XVII Encuentro de Cooperación Farma-Biotech Proyectos Avanzados

# GOAT (Ghrelina-O-aciltransferasa), nuevo biomarcador en orina para el diagnóstico de cáncer de próstata





Madrid, 28th November, 2018





MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española



# **Content**

- 1. The Institution and the team
- 2. The Product
  - a) Target Indications
  - b) Innovative mechanisms of action
  - c) Differential features facing the market
  - d) Current status of development
  - e) IPR protection
  - f) Pitfalls & Risks to be considered
- 3. Partnering Opportunities











# **Content**

- 1. The Institution and the team
- 2. The Product
  - a) Target Indications
  - b) Innovative mechanisms of action
  - c) Differential features facing the market
  - d) Current status of development
  - e) IPR protection
  - f) Pitfalls & Risks to be considered
- 3. Partnering Opportunities













1. The Institution

## University of Cordoba

- Established in 1972
- 11 Faculties
- Students:
  - 16,694 undergraduate students
  - 1,245 in Master's Programmes
  - 1,384 in Doctoral Programmes
- PhD
  - 1,384 PhD candidates
  - 228 International PhD candidates
  - 125 PhD dissertations/year
  - 21% of them with European PhD award
  - U-Ranking (from Ivie/BBVA fundation): <u>top 6 in Spain</u> (top 1 in Andalusia; Total of 61 public and private Universities)























#### 1. The Institution



#### <u>5 scientific programmes</u>





MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española







#### 1. The team

#### Department of Cell Biology, Physiology and Immunology (UCO) GC27: OncObesity and Metabolism (IMIBIC)



Traslational group (basic and clinical researchers)

Research topics:

- \* Neuro-endocrine/metabolic (dys)regulation in tumoral pathologies, including:
  - Prostate cancer
  - Breast cancer
  - Pituitary adenomas
  - Neuroendocrine tumors

UNIVERSIDAD D. CORDOR.

- Gastro-entero-pancreatic
- Lung NETs
- Thyroid
- Adrenal

#### motivated and committed Brain tumors Prize of the Spanish Society of with the project Hepatocarcinoma Endocrinology and Nutrition for the research career of the group **Department of Innovation (IMIBIC)** SFFN Begoña Roibas da Torre Sociedad Española de **Rosa Natera** Endocrinología y Nutrición **farmai**ndustria MEDICAMENTOS INNOVADORES MAIMONIDES BIOMEDICA RESEARCH INSTITUTE OF **IMIBIC** Plataforma Tecnológica Española

Team fully capable,

#### 1. The team

Other associated research groups at the HURS, UCO and IMIBIC



- **Blood/Urine samples**
- Collaborative projects
- Río Hortega PhD • student



Hospital Universitario Reina Sofia





MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española





**Internal Medicine Service** 



•

Pathological analysis

**Blood/Urine samples** 

Collaborative projects

- Collaborative projects
- PhD students



1. The team

#### Background in the identification of novel tumoral biomarkers







Plataforma Tecnológica Española



UNIVERSIDAD D CORDOBA

1. The team

#### Background in the identification of novel tumoral biomarkers



2. Novel biomarkers in other tumoral pathologies



UNIVERSIDAD D CORDOBA

1. The team







#### Experience in research transfer



# Proyectos de desarrollo tecnológico en salud (DTS)



Instituto de Salud Carlos III - Acuse de recibo

DATOS GENERALES		
Asunto:	Solicitud del expediente: DTS17/00061	
Procedimiento:	Acción Estratégica de Salud, Ayudas y Subvenciones	
Órgano destinatario:	SG de Evaluación y Fomento de la Investigación	
Número de expediente:	ISCIII-AES-2017/001207	
Número de asiento registral;	2017999E001282	
Fecha:	25/05/2017 11:19:29	





Córdoba (IMIBIC / UCO)

MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española

2017







# **Content**

- 1. The Institution and the team
- 2. The Product
  - a) Target Indications
  - b) Innovative mechanisms of action
  - c) Differential features facing the market
  - d) Current status of development
  - e) IPR protection
  - f) Pitfalls & Risks to be considered
- 3. Partnering Opportunities











### 2. The Product: a) Target Indications



**IMIBIC** 

**farma**industria

UNIVERSIDAD D. CORDOR

GOBIERNO DE ESPANA V COMPETITIVIDAD



K

#### 2. The Product: a) Target Indications



- Non-invasive (plasma levels)
- Specific and sensible
- Relevant to the decision
- Prognostic biomarker

$\Lambda$		
Test characteristic	PSA (normal <4 NG/ML)	PSA (normal <3 NG/ML)
Test positivity (%)	12	18
Cancer detection rate (%)	3	4
Sensitivity (%)	21	32
Sensitivity (%) for high grade cancer, i.e., gleason score >8	51	68



"Elevated PSA levels may be driven by benign conditions (i.e. prostatic hyperplasia or prostatitis)"



#### 2. The Product: b) Innovative mechanisms of action



#### 2. The Product: b) Innovative mechanisms of action



## 2. The Product: b) Innovative mechanisms of action



Hormaechea-Agulla et al. / Cancer Letters 383 (2016)

![](_page_15_Figure_4.jpeg)

UNIVERSIDAD D CORDOBA

Non diabetic

patients GOAT ng/ml 6.

2

Control

(n=19)

## 2. The Product: b) Innovative mechanisms of action

![](_page_16_Figure_2.jpeg)

**GOAT** levels can be detected in **plasma**, where it discriminates between prostate cancer patients and controls.

Hormaechea-Agulla et al. / Cancer Letters 383 (2016)

\*\*\*

PCa

(n=60)

100

80

60

40

20

0

0

20

40

100% - Specificity%

Sensitivity%

# The difference was even bigger in the non-diabetic population

![](_page_16_Picture_5.jpeg)

![](_page_16_Picture_6.jpeg)

MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española

![](_page_16_Picture_8.jpeg)

![](_page_16_Picture_9.jpeg)

![](_page_16_Picture_10.jpeg)

AUC=0.854

p<0.0001

60

80 100

#### 2. The Product: b) Innovative mechanisms of action

**GOAT** in prostate cancer

Hormaechea-Agulla et al. / Cancer Letters 383 (2016)

![](_page_17_Figure_4.jpeg)

Most importantly, **GOAT** levels can be detected in **urine**, where it discriminates between prostate cancer patients and controls.

![](_page_17_Picture_6.jpeg)

![](_page_17_Picture_7.jpeg)

![](_page_17_Picture_9.jpeg)

![](_page_17_Picture_10.jpeg)

![](_page_17_Picture_11.jpeg)

#### 2. The Product: c) Differential features facing the market

**GOAT** better diagnostic tool than PSA:

- Higher sensitivity than previous methods
  - GOAT levels in plasma: (cut-off 1.22 ng/mL) <u>81.1% sensitivity</u>
  - GOAT levels in urine: (cut-off 1.061 ng/mL) 75% sensitivity
  - **PSA** levels in **plasma**:
    - Cut-off 3 ng/mL: 32% sensitivity for any prostate cancer and <u>68%</u> for high-grade cancers (Gleason ≥8)

TABLE 2. PSA Screening Test Characteristics as a Function of Threshold for a Positive Test Wolf et al., CA Cancer J Clin 2010

TEST CHARACTERISTIC	PSA (NORMAL <4 NG/ML)	PSA (NORMAL < 3 NG/ML)
Test Positivity (%)	12	18
Cancer Detection Rate (%)	3	4
Sensitivity (%)	21	32
Sensitivity (%) for High Grade Cancer, i.e., Gleason Score $\geq$ 8	51	68
Specificity (%)	91	85
Positive Predictive Value (%)	30	28

ACS Guideline for the Early Detection of Prostate Cancer -

#### Easy to assess

GOAT levels can be measured using simple, easy to use and rapid methods: ELISA plate reader in contrast to other assays that require qPCR or automated systems

## 2. The Product: c) Differential features facing the market

	GOAT	PSA	PCA3	4KScore	SelectMDx
Assay type	ELISA	ELISA	PCR	ELISA	PCR
Sample type	Plasma, urine	Plasma	Urine (post- massage)	Plasma	Urine
Time	Few hours	Few hours	14 Days	Few days	Days
Resources needed	Plate reader	Plate reader	External assay	External assay	External assay
Sensitivity	81%	32%	65%	89%	_
Specificity	68%	85%	73%	61%	_
Hormaechea-Agulla et al., Cancer Lett 2016 10.1016/j.canlet.2016.09.022 Wolf et al., CA Cancer J Clin 2010					http://mdxhealth.com
				<b>farmai</b> ndustri	
COMPETITIVI	DAD Plataf	orma Tecnológica Española		UNIVERSIDAD & CORDO	

#### 2. The Product: d) Current status of development

![](_page_20_Picture_2.jpeg)

Home > Projects > Novel non-invasive biomarker for prostate cancer

Novel non-invasive biomarker for prostate cancer

# Proyectos de desarrollo tecnológico en salud (DTS)

![](_page_20_Picture_6.jpeg)

#### Instituto de Salud Carlos III - Acuse de recibo

DATOS GENERALES		
Solicitud del expediente: DTS17/00061		
Acción Estratégica de Salud. Ayudas y Subvenciones		
SG de Evaluación y Fomento de la Investigación		
ISCIII-AES-2017/001207		
2017999E001282		
25/05/2017 11:19:29		
	Solicitud del expediente: DTS17/00061 Acción Estratégica de Salud. Ayudas y Subvenciones SG de Evaluación y Fomento de la Investigación ISCIII-AES-2017/001207 2017999E001282 25/05/2017 11:19:29	

![](_page_20_Picture_9.jpeg)

![](_page_20_Picture_10.jpeg)

MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española

![](_page_20_Picture_12.jpeg)

![](_page_20_Picture_13.jpeg)

#### Resolución definitiva de la Convocatoria del segundo plazo de Ayudas de la Modalidad II: Protección de Resultados de la Investigación

#### III Plan Propio Galileo de Innovación y Transferencia de la Universidad de Córdoba

Tras la publicación en el Boletín Oficial de la UCO, con fecha 12/10/2017, de la relación provisional del segundo plazo de ayudas de la Modalidad II: Protección de resultados de la investigación concedidas de acuerdo con los criterios establecidos en las bases de la convocatoria del III Plan Propio Galileo de Innovación y Transferencia, y una vez finalizado el plazo de presentación de alegaciones, el Consejo de Gobierno aprueba la siguiente relación de ayudas concedidas por la Comisión de Innovación y Transferencia:

Solicitante	Importe solicitado	Importe concedido
Gil Ribes, Jesús Antonio	5.000,00€	5.000,00 €
Guerrero Vaca, Guillermo	3.309,35€	3.309,35 €
Luque Huertas, Raúl Miguel	5.000,00€	5.000,00 €
Ramos Ruiz, José	5.000,00€	5.000,00 €

![](_page_20_Picture_18.jpeg)

![](_page_20_Picture_19.jpeg)

![](_page_20_Picture_20.jpeg)

## 2. The Product: d) Current status of development

#### Valorization Strategy

## Current Status: promising results

- 113 plasma samples cohort
- 113 urine samples cohort
- 64 tissue samples cohort
- Good preliminary results

![](_page_21_Picture_8.jpeg)

Valorize this tool

#### **Expected Results**

- 1) Expand to 1000-1300 plasma/urine samples cohort
- 2) Perform a regulatory and transfer plan and a budget Impact study

Generate a <u>STRONG PROOF OF CONCEPT</u> and a way for the <u>TRANSFERRING OF THE ASSET</u>

#### Goal and associated main objectives

- 1. To obtain a strong proof-of-concept (diagnostic tool: >1,000-1,300 patients, MULTICENTER study; Explore the feasibility and validity of GOAT as prognostic tool compared with PSA).
- 2. To develop and optimize new antibodies against GOAT (to improve the screening ability and the sensibility of the technology => development of a series of diagnostic kits)
- 3. To continue and implement the protection of the asset (patent).

**4.** To perform a Market Research and Budget Impact study comparing GOAT with the gold standard, PSA, and other available technologies and its impact in the healthcare system.

5. Delineate a Business Plan to be presented to the investors.

![](_page_21_Picture_19.jpeg)

![](_page_21_Picture_20.jpeg)

MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española

![](_page_21_Picture_22.jpeg)

![](_page_21_Picture_23.jpeg)

![](_page_21_Picture_24.jpeg)

#### 2. The Product: d) Current status of development

![](_page_22_Figure_2.jpeg)

## 2. The Product: d) Current status of development

#### **GOAT** in prostate cancer

GOAT, but not PSA, levels can <u>discriminate between</u> <u>PCa patients and controls with high sensitivity</u>, in the so-called <u>grey zone of PSA (3-10ng/ml)</u>

![](_page_23_Figure_4.jpeg)

GOAT levels positively correlates with
 <u>Gleason Score</u>

Potential utility as Prognostic value

MEDICAMENTOS INNOVADORES

Plataforma Tecnológica Española

![](_page_23_Figure_7.jpeg)

UNIVERSIDAD D CORDOBA

2. The Product: d) Current status of development

 GOAT outperforms the capacity of the actual gold-standar (PSA) to predict the presence of PCa, specially in the case of those patients in the so-called grey-zone
 that GOAT levels also may also be used as a prognostic tool of PCa agresiveness

> Therefore, GOAT levels could represent a novel PCa biomarker that can complement, or even substitute, PSA for PCa detection.

![](_page_24_Picture_4.jpeg)

![](_page_24_Picture_5.jpeg)

![](_page_24_Picture_6.jpeg)

MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española

![](_page_24_Picture_8.jpeg)

![](_page_24_Picture_9.jpeg)

![](_page_24_Picture_10.jpeg)

#### 2. The Product: d) Current status of development

![](_page_25_Picture_2.jpeg)

#### **Eladio Crego Gil**

Consultant at EFT Consulting Santiago de Compostela, Galicia, España Servicios financieros

 Actual
 EFT Consulting, Mtrap Inc, Nasasbiptech

 Anterior
 UNINVEST, Unirisco Galicia, Hijos d

 Educación
 ESADE

# Proyectos de desarrollo tecnológico en salud (DTS)

GOBERNO PRISTRUO DE ERANA DE ECONORA NOUTRA VCOPETITIMO D

Instituto de Salud Carlos III - Acuse de recibo

#### DATOS GENERALES

Regulatory strategy roadmap for the diagnostic kit for GOAT Project

**Roadmap report** 

![](_page_25_Picture_12.jpeg)

![](_page_25_Picture_13.jpeg)

MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española

![](_page_25_Picture_15.jpeg)

![](_page_25_Picture_16.jpeg)

Biomed

GENESIS

Project code 18-026-01

FIPSE FUNDACIÓN PARA LA INNOVACIÓN Y LA PRO EN SALUD EN ESPARA

Estudios de Viabilidad de las innovaciones en Salud

**GOAT Project** 

![](_page_25_Picture_17.jpeg)

#### 2. The Product: e) IPR protection

Level of development and protection of the asset

![](_page_26_Picture_3.jpeg)

"GHRELINA-O-ACIL TRANSFERASA (GOAT) Y SUS USOS"

Spanish Patent (P201531731) was requested on December 27<sup>th</sup>, 2015

Número de solicitud:	P201531731
Fecha de recepción:	27 noviembre 2015, 15:41 (CET)
Oficina receptora:	OEPM Madrid
Su referencia:	901 049
Solicitante:	Universidad de Córdoba
Número de solicitantes:	2
País:	ES
Título:	Ghrelina-O-acil transferasa (GOAT) y sus usos
	1

- Patent extension to <u>PCT</u> was carried out on November 28<sup>th</sup>, 2016, patent number: PCT/ES2016/070844.

Número de presentación	300214586	
Solicitud Número PCT	PCT/ES2016/070844	
Fecha de recepción	28 noviembre 2016	
Oficina Receptora	Oficina Española de Patentes y Marcas, Madrid	
Referencia del expediente del solicitante o mandatario	901 871	
Solicitante	UNIVERSIDAD DE CÓRDOBA	
Número de solicitantes	2	
País	ES	DMEDICAL TUTE OF
Título de la invención	Ghrelina-O-acil transferasa (GOAT) y sus usos	

![](_page_26_Picture_9.jpeg)

![](_page_26_Picture_10.jpeg)

![](_page_26_Picture_11.jpeg)

#### 2. The Product: f) Pitfalls & Risks to be considered

#### Risk Plan

KOLs: key opinion leaders

POSITIVE	NEGATIVE
HIGH IMPORTANCE	HIGH IMPORTANCE
ΝΔ	<ul> <li>Appearance of a good novel biomarker</li> </ul>
NA	- KOLs negative opinion of the asset
MEDIUM IMPORTANCE	MEDIUM IMPORTANCE
Early licencing of the asset	- Industry not interested in GOAT after valorization
- Early licensing of the asset	- Negative Market Research or Budget Impact study
LOW IMPORTANCE	LOW IMPORTANCE
NA	NA

#### **Contingency Plan** (two main risks)

- Negative Market Research or Budget Impact study:
  - To implement methodological improvements
  - To explore putative combinations with other markers in order to increase the power of the asset.
- KOLs negative opinion of GOAT.
  - To prepare scientific papers and documents comparing PSA with GOAT in order to convince scientific society of GOAT abilities and possible impact.

![](_page_27_Picture_11.jpeg)

![](_page_27_Picture_12.jpeg)

![](_page_27_Picture_14.jpeg)

![](_page_27_Picture_15.jpeg)

![](_page_27_Picture_16.jpeg)

# **Content**

- 1. The Institution and the team
- 2. The Product
  - a) Target Indications
  - b) Innovative mechanisms of action
  - c) Differential features facing the market
  - d) Current status of development
  - e) IPR protection
  - f) Pitfalls & Risks to be considered
- 3. Partnering Opportunities

![](_page_28_Picture_11.jpeg)

![](_page_28_Picture_12.jpeg)

![](_page_28_Picture_14.jpeg)

![](_page_28_Picture_15.jpeg)

![](_page_28_Picture_16.jpeg)

#### 3. Partnering Opportunities

"COLLABORATION is the best way to became the traslational research into reality."

#### Licensing strategy

We are looking for an early license to a company that can finance the clinical development

#### **Co-development**

We are looking for an collaboration agreement with the industry which allows:

Analysis of combination of GOAT with other biomarkers

Development of a new ELISA kit

We offer you the opportunity to participate in the development, manufacturing and explotation of an strategic opportunity in prostate cancer biomarker area.

#### Commercialization

We are looking for a company that would also carry out the market launch

![](_page_29_Picture_12.jpeg)

![](_page_29_Picture_13.jpeg)

MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española

![](_page_29_Picture_15.jpeg)

![](_page_29_Picture_16.jpeg)

![](_page_29_Picture_17.jpeg)

XVII Encuentro de Cooperación Farma-Biotech Proyectos Avanzados

# GOAT (Ghrelina-O-aciltransferasa), nuevo biomarcador en orina para el diagnostico de cáncer de próstata

![](_page_30_Picture_2.jpeg)

![](_page_30_Picture_3.jpeg)

Madrid, 28th November, 2018

![](_page_30_Picture_5.jpeg)

![](_page_30_Picture_6.jpeg)

MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española

![](_page_30_Picture_8.jpeg)