# Nowe możliwości diagnostyki i terapii izotopowej EANM 2022



dr n. med. Maciej Kołodziej Klinika Endokrynologii i Terapii Izotopowej Wojskowy Instytut Medyczny – Państwowo Instytut Badawczy Kierownik Kliniki: prof. dr hab. n. med. Grzegorz Kamiński

MAT-PL-2202548-1.0-11/2022

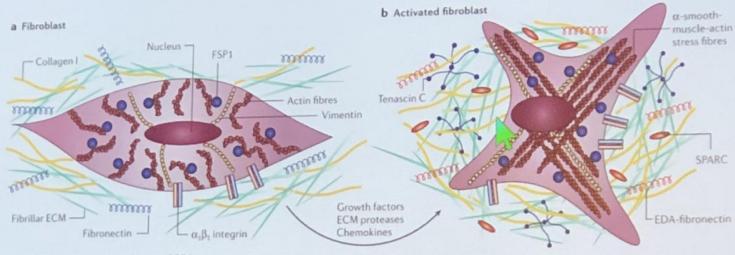


- 1. Diagnostyka i terapia z użyciem FAPI podsumowanie sesji
- 2. Analogi somatostatyny znakowane 18-fluorem Nagroda Marii Curie



# \_00

### Cancer-associated fibroblasts



Kalluri Nature Rev Cancer 2006

#### Normal fibroblasts:

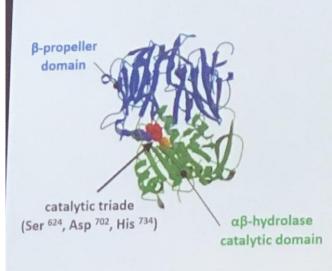
- embedded in the extracellular matrix (ECM) of connective tissue
- support function by the production of collagen
- physiological role during wound healing

#### Activated fibroblasts:

- · changes in morphology
- increased secretion of ECM-proteins, such as Collagen-I, Tenascin C
- pathological role during development, growth and metastases of cancer
- associated with poor prognosis
- •Involved in therapy resistance

### UniversitätsKlinikum Heidelberg

### Fibroblast activation protein



TM domain

7-25

- 170 kDa membrane-bound dimer, gelatinase, seprase, localized to invadopodia
- selective expression in epithelial tumors (breast, colon, pancreas, lung head and neck), bone- and soft tissue sarcomas, wound healing
- no or low expression in normal, adult tissues or in benign
   epithelial tumors
- DPPIV and FAP show similar dipeptidyl peptidase activity;
- •identical domain structure with 50% or 70% sequence identity in the entire sequence or the catalytic domain
  •unique endopeptidase activity to cleave gelatin, collagen type I and a2-antiplasmin, neuropeptide Y, B-natriuretic peptide, substance P, peptide YY

β-propeller domain

99-499

αβ-hydrolase catalytic domain

26-98

500-761

Extracellular domain (26-761)



Title: Target Expression and FAP-Directed Tumour Imaging in a Large, Single-Centre PET Database of 324 Patients and 21 Tumour Entities

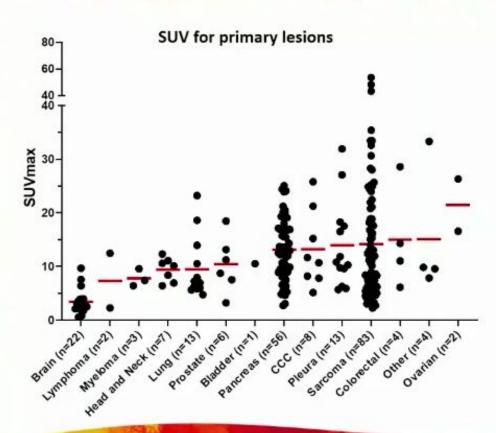
Wolfgang P. Fendler et al.

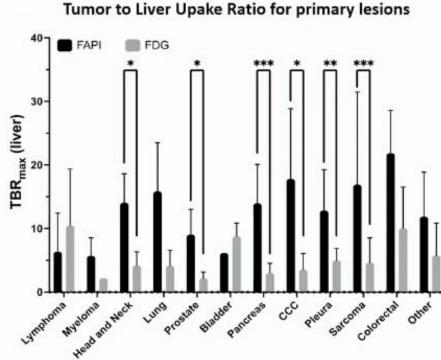
Department of Nuclear Medicine, West German Cancer Center, University Hospital Essen, Essen, Germany



WOJSKOWY INSTYTUT MEDYCZNY

### FAPI and FDG PET for different tumor entities





**OP-354** 



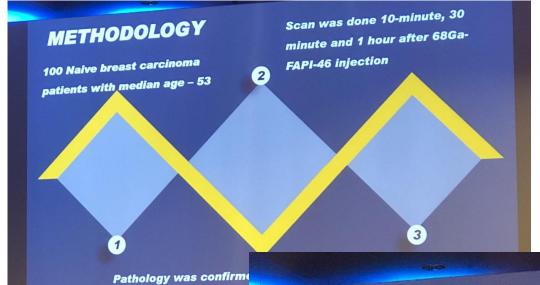


### Abstract #2342

### Comparison of 68Ga-FAPI-46 PET/CT and 18-FDG PET/CT in breast carcinoma staging: Results of 100 patients:

F. Novruzov<sup>1</sup>, E. Mehdi<sup>1</sup>, N. Orucova<sup>1</sup>, G. Aliyeva<sup>1</sup>, F. Giesel<sup>2</sup>, F. Valla<sup>3</sup>, S. Rahimzade<sup>4</sup>, J. Aliyev<sup>5</sup>;

Azerbaijan National Centre of Oncology, Department of Nuclear Medicine, Baku, AZERBAIJAN, 2University Hospital Düsseldorf, Department of Nuclear Medicine, Dusseldorf, GERMANY, 3SOFIE, Director RCM, Totowa, NJ, UNITED STATES OF AMERICA, 4Azerbaijan National Centre Of Oncology, Department of Woman Health, Baku, AZERBAIJAN, 5Azerbaijan National Centre Of Oncology, Department of General Surgery, Baku, AZERBAIJAN.



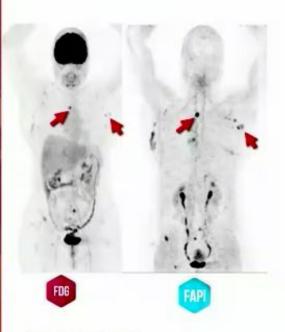
# Time is money ©

When aorta SUV mean values taken as a background, 30<sup>th</sup> minute tumor-to-background ratio was significantly higher than 10<sup>th</sup> minute scan values (p=0.001).

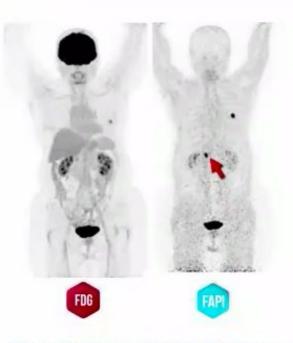




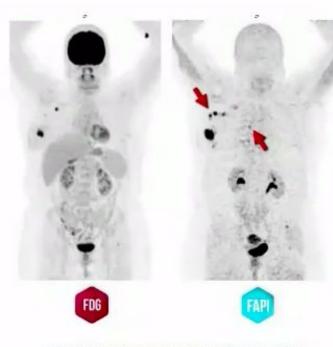
## **FAPI** extra findings



Same lesions but with high tumor-to-background ratio



FAPI reveals extra pancreatic lesion with pathology proven adenocarcinoma



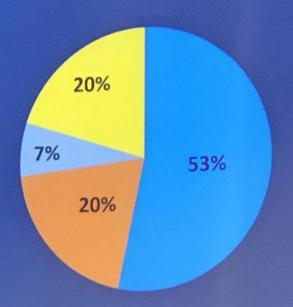
FAPI found extra internal mammarian and axillary lymph nodes

OP-351





# **Extra findings of FAPI**



- in same
  breast, n=8
- Distant lymh
  node
  metastasis,
  n=3

21 out of 100 patients had mild to high FAPI-46 uptake in benign inflammatory and degenerative changes





### CONCLUSIONS

STEP 01 In contrast to 18F-FDG, no diet or fasting in preparation is necessary, and scans can be started even 30 minute after injection

O2

Better tumor-to-background ratio and precis lymph node detection of FAPI-46

STEP 03 Potential tool for targeted radionuclide treatment with beta and alpha emitters in the near future.



# First Results of FAPI-PET/MRI to Assess Response to Neoadjuvant Chemotherapy in Breast Cancer

P. Backhaus<sup>1,2,3</sup>, M. C. Burg<sup>4</sup>, I. Asmus<sup>1</sup>, M. Pixberg<sup>1</sup>, F. Büther<sup>1,2</sup>, H. Breyholz<sup>1</sup>, S. Weigel<sup>4</sup>, P. Stichling<sup>4</sup>, W. Heindel<sup>4</sup>, S. Bobe<sup>5</sup>, P. Barth<sup>5</sup>, J. Tio<sup>6</sup>, M. Schäfers<sup>1,2</sup>



<sup>&</sup>lt;sup>1</sup>Department of Nuclear Medicine, University Hospital Münster, Germany

<sup>&</sup>lt;sup>2</sup>European Institute for Molecular Imaging, University of Münster, Germany

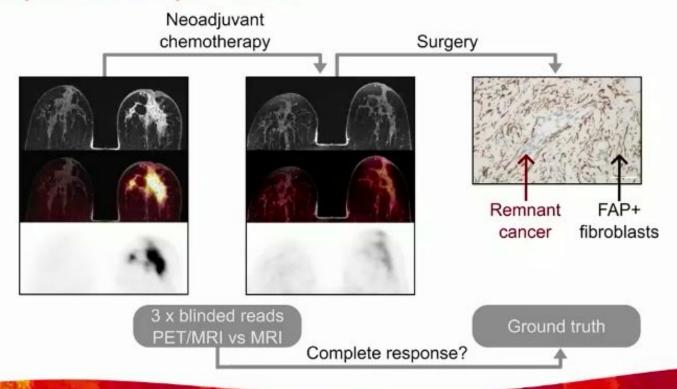
Molecular Imaging and Therapy Service, Department of Radiology, Memorial Sloan Kettering Cancer Center, NYC, USA

<sup>&</sup>lt;sup>4</sup>Clinic for Radiology, University Hospital Münster, Germany

<sup>&</sup>lt;sup>5</sup>Gerhard-Domagk Institute for Pathology, University Hospital Münster, Germany

<sup>&</sup>lt;sup>6</sup>Department of Gynecology & Obstetrics, University Hospital Münster, Germany

# Can FAPI-PET/MRI predict pathological complete response?

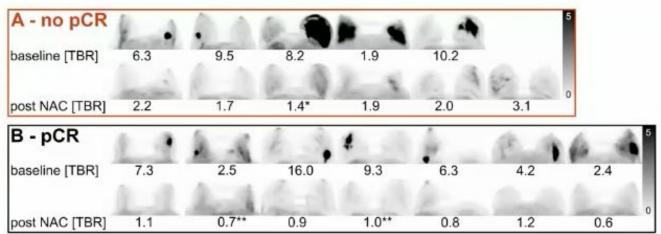


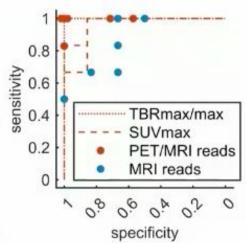






# FAPI-PET/MRI predicts response better than MRI alone in a small study sample





OP-348





# MATERIALS AND METHODS

Prospective interventional monocentric explorative study

Thoracic surgery and interventional pulmonology Patients referred to the Nuclear Medicine department of IRCCS AOU of Bologna, Policlinico S. Orsola from June 2021 to March 2022

#### Inclusion criteria:

- Patients with lung cancer suspicion/new diagnosis and an inconclusive or equivocal 18F-FDG PET/CT
- Age ≥18 years old/All genders
- Signed informed consent

### **Exclusion criteria:**

- More than 14 days between the two PT/CT scans
- Oncological treatment between the two PET/CT scans and in the 3 months prior to them
- Pregnancy/breastfeeding/patients unable to perform PET

FAPI Uptake at 10 (early scan) and 60 minutes (late scan) after injection

### Tumor-to-background ratios

#### For 68Ga-FAPI-46 PET/CT:

TBR: lesionSUVmax/surrounding healthy background SUVmean;

#### For 18F-FDG PET/CT:

TBR L (Liver): lesion SUVmax / healthy liver SUVmean

TBR B (Background): lesion SUVmax / surrounding healthy background SUVmean

### Criteria to define a malignant/suspicious lesion:

**FAPI**: lesion SUVmax > 1.5 x healthy background SUVmax

FDG: lesion SUVmax > blood poolSUVmax

# RESULTS: SUVmax/SUV mean analysis

- 30/32 Patients performed 10' and 60' 68Ga-FAPI-46 PET/CT scan; 1/32 performed the early (10') scan; performed the late (60') scan.
- The same malignant/suspicious lesions were observed for each patient in early and late scan (T, N, M)
- No statistical differences were found comparing FAPI/FDG lesion SUVmax/SUVmean values.

Mean SUVmax	FDG	FAPI 10'	FAPI 60'
T	9,4(range:0,8-35,7)	10,4(range:1,2-31)	10,6(range1,5-31,5)
N	6,1(range0,5-17,1)	7,6(range1-20)	7,6(range1,1-17,7)
M	12(range6,9-17,9)	11,2(range5,5-21,4)	12,8(range3,4-28)

### RESULTS: TBR

**FDG T TBR B** (background) was significantly lower than **FAPI 60'**TBR (p=0,05).

Early scan **FAPI T TBR** values were lower than the late scan ones (p=0,03).



**FDG T, N, M TBR L** (Liver) values were lower than **FAPI TBR** values and a statistical difference was found in evaluating both **T** and **N** parameters (FDG vs FAPI 10';FDG vs FAPI 60';p<0,001).

# **RESULTS:** number of lesions

FAPI and FDG PET/CT agreement:

T = 75%

N = 65.6%

M= 100% (limitation of the small M observation number)

	ACCURACY (FDG;FAPI)	SENSITIVITY (FDG;FAPI)	SPECIFICITY (FDG;FAPI)
T	67%; 89%	70%;100%	50%;25%
N	75%; 90%	60%;100%	80%;93%



### CLINICAL CASE

62-yo female patient with suspected LC + suspected malignant LN on chest CT

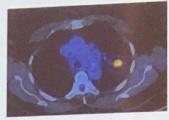
T FDG uptake (SUVmax=10.3), LN with faint equivocal uptake

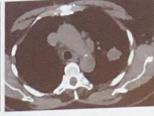
FAPI: T +LN clearly positive (SUVmax=20)

The patient had an adenocarcinoma with positive mediastinal lymphnodes and was not eligible for surgery so underwent chemotherapy

FDG T2aN0M0 FAPI T2aN3M0

### **FDG**

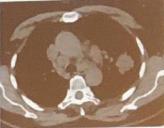






### **FAPI**













FAPI, PSMA and FDG PET/CT in patients with advanced metastatic castration-resistant prostate cancer (mCRPC): a triple tracer comparison

POLICLINICO DI SANT'ORSOLA









# Material and Methods:

- 10 patients with advanced mCRPC underwent [18F]F-PSMA/[68Ga]Ga-PSMA, [18F]F-FDG and [68Ga]Ga-FAPI-46 PET/CT scans for evaluation of RLT options.
- Inclusion criteria for imaging and potential PSMA RLT were:
  - Condition after chemotherapy and Enzalutamide/Abiraterone
  - GFR >50 ml/min/1.73m³ BSA
  - WBC > 3.0/nl, Hemoglobin >8.0 mg/dl and Platelets > 75/nl
- Clinical inclusion criteria for PSMA RLT were:
  - Adequate PSMA uptake in the majority of tumor lesions (at least > liver ([68Ga]Ga-PSMA)/
     > spleen ([18F]F-PSMA))
  - Lack of PSMA/FDG mismatches

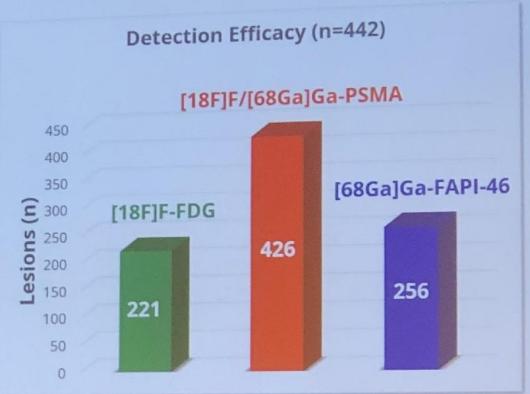




# Lesion-based analysis:

- Detection Efficacy:
  - PSMA demonstrates highest detection rate (p<0.001)</li>
  - FAPI was superior to FDG (p<0.05)</li>

- · Mismatches:
  - PSMA negative/FDG positive: 11 lesions
  - PSMA negative/FAPI positive: 10 lesions







### Conclusion:

# How does the promising tracer FAPI compare to PSMA and FDG...?

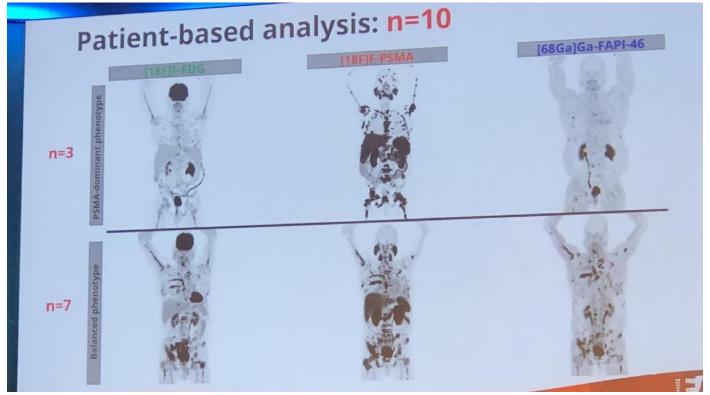
- Lesion-based analysis:
  - PSMA still shows highest detection rate of tumor lesions
  - However, FAPI is significantly superior to FDG regarding detection efficacy

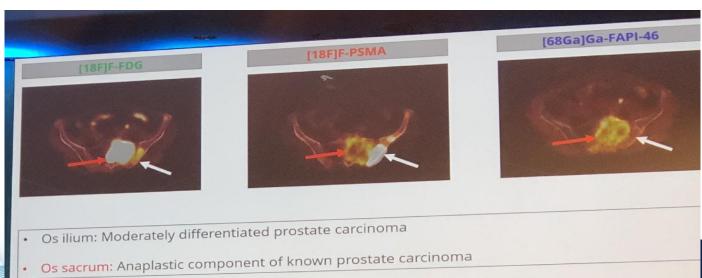
# ...and may FAPI RLT represent a new treatment option?

- Patient-based analysis:
  - Identification of 2 phenotypes: PSMA-dominant and PSMA/FAPI/FDG balanced phenotype









ZNY



# Head-to-head comparison of new FAP binders designed to enhance tumor residence for Targeted Radionuclide Therapy

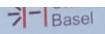
J. Millul<sup>1</sup>, L. Koepke<sup>2</sup>, R.H. Gaonkar<sup>1</sup>, K. Sparrer<sup>2</sup>, R. Mansi<sup>1</sup> and M. Fani<sup>1</sup>

<sup>1</sup>Division of Radiopharmaceutical Chemistry, Universitätsspital Basel, Basel, Switzerland <sup>2</sup>Institute of Molecular Virology, Universitäts Ulm, Ulm, Germany

17th October 2022





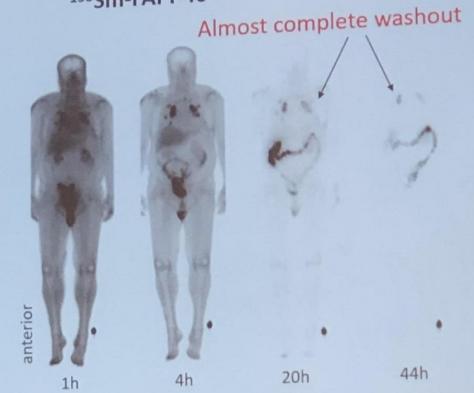


# Main limitation of FAPIs as targeted radiotherapeutics

153Sm-FAPI-46



68Ga-FAPI-04 3h MIP anterior



FAPIs have a fast washout from the tumor which impairs their use as radiotherapeutics



# Proposed solutions from the literature

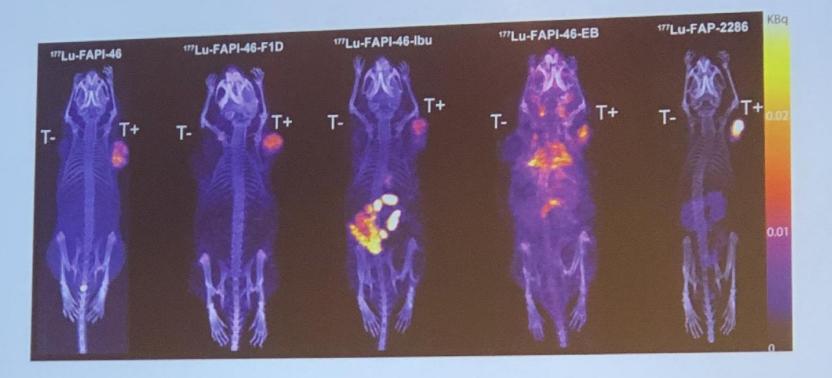
- Increase the residence time of FAPI-46 by dimerizing the binding moiety (DOTA-2P(FAPi)2, DOTAGA.(SA.FAPi)2, ND-bisFAPI and BiOncoFAP)
- Increase the bloodstream circulation by albumin binding (e.g., Evan's Blue conjugates, fatty acid conjugates)
- Different class of molecules: cyclic peptide (FAP-2286)

Aim of the work:

Which of the proposed strategies presents the best therapeutic index?

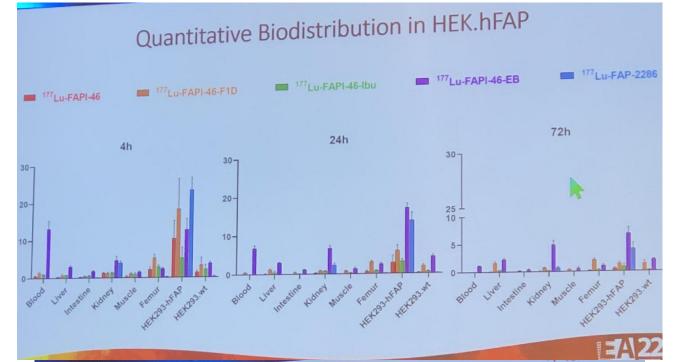


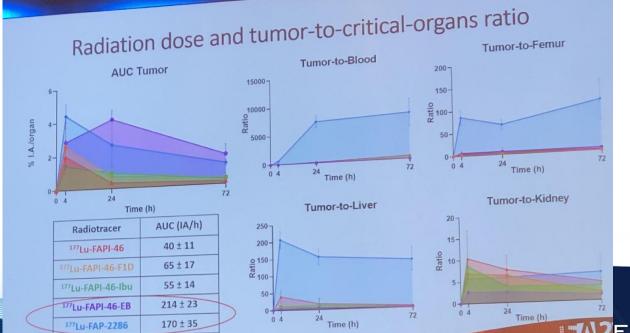
# SPECT-CT imaging in HEK.hFAP (high FAP expression)



4h p.i., 0.5 nmol, 12-15 MBq





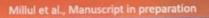




# Conclusions and Outlooks

- Among the tested strategies, the peptide FAP-2286 presents the best therapeutic index
- The study suggests that FAP-2286 could be used as a successful molecule for targeted radiotherapy targeting FAP
- The washout remains a main liability of FAP-targeted radiotherapy
- Further evaluation of the proposed strategies is currently ongoing in animal models bearing low-density FAP tumors







# LuMIERE Trial With 68Ga/177Lu-FAP-2286

- FAP-2286 is a cyclic peptide that binds to FAP with high affinity<sup>1,2</sup>
- LuMIERE (NCT04939610) is an ongoing multicenter open-label phase 1/2 study investigating <sup>177</sup>Lu-FAP-2286 in adult patients with advanced/metastatic solid tumors
- Prolonged tumor retention of <sup>177</sup>Lu-FAP-2286 has been observed in preclinical studies<sup>3</sup>

FAP-2286

<sup>68</sup>Ga-FAP-2286 and <sup>177</sup>Lu-FAP-2286 are investigational agents. FAP, fibroblast activation protein.

1. Zboralski et al. Eur J Nucl Med Mol Imaging. 2022;49:3561-67. 2. Kwan et al. Mol Cancer Ther. 2021;20(12\_Supplement):LBA032\_

3. Baum et al. J Nucl Med. 2022;63:415-23.





# LuMIERE Phase 1 Patient Characteristics and Disposition

at a disting	Total (N=11)
Characteristics	64.0 (27-71)
Median age, years (range)	4 (36.4)
Female, n (%)	
Race, n (%)	5 (45.5)
White	4 (36.4)
Black or African American	
Asian	1 (9.1)
Not reported	1 (9.1)
ECOG PS 0, n (%)	5 (45.5)
Tumor and histological type, n (%)	
Colorectal adenocarcinoma	3 (27.3)
Pancreatic ductal adenocarcinoma	2 (18.2)
Adenoid cystic carcinoma	1 (9.1)
Gallbladder adenocarcinoma	1 (9.1)
Head and neck squamous cell carcinoma	1 (9.1)
Neuroblastoma	1 (9.1)
Pseudomyxoma peritonei of appendiceal origin	1 (9.1)
Soft-tissue sarcoma desmoplastic small round cell tumor	1 (9.1)
3 Prior anticancer therapies, n (%)	11 (100)

- 11 patients imaged with <sup>68</sup>Ga-FAP-2286 and treated with 177Lu-FAP-2286 across cohorts
  - 3.7 GBq (n=3), 5.55 GBq (n=6), and 7.4 GBq (n=2)
- 8/11 of patients discontinued treatment due to disease or clinical progression, physician decision, or withdrawal of consent to treatment
- 1 patient completed 6 doses of 3.7 GBq <sup>177</sup>Lu-FAP-2286 with a confirmed PR and continues without disease progression or subsequent anti-cancer therapy >12 months after first dose
- Treatment in the 7.4 GBq cohort is ongoing

Data cutoff: Oct 3, 2022.

ECOG PS, Eastern Cooperative Oncology Group performance status; FAP, fibroblast activation protein; GBq, gigabecquerel; PR, partial response.



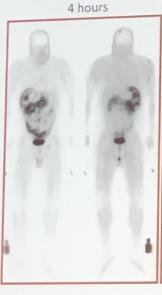


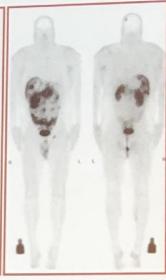
# <sup>177</sup>Lu-FAP-2286 Post-Therapy Imaging Shows Good Tumor Uptake and Retention

47-year-old man with metastatic colon cancer



Pre-therapy FAP-PET









7 days

FAP, fibroblast activation protein; PET, positron emission tomography.



Radiation-absorbe doses, mean (SD), Gy/GBq		177Lu-DOTATATE1	<sup>177</sup> Lu-PSMA-617 <sup>2,3</sup>
Kidneys	0.402 (0.162)	0.654 (0.295)	0.43 (0.16)
Red marrow	0.026 (0.014)	0.035 (0.029)	0.04 (0.02)

# 177Lu-FAP-2286 Adverse Events Assessment

- TEAEs were mostly Gr 1 and 2 across cohorts
- One Gr 4 lymphopenia related to the study drug was observed in 1 patient in the 5.55 GBq cohort and was considered a DLT\*
- No serious AEs and no treatment discontinuations related to the study drug were reported

	Safety population (N=11)		
Most common TEAEs*	Any grade, n (%)	Grade ≥3, n (%)	
At least 1 TEAE	10 (90.9)	5 (45.5)	
Fatigue <sup>b</sup>	5 (45.5)	0	
Anemia <sup>b</sup>	3 (27.3)	0	
Arthralgiab	3 (27.3)	0	
Abdominal distension	2 (18.2)	1 (9.1)	
Back pain	2 (18.2)	0	
Constipation	2 (18.2)	0	
Diarrheab	2 (18.2)	0	
Cholangitis	1 (9.1)	1 (9.1)	
Hyponatremia	1 (9.1)	1 (9.1)	
Increased blood bilirubin	1 (9.1)	1 (9.1)	
Lymphopenia*,b	1 (9.1)	1 (9.1)	
Spinal compression fracture	1 (9.1)	1 (9.1)	

Data cutoff: Oct 3, 2022.

AEs, adverse events; DLT, dose-limiting toxicity; FAP, fibroblast activation protein; Gr, grade; GBq, gigabecquerel; TEAE, treatment-emergent adverse event.





<sup>\*</sup>Patient had grade 2 lymphopenia at baseline.

<sup>\*</sup>TEAEs (any causality) either any grade events occurring in ≥2 patients or any grade ≥3. Treatment-related TEAEs.

### Conclusions

- FAP is a promising theranostic target with expression across many tumor types
- 68Ga-FAP-2286 demonstrated high uptake across multiple types of solid tumors
  - Intra- and interpatient heterogeneity observed
- A total of 11 patients treated to date at doses up to 7.4 GBq
  - Grade 4 lymphopenia related to the study drug was considered a DLT in 1 of 6 patients in the 5.55 GBq cohort
  - No SAEs, treatment discontinuations, or deaths related to the study drug were observed
  - Confirmed partial response in 1 patient who completed 6 doses of 3.7 GBq <sup>177</sup>Lu-FAP-2286
  - Stable disease in 1 patient in the 5.55 GBq cohort who was heavily pretreated
- 177Lu-FAP-2286 demonstrated a manageable safety profile with some preliminary evidence of antitumor activity



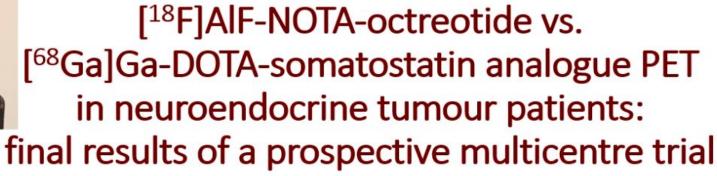












Elin Pauwels<sup>1</sup>, Frederik Cleeren<sup>2</sup>, Térence Tshibangu<sup>2</sup>, Michel Koole<sup>1</sup>, Kim Serdons<sup>1</sup>, Lennert Boeckxstaens<sup>1</sup>, Jeroen Dekervel<sup>3</sup>, Timon Vandamme<sup>4,5</sup>, Willem Lybaert<sup>5</sup>, Bliede Van den Broeck<sup>6</sup>, Paul M. Clement<sup>7</sup>, Karen Geboes<sup>8</sup>, Eric Van Cutsem<sup>3</sup>, Sigrid Stroobants<sup>9</sup>, Chris Verslype<sup>3</sup>, Guy Bormans<sup>2</sup>, Christophe M. Deroose<sup>1</sup>

<sup>1</sup>Nuclear Medicine, University Hospitals Leuven; Nuclear Medicine and Molecular Imaging, Department of Imaging and Pathology, KU Leuven; Leuven, Belgium; <sup>2</sup>Radiopharmaceutical Research, Department of Pharmacy and Pharmacology, KU Leuven; Leuven, Belgium; 3Digestive Oncology, University Hospitals Leuven; Leuven; Leuven, Belgium; 4Center for Oncological Research (CORE), Integrated Personalized and Precision Oncology Network (IPPON), University of Antwerp; Antwerp, Belgium; Soncology, NETwerk Antwerpen-Waasland CoE, Belgium; Nuclear Medicine, Ghent University Hospital; Ghent, Belgium; Ghent, Belgium; Ghent, Belgium; University Hospitals Leuven; Leuven, Belgium; Digestive Oncology, Department of Gastroenterology, Ghent University Hospital; Ghent, Belgium; "Nuclear Medicine, Antwerp University Hospital; Molecular Imaging and radiology, Faculty of Medicine and Health Sciences, University of Antwerp; Wilrijk, Belgium





### Introduction

### [18F]AIF-NOTA-octreotide ([18F]AIF-OC)

European Journal of Nuclear Medicine and Molecular Imaging (2020) 47:3033–3046 https://doi.org/10.1007/s00259-020-04918-4

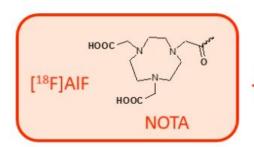
ORIGINAL ARTICLE

#### **ORIGINAL ARTICLE**

[<sup>18</sup>F]AIF-NOTA-octreotide PET imaging: biodistribution, dosimetry and first comparison with [<sup>68</sup>Ga]Ga-DOTATATE in neuroendocrine tumour patients

Elin Pauwels<sup>1,2</sup> • Frederik Cleeren<sup>3</sup> • Térence Tshibangu<sup>3</sup> • Michel Koole<sup>1,2</sup> • Kim Serdons<sup>1,2</sup> • Jeroen Dekervel<sup>4</sup> • Eric Van Cutsem<sup>4</sup> • Chris Verslype<sup>4</sup> • Koen Van Laere<sup>1,2</sup> • Guy Bormans<sup>3</sup> • Christophe M. Deroose<sup>1,2</sup>

Received: 9 April 2020 / Accepted: 7 June 2020 / Published online: 2 July 2020 Springer-Verlag GmbH Germany, part of Springer Nature 2020



Clinical Application of <sup>18</sup>F-AIF-NOTA-Octreotide PET/CT in Combination With <sup>18</sup>F-FDG PET/CT for Imaging Neuroendocrine Neoplasms

Tingting Long, MD, PhD,\* Nengan Yang, BS,\* Ming Zhou, MM,\* Dengming Chen, MD,\* Yulai Li, MD, PhD,\* Jian Li, MD, PhD,\* Yongxiang Tang, MD,\* Zhaoqian Liu, PhD,† Zibo Li, PhD,‡ and Shuo Hu, MD, PhD\*§

(Clin Nucl Med 2019;44: 452-458)



No comparison with [68Ga]Ga-DOTA-TATE/TOC/NOC





### Materials and methods

### Prospective, multicentre trial

Aim: demonstrate non-inferiority of [18F]AlF-OC compared with [68Ga]Ga-DOTA-somatostatin analogue PET in NET patients

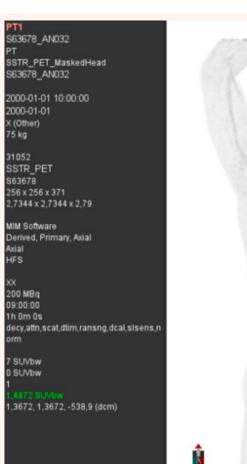
### Inclusion criteria:

- Histologically confirmed NET
- < 3 month interval with routine clinical [68Ga]Ga-DOTA-TATE/NOC/TOC PET</li>
- ≥ 1 known tumour lesion outside head region

A 22 WORLD WESTERS

clinicaltrials.gov identifier: NCT04552847







### Study scan:

Materials and methods

- 4 MBq/kg [<sup>18</sup>F]AlF-OC
- Imaging @ 2 hours p.i.
  - TOF (GE MI4): 3 min/bed
  - Non-TOF (Siemens TP): 4 min/bed

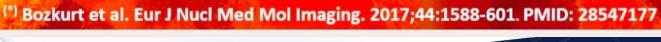
### Clinical routine scan:

- According to EANM guidelines<sup>(\*)</sup>
- [<sup>68</sup>Ga]Ga-DOTA-TATE or –NOC:
  - IA [68Ga]-DOTATATE: 139 ± 27 MBq
  - IA [68Ga]-DOTANOC: 114 ± 20 MBq
- 2.5 min/bed

Randomised, blinded consensus read

**Differential Detection Ratio:** 

$$DDR = DR_{F18} - DR_{Ga68}$$





n = 75

Characteristic		No. (%) of patients or Median (range)	
Age (years)		65 (37–84)	
Sex	М	46 (61.3%)	
	F	29 (38.7%)	
Primary tumour	Intestine	45 (60.0%)	
	Pancreas	18 (24.0%)	
	Lung	7 (9.3%)	
	Unknown primary	4 (5.3%)	
	Paraganglioma	1 (1.3%)	
Tumour grade	G1	35 (46.7%)	
	G1/G2 (i.e. Ki-67<5%)	2 (2.7%)	
	G2	34 (45.3%)	
	G3	2 (2.7%)	
	NA	2 (2.7%)	
Routine tracer	[ <sup>68</sup> Ga]Ga-DOTA-TATE	56 (74.7%)	
	[ <sup>68</sup> Ga]Ga-DOTA-NOC	19 (25.3%)	
Interval between [ <sup>1</sup> [ <sup>68</sup> Ga]Ga-DOTA-TAT		7 (-30 – 32)	

Results





### Primary endpoint

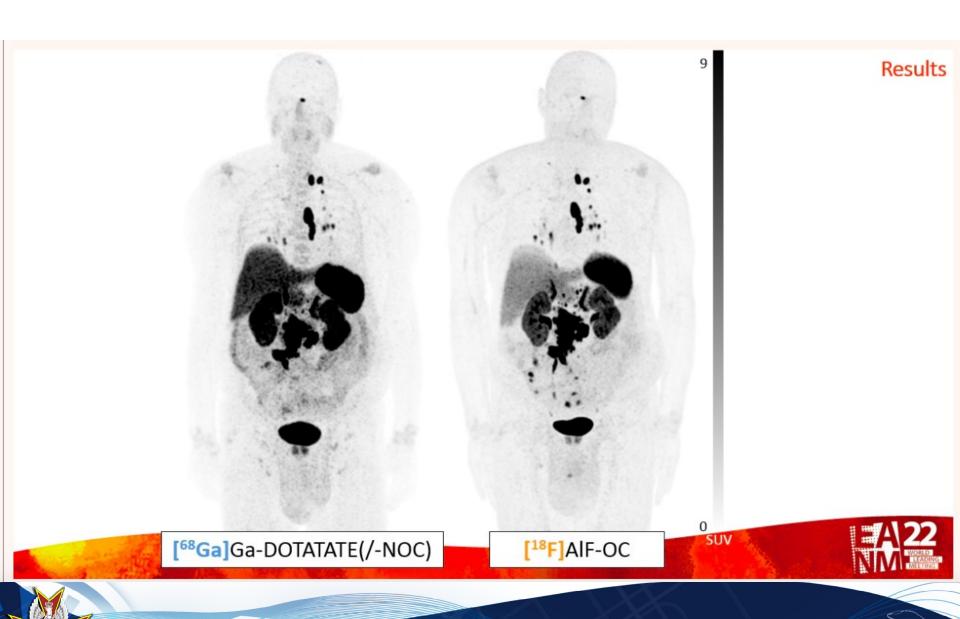
The primary objective will be met if the lower margin of the 95% confidence interval (95% CI) for the mean DDR is higher than -15%.

	[68Ga]Ga-DOTA-TATE/NOC	[18F]AIF-OC	
Number of lesions	3454	4278	N <sub>union</sub> = 4709
mean DR	75.3%	91.1%	

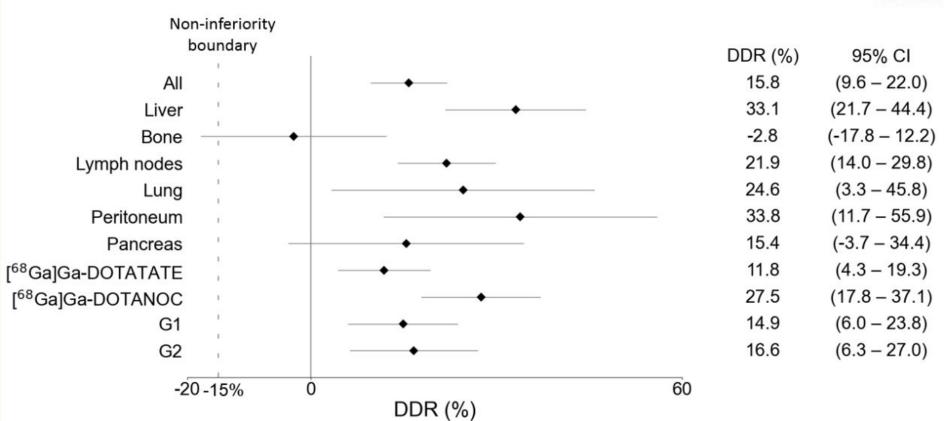
mean DDR = 15.8% (95% CI: 9.6% - 22.0%)







### Results







### Results

# [18F]AIF-OC vs. [68Ga]Ga-DOTA-TATE/NOC

	[68Ga]Ga-DOTA-TATE/NOC	[18F]AIF-NOTA-octreotide	р
Number of lesions	3454	4278	< 10 <sup>-4</sup>
mean DR	75.3 %	91.1 %	< 10 <sup>-5</sup>
mean SUV <sub>max</sub> (*)	22.4 ± 15.6	20.0 ± 14.5	0.067
mean TBR <sup>(*)</sup>	25.1 ± 32.7	31.7 ± 36.5	0.0013

<sup>(\*)</sup> mean values on the patient level for quantifiable lesions detected on both scans (N = 3034), incl. head region





### Conclusion

### Conclusion

[18F]AIF-OC vs. [68Ga]Ga-DOTA-TATE/NOC PET: mean DDR = 15.8% (95% CI: 9.6% – 22.0%)

### [18F]AIF-NOTA-octreotide:

- non-inferior, even <u>superior</u> compared with [68Ga]Ga-DOTATATE/NOC
- validated alternative for clinical practice SSTR PET







# Congrats Elin!





Marie Skłodowska-Curie Award 2022



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Dziękuję za uwagę

