19 de noviembre de 2025

BRITE-A, an advanced nanosystem for the precision treatment of obesity

BRITE-A
Shaping a Healthier Future

ibima
Plataforma BIONAND

Rajaa El Bekay

MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES
AGENCIA ESTATAL DE INVESTIGACIÓN

MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

farmaindustria

Content

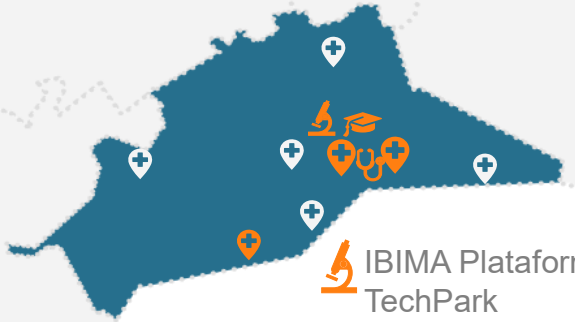
1. IBIMA Plataforma BIONAND
2. The Product: BRITE-A
    a) Target Indication: Obesity
    b) Innovative mechanism of action: induction of adipose-tissue browning
    c) Differential features vs. current therapies
    d) Development Status: Validation in an animal model (preclinical)
    e) IP protection: Two patent families.
    f) Pitfalls & Risks to consider
3. Partnering Opportunities

The Institution

The Institute of Biomedical Research of Málaga and Nanomedicine Platform (IBIMA–Plataforma BIONAND) is a health research institute accredited by Spain's Institute of Health Carlos III (ISCIII)

The Institution: Our Location

- Located in the province of Málaga, the institute is centered around three main hospitals — Regional University Hospital of Málaga, Virgen de la Victoria University Hospital, and Costa del Sol University Hospital — together with the University of Málaga
- High-level research center at Málaga TechPark and two dedicated Clinical Trials Units, based at the Virgen de la Victoria University Hospital and the Regional University Hospital of Málaga



IBIMA Plataforma BIONAND. Málaga TechPark

Regional, Virgen de la Victoria and Costa del Sol Hospitals

University of Malaga

Clinical Trials Units

Other public hospitals in the province

1,300 researchers

76 groups

9,600m² for research

The Research Group:
Endocrinology and Nutrition, Diabetes, and Obesity

Basic researchers

+

Clinical researchers

(Endocrinology and Nutrition Clinical Unit from the Regional University Hospital of Malaga)

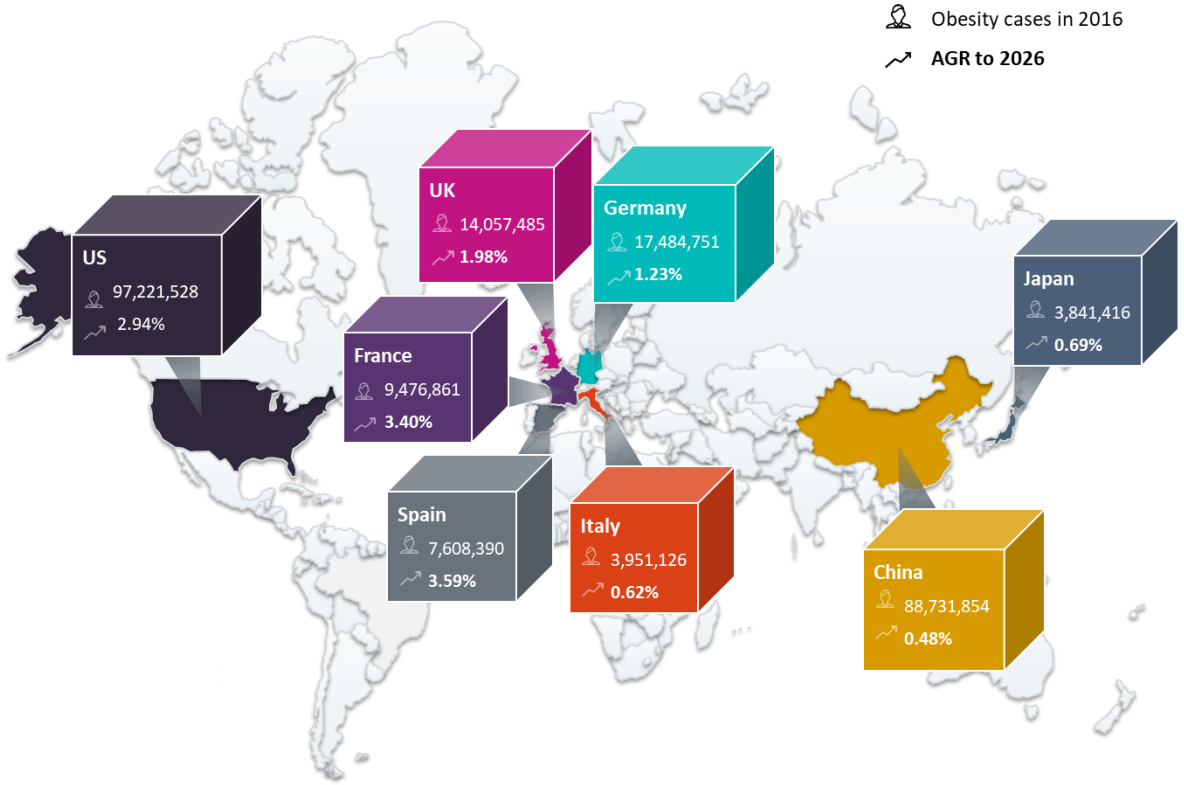
6
patent families

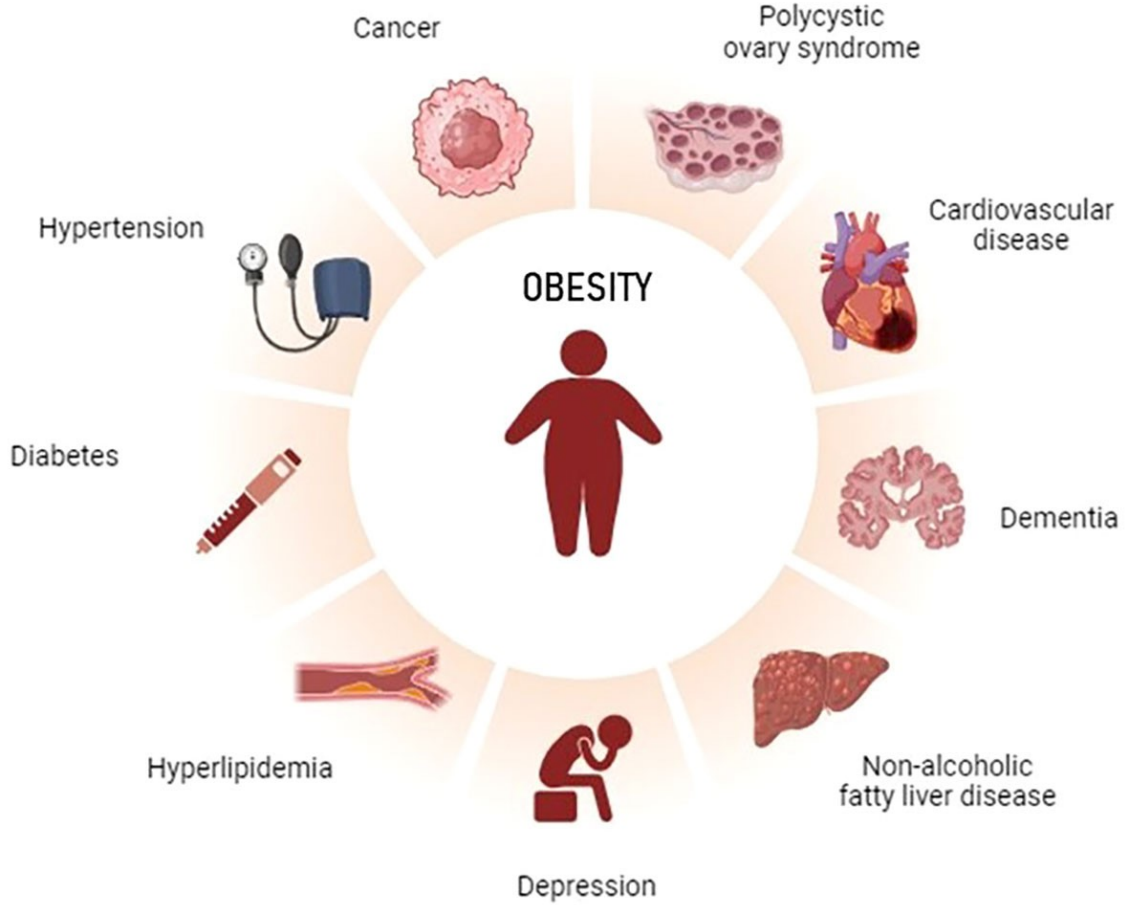
35
active projects

>250
Scientific publications

The Product: Target Indication

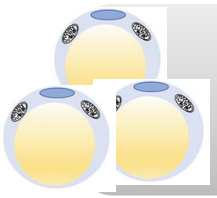
Obesity s considered the pandemic of the 21st century by the World Health Organization



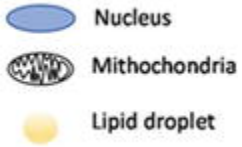


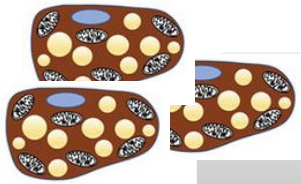
Source: GlobalData, October 2018. "Obesity: Competitive Landscape to 2026". Report code: GDHC017CL

The Product: Innovative Mechanism of Action; BROWNING



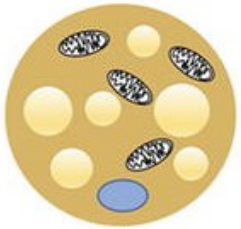
White Adiposse Tissue: Energy storage as triacylglycerols





Brown Adiposse Tissue: Heat production through metabolism of lipids and glucose

BROWNING



BRITE Adipocyte: Heat production (like BAT)

From energy storage

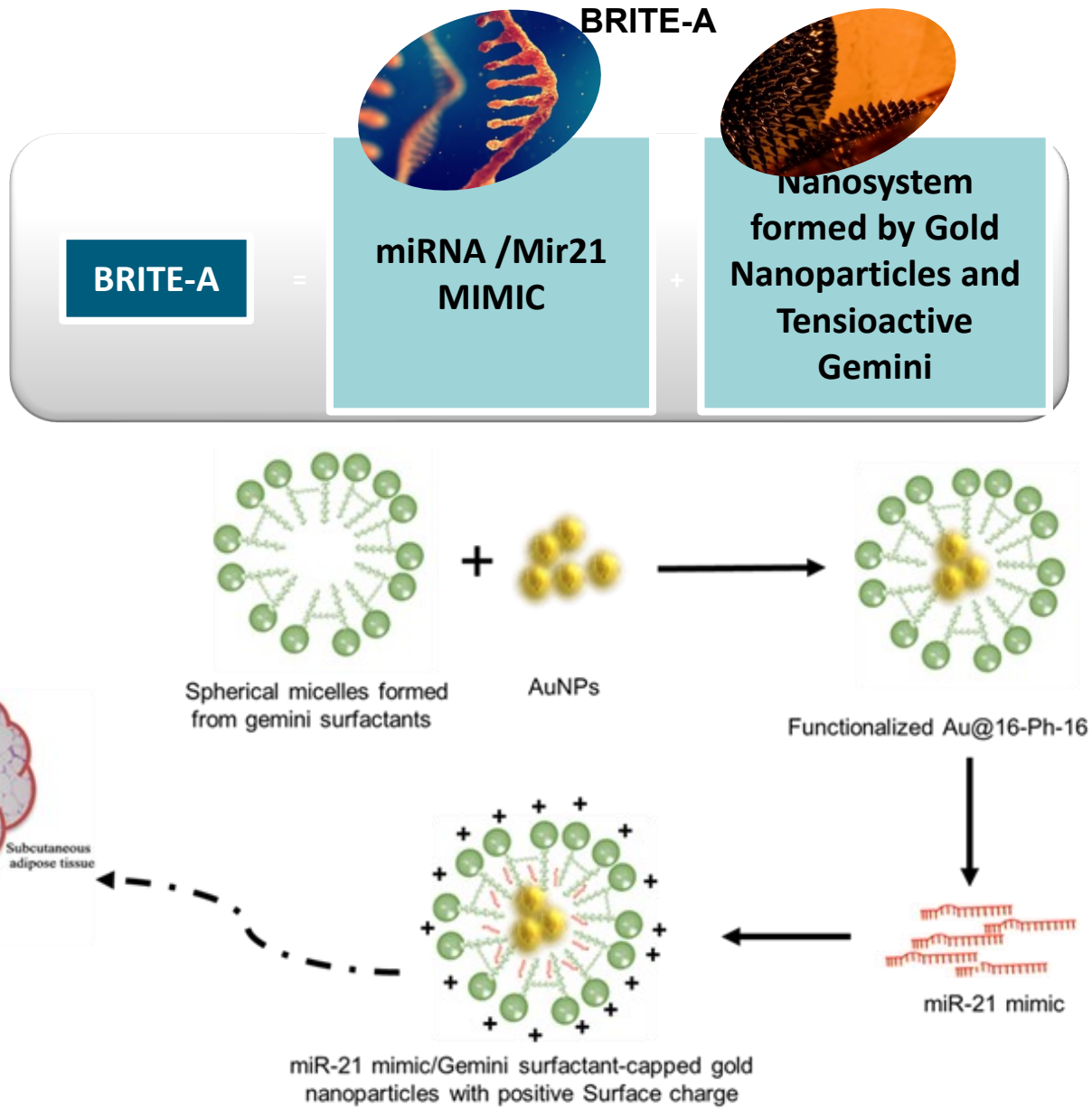
To heat generation

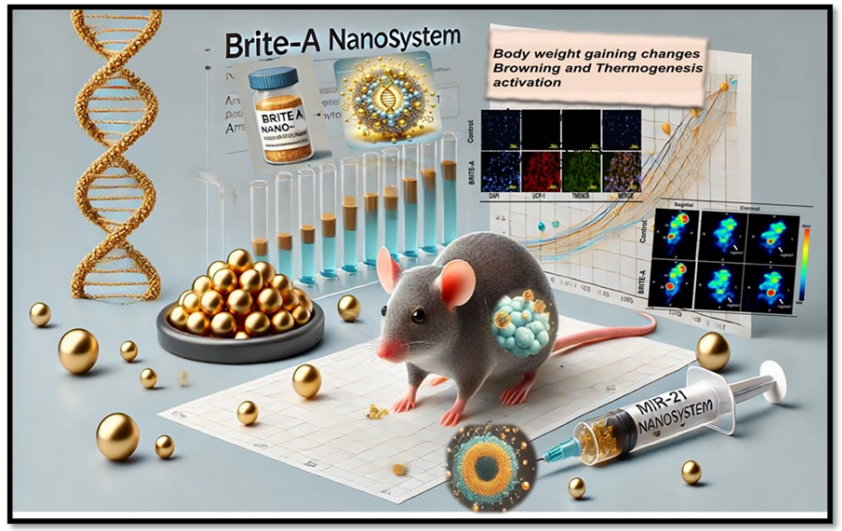
Glucose ↓
Lipids ↓
Insuline sensibility↑

Current treatments

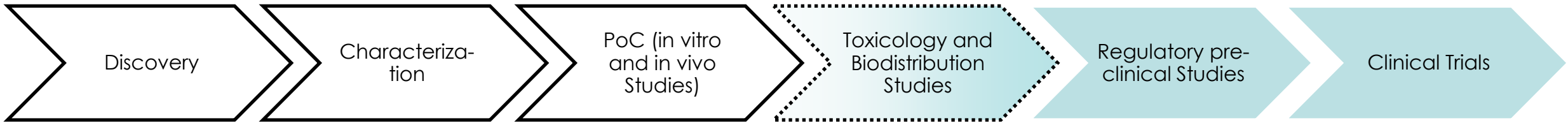
VS.

- Decreased appetite
- Reduced intestinal absorption


BRITE-A
BRITE-A
=
miRNA /Mir21 MIMIC
+
Nanosystem formed by Gold Nanoparticles and Tensioactive Gemini
Spherical micelles formed from gemini surfactants
AuNPs
Functionalized Au@16-Ph-16
miR-21 mimic
miR-21 mimic/Gemini surfactant-capped gold nanoparticles with positive Surface charge
Subcutaneous adipose tissue


Brite-A NanoSystem
Body weight gaining changes
Browning and Thermogenesis activation
MiR-21 NANOSYSTEM

The Product: Development Status



The Product: Development Status

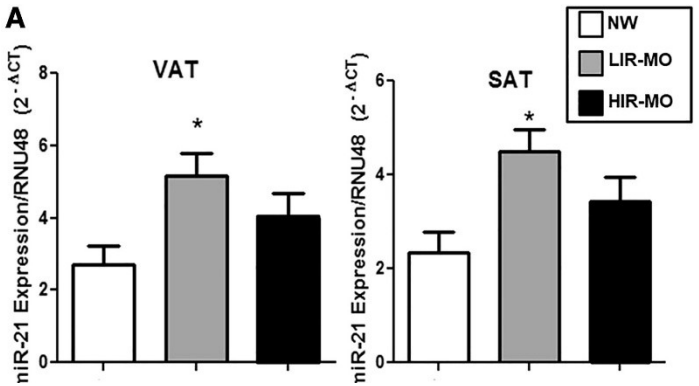
Discovery → Characterization → PoC (in vitro and in vivo Studies) → Toxicology and Biodistribution Studies → Regulatory pre-clinical Studies → Clinical Trials

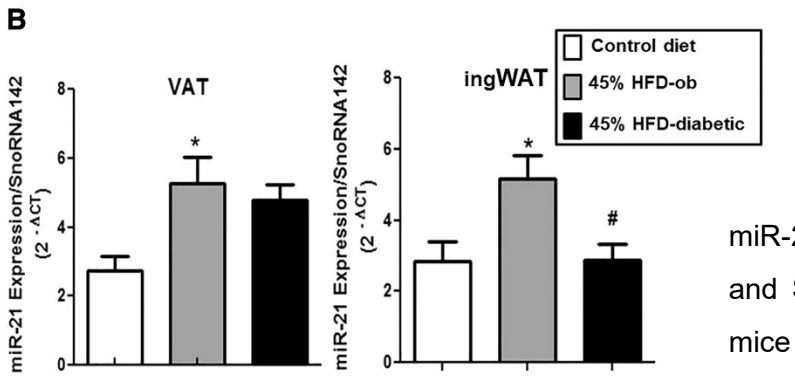
ORIGINAL ARTICLE | VOLUME 26, P401-416, DECEMBER 03, 2021

miR-21 mimic blocks obesity in mice: A novel therapeutic option

Said Lhamyani [13] • Adriana-Mariel Gentile [13] • Rosa M. Giráldez-Pérez • ... Gabriel Olveira • Francisco J. Tinahones • Rajaa El Bekay • Show all authors • Show footnotes

Open Access • Published: July 01, 2021 • DOI: https://doi.org/10.1016/j.omtn.2021.06.019 •





miR-21 expression levels in VAT and SAT from humans (A) and mice (B)

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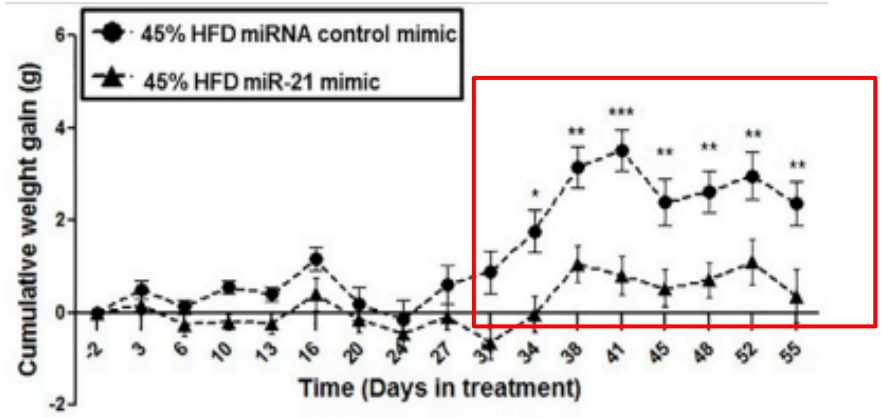
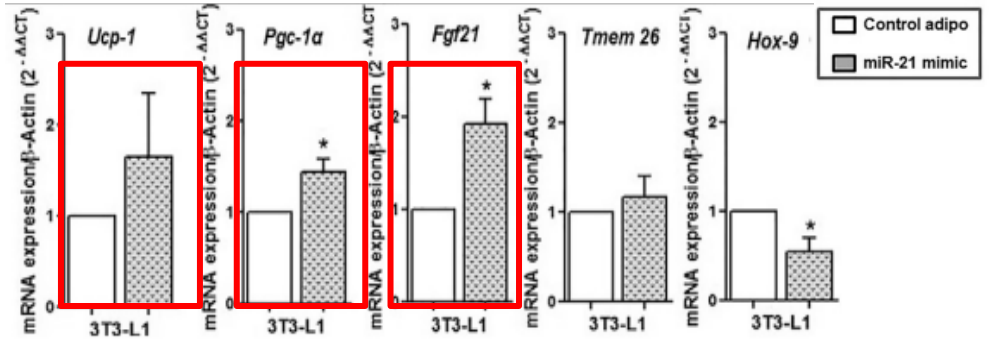




mRNA level of **browning and thermogenesis** genes

The Product: Development Status

Discovery → **Characteriza-tion** → PoC (in vitro and in vivo Studies) → Toxicology and Biodistribution Studies → Regulatory pre-clinical Studies → Clinical Trials

Characterization

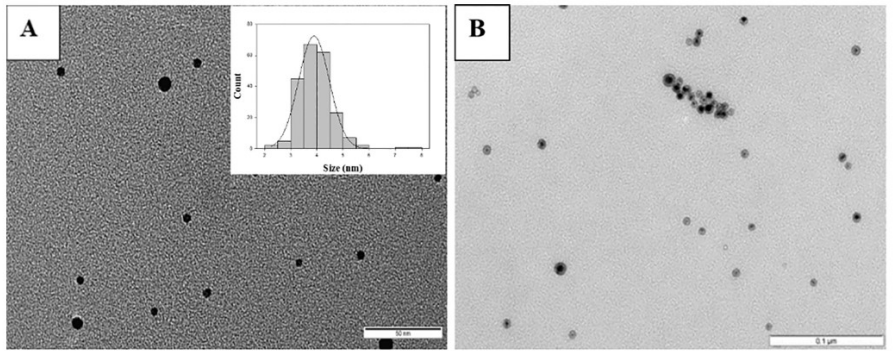
ELSEVIER

Journal of Molecular Liquids
Volume 313, 1 September 2020, 113577

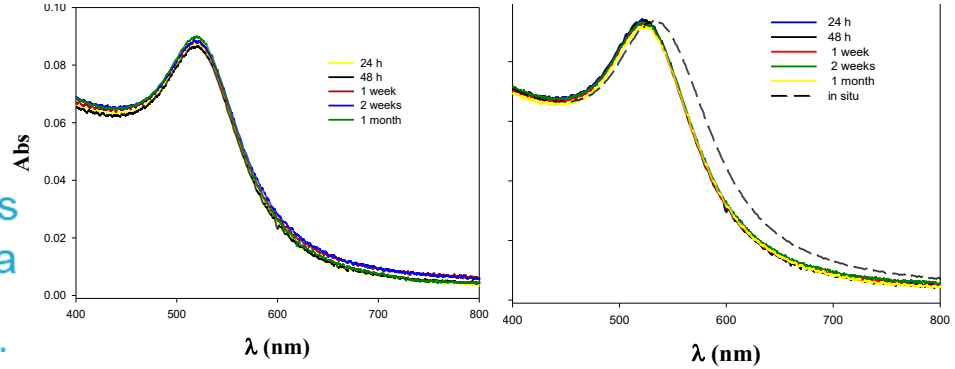
miR-21/Gemini surfactant-capped gold nanoparticles as potential therapeutic complexes: Synthesis, characterization and *in vivo* nanotoxicity probes

Rosa M. Giráldez-Pérez [a b 1], Elia Grueso [b 1], Said Lhamyani [c], Pilar Perez-Tejeda [b], Adriana-Mariel Gentile [c], Edyta Kuliszewska [d], J. Roman-Perez [e], Rajaa El Bekay [c f]

- The system demonstrated high capacity to compress miRNAs, to preserve miR21 mimic stability for over a month, and to facilitate cell-entry capability.



TEM image and corresponding size distribution of Au@16-Ph-16 nanosystem in water. (A) Free Au@16-Ph-16. (B) Au@16-Ph-16/miR-21.



Stability and complexation for nanoparticles. Au@16-Ph-16 precursor. Au@16-Ph-16/miR-21

The Product: Development Status

Discovery → Characteriza-tion → PoC (in vitro and in vivo Studies) → Toxicology and Biodistribution Studies → Regulatory pre-clinical Studies → Clinical Trials

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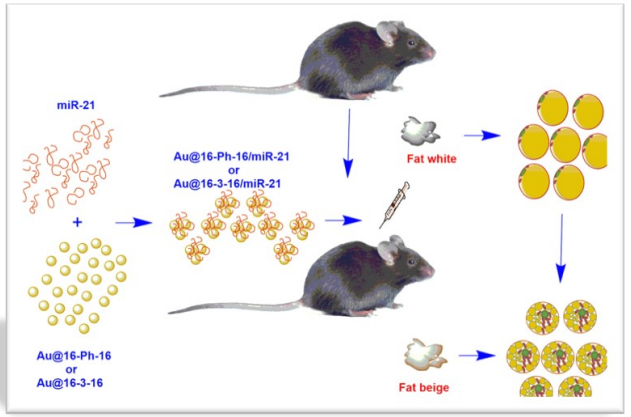
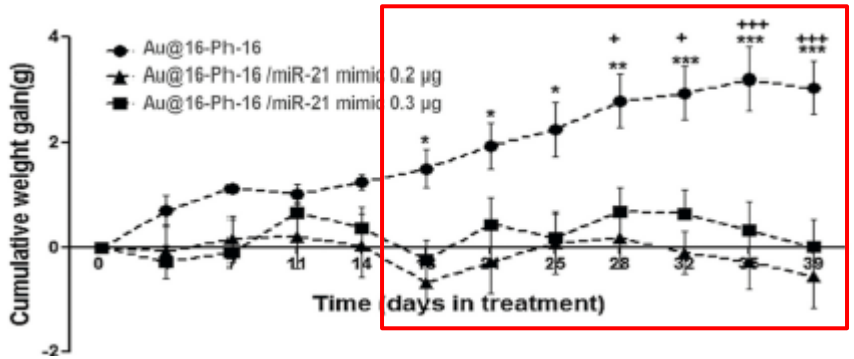
Au@16-pH-16/miR-21 mimic nanosystem: An efficient treatment for obesity through browning and thermogenesis induction





Cumulative weight gain.

The Product: Development Status

Discovery → Characteriza-tion → PoC (in vitro and in vivo studies) → **Toxicology and Biodistribution Studies** → Regulatory pre-clinical Studies → Clinical Trials

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miR-21/Gemini surfactant-capped gold nanoparticles as potential therapeutic complexes: Synthesis, characterization and *in vivo* nanotoxicity probes

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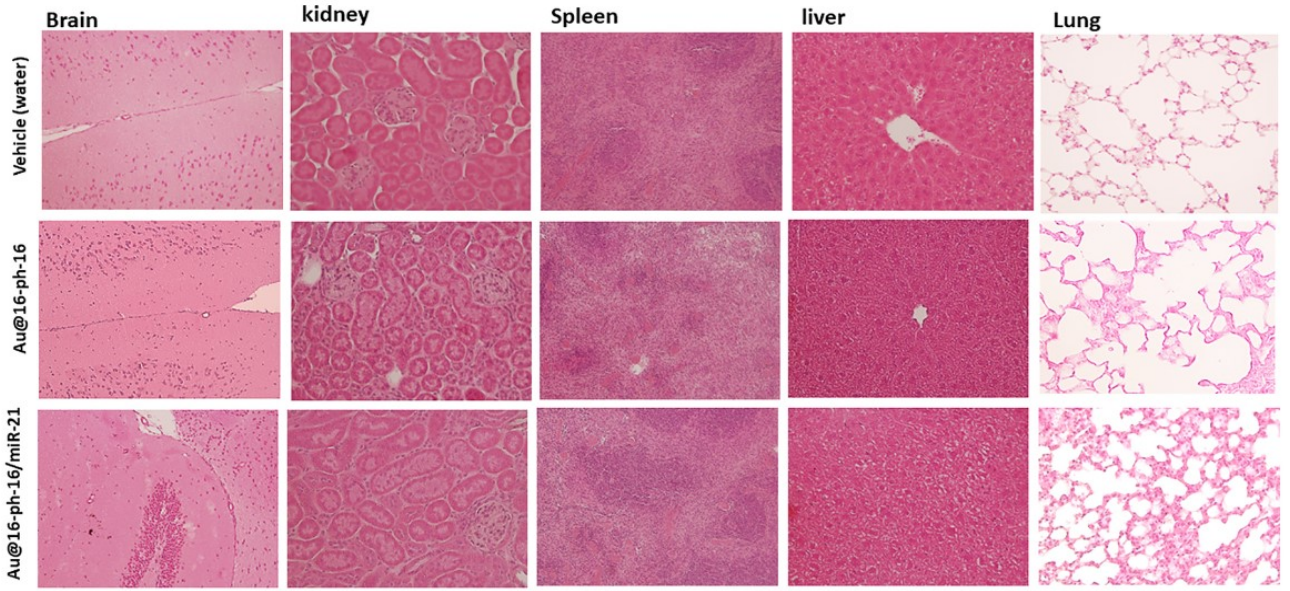
- It exhibits no toxicity, antimicrobial, and biocompatible activities



***In vivo* nanotoxicity probes**

Photomicrographs showing histochemical study with hematoxylin and eosin, in different treatments

Magnification: 10× for brain, spleen and lung; 20× for kidney and liver.

The Product: Differential Features

Aspect	Semaglutide (GLP-1 RA)	Tirzepatide (GIP/GLP-1)	BRITE-A (preclinical)
Mechanism	GLP-1 receptor agonist → ↓ appetite, ↓ gastric emptying	Dual GIP/GLP-1 → ↓ appetite, ↑ satiety	Pro-browning miRNA + nanoparticles **targeted to adipose tissue**
Duration after discontinuation	❌ Frequent rebound	❌ Frequent rebound	✅ **Partial persistence** post-treatment (**in mouse**)
Safety	⚠️ Frequent GI events; pancreatic risk	⚠️ GI events; high cost	✅ **Local design to minimize systemic effects** (to be confirmed)
Tissue specificity	❌ Systemic action	❌ Systemic action	✅ **Localized action in adipose tissue**
Route of administration	Weekly s.c. injection	Weekly s.c. injection	s.c. injection
Fit with GLP-1	—	—	✅ **Complementary** (combo or sequential)

*Abbreviations: **RA** = receptor agonist; **GIP** = glucose-dependent insulinotropic polypeptide; **GI** = gastrointestinal; s.c. = subcutaneous.*

The Product: Preclinical Development Plan. Upcoming phase.

Main Activity	Description	Estimated Cost (€)	Estimated Duration	Investment Year
Optimization and GMP production of the nanosystem	Development of the formulation and validation of GMP pilot batches.	400–700K €	4–6 months	Year 1
Pharmacological studies	hERG studies.	50–100K €	3–4 months	Year 1
Pharmacokinetic studies	Protein binding, CYP and UGT studies, bioanalytical validation, and in vivo PK study.	100–250K €	4–6 months	Year 1 – Year 2
Regulatory toxicology studies	DRF, pilot toxicity study, repeated-dose toxicity, genotoxicity, reproductive and developmental toxicity studies.	400–700K €	6–9 months	Year 2
Regulatory documentation (IMPD)	Preparation of the IMPD dossier and submission for clinical trial authorization.	80–150K €	2–3 months	Year 2

The Product: IP Protection

Scientific Developers	ibima Plataforma BIONAND; SERVICIO ANDALUZ DE SALUD Consejería de Salud y Consumo; UNIVERSIDAD DE MÁLAGA; UNIVERSIDAD DE SEVILLA	
Candidates	**BRITE-A**	**New targeting system**
Indications	Obesity, insulin resistance	Adipose tissue drug targeting
Priority Date	15/02/2019	In writing
Patent Agent	Hoffmann Eitle	Hoffmann Eitle
National Phases	USA, Europe	Pending

New indication pending patent filing

The Product: Pitfalls & Risks to consider

Scientifc & Technical Risks

Risks	Mitigation strategies
Variability in nanoparticle synthesis and reproducibility under GMP conditions	Preliminary study of the production process conducted by ICTS Nanbiosis
Potential instability of the miRNA or incomplete release at target sites	Preliminary instability studies performed with positive results
Unpredictable biodistribution or off-target accumulation (e.g., liver, spleen).	In vivo studies showed no presence of BRITE-A in non-target tissues
Limited translation of thermogenic effects from animal models to humans	Evolutionary conservation of the miR-21 regulatory network supports translational potential; functional confirmation in human adipose models planned

The Product: Pitfalls & Risks to be considered

Regulatory & Safety Risks

Risks	Mitigation strategies
Complexity of demonstrating safety for hybrid nanomaterials (miRNA + inorganic core).	Early dialogue with AEMPS/EMA through scientific advice (already done). Parallel development of stability and release assays (preliminary studies already done).
Regulatory uncertainty on classification and requirements (drug vs. ATMP vs. nanomedicine).	Early dialogue with AEMPS/EMA through scientific advice (already done).
Potential toxicological findings delaying GLP completion.	Early pilot toxicity (already done) and dose-range finding studies (pending)

Partnering Opportunities

Licence agreement

Co-development agreement

- Preclinical regulatory
- Clinical trials
- Commercialization

New company

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