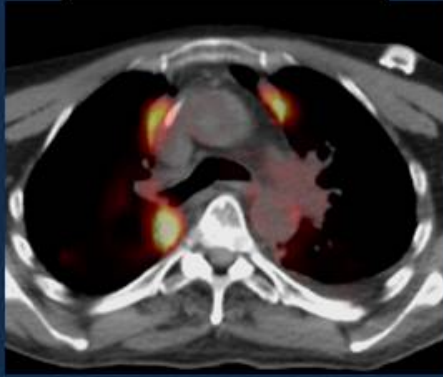
**<sup>18</sup>F-FDG PET/CT**



**<sup>124</sup>I-CLR1404 PET/CT**



**<sup>124</sup>I-CLR1404 PET/CT**



**65M with bronchogenic carcinoma**

PRESENTED AT:



# Limitations

- Early phase investigation in humans
  - Imaging protocols not standardized or optimized, precluding quantitative analysis
  - $^{131}\text{I}$ -CLR1404 doses subtherapeutic
  - Wide variety of cancer types (proof of concept)
- No iodine correction
- 2D mode of acquisition for PET studies

PRESENTED AT:





# Further Research Opportunities

- Selective tumor uptake of CLR1404 with prolonged retention within a broad spectrum of historically difficult-to-treat metastatic cancers
  - Regardless of the site of metastatic disease
- Potential advantages over FDG PET observed:
  - Detection in cases of FDG false-negatives
  - Lack of uptake in cases of FDG false-positives
  - $^{124}\text{I}$ -CLR1404 may improve accuracy for oncologic PET imaging

PRESENTED AT:



# Further Research Opportunities

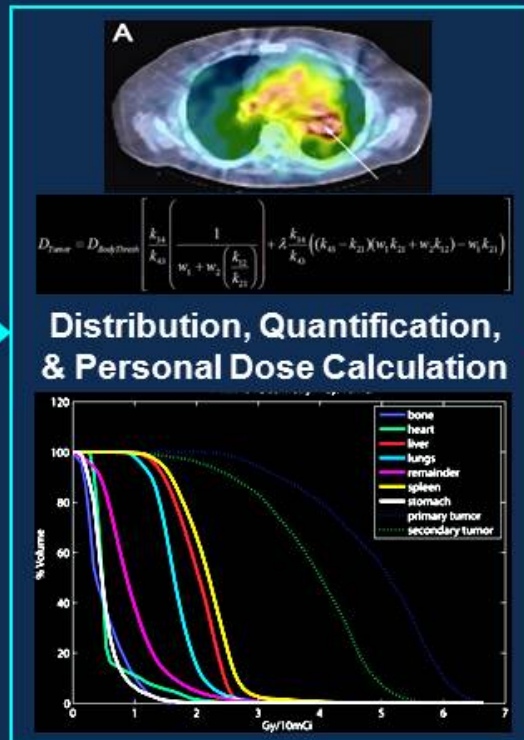
- Combined diagnosis and therapy (“**diapeutic**”) using the *same* molecule (CLR1404) may allow for truly personalized cancer care:
  - Ensuring pre-treatment tumor-specific uptake
  - Providing patient-specific dose planning
  - Enabling treatment-specific imaging surveillance

PRESENTED AT:





# Diapeutic Treatment Paradigm



**<sup>131</sup>I-CLR1404  
Therapy Dose  
Injection**



**Monitor  
Response  
w/ <sup>124</sup>I-CLR404  
PET/CT**

PRESENTED AT:



# Thank You



PRESENTED AT:

