MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

farmaindustria

XXVI Encuentro de Cooperación Farma-Biotech

Miércoles 19 de noviembre de 2025

El Programa Farma-Biotech tiene por objeto establecer un punto de encuentro para la cooperación entre compañías farmacéuticas nacionales e internacionales, empresas españolas de biotecnología y grupos de investigación, en torno al desarrollo de nuevos medicamentos innovadores.

La presente jornada, que hace la número 26 desde que se inició el programa en el año 2011, está enfocada a la presentación de proyectos de medicamentos innovadores desarrollados en distintos centros de investigación y pequeñas empresas *spin-offs*, que han sido seleccionados por su potencial y prometedor estado de desarrollo, dentro del ámbito de la investigación preclínica.

En esta jornada se presentarán y discutirán **siete propuestas** que se considera han alcanzado un **grado de madurez** razonable, lo que permite estudiar posibles **acuerdos de cooperación** con la industria farmacéutica en condiciones ventajosas técnico-económicas. Consecuentemente, pensamos que esta jornada reviste especial interés para las compañías farmacéuticas invitadas, incluyendo responsables de sus **unidades de desarrollo de negocio** e inversiones.

El grado de información manejado durante la jornada se clasifica como “no confidencial” por lo que no se requiere ningún acuerdo previo al respecto.

La jornada se configura como un foro individualizado no abierto a terceras partes, y en donde se desea generar un **clima de interacción** suficiente que permita identificar el valor añadido derivado del intercambio de información entre demanda y oferta, con suficiente contenido diferencial e innovador en el ámbito de las nuevas terapias y los medicamentos avanzados.

Esta jornada tendrá lugar de forma presencial en la sede de Farmaindustria en Madrid. Para cualquier duda o aclaración adicional por favor contactar con: plataforma@farmaindustria.es

Tfno. 915159350

XXVI Encuentro de Cooperación Farma-Biotech

MADRID. Miércoles 19 de noviembre de 2025

Agenda

El programa Farma-Biotech, patrocinado por FARMAINDUSTRIA, pretende dar énfasis tanto a las presentaciones como a la interacción personal entre los asistentes, de acuerdo con la siguiente agenda:

Hora	Presentación	Ámbito terapéutico	Ponente
09:00	Recepción, contactos informales, café		
09:30 10:00	*Bienvenida y presentación de la jornada*		***Javier Urzay*** FARMAINDUSTRIA
10:00 10:30	*RUTI®, a therapeutic vaccine for multidrugresistance tuberculosis*	Infección	***Mercè Amat*** ARCHIVEL FARMA
10:30 11:00	*FIBROKIT, non-invasive diagnostic platform for renal fibrosis*	Nefrología	***Marta Clos*** DEBIOS DIAGNOSTICS
11:00 11:30	*PVT-1, NK1R antagonist with nanoformulation for NSCLC treatment*	Oncología	***Fran Guillén*** PLUSVITECH
11:30 12:00	*BRITE-A, an advanced nanosystem for the precision treatment of obesity*	Obesidad	***Rajaa El Bekay*** IBIMA Plataforma BIONAND
	DESCANSO. Café y refrescos. Contactos informales		
12:15 12:45	*Ohmline therapeutic nanocarrier for treatment of metastatic cancer*	Oncología	***Ana Bouchet*** LIFESOME THERAPEUTICS
12:45 13:15	*BO-112, a non-coding double-stranded ribonucleic acid (dsRNA)*	Oncología	***Marisol Quintero*** HIGHLIGHT THERAPEUTICS
13:15 13:45	*NRF2 Activation, pharmacological innovation against Fatty Liver Disease*	Hepatología	***Antonio Cuadrado*** SERVATRIX
	FINAL. Aperitivos y refrescos. Contactos informales		

Todas las presentaciones se harán en español, si bien la documentación escrita se dispondrá en inglés para facilidad de circulación interna entre los órganos de las compañías internacionales

Lugar de celebración: **sede de Farmaindustria en Madrid. Calle María de Molina nº 54. 7ª planta**

Fecha: **miércoles 19 de noviembre de 2025**

La Plataforma Tecnológica Española Medicamentos Innovadores cuenta con la Ayuda (PTR2024-002838) financiada por MCIU/AEI/10.13039/501100011033

PRESENTACIONES QUE TENDRÁN LUGAR EN ESTA JORNADA

PROFILE

Archivel Farma is a biopharmaceutical company based in Barcelona, focused on developing innovative immunotherapies. Its lead product, RUTI®, is a therapeutic vaccine designed to boost immunity against tuberculosis, currently in clinical phase IIb development for multidrugresistant TB. Since 2022 Archivel also operates as a CDMO, offering expertise in drug development and manufacturing.

SPEAKER

Mercè Amat *is a PhD in Biochemistry, has been R&D Manager at Archivel Farma since 2008 and has led the RUTI® project since 2022. She has contributed to CMC development, driving the scale-up of the Drug Substance and defining RUTI®'s final formula. Her current focus is on RUTI® clinical development in multidrug-resistant TB. Prior Archivel, she spent 10 years leading respiratory and rheumatoid arthritis projects at Almirall and Menarini Laboratories.*

merce.amat@archivelfarma.com

PRODUCT

RUTI®, a therapeutic vaccine for multidrug-resistance Tuberculosis

MECHANISM OF ACTION

The mechanism of action of the RUTI® it to boost and refocus the immune-response inducing an efficient cell-mediated immune response that helps to eliminate Mycobacterium tuberculosis and boost innate immunity through the mechanism of trained immunity as described for other tuberculosis-derived immunological products.

RUTI®'s mechanism of action combines a polyantigenic cellular response, mainly T1 cell response, against tuberculosis antigens, but also a non-specific stimulation of the innate immunity.

The IMP RUTI® is presented as a dry powder for reconstitution with water for injection and it is stable at 5ºC for at least 4 years. RUTI® is a liposomal suspension of the Drug Substance with sucrose as charge excipient. The drug substance (DS) consists on purified, pasteurised and freeze-dried cell-wall fragments from Mycobacterium tuberculosis (Mtb RUTI strain) which has grown under stress conditions. These nano-fragments of Mtb cell wall express multiple antigens classically described as representative of replicating and non-replicating Mtb.

TARGET INDICATIONS

The main value driver for RUTI® is the indication for tuberculosis (TB), specifically multi-drug resistance TB. The treatment is based on an adjunctive immunotherapy to antibiotic TB treatment, boosting and broadening the immune response to natural infection. The aim is shortening and/or simplifying current drug treatment in TB and preventing relapse. And beyond TB, the indication for Non-Muscle Invasive Bladder Cancer (NMIBC) based on heterologous prime-boost immunotherapy to BCG treatment.

CURRENT STATUS

- RUTI® has demonstrated a good safety and toxicology profile in animal studies, with no significant adverse effects observed.
- Early clinical trials in healthy volunteers and patients with LTBI confirmed its safety and immunogenicity.
- Currently, clinical development is focused on the use of RUTI® as a therapeutic vaccine combined with standard treatment for drug-resistant tuberculosis, with the aim of accelerating the elimination of bacteria, reducing treatment duration and preventing relapses.
- Two phase II trials in Ukraine and India have evaluated its safety and efficacy in combination with standard tuberculosis treatment.
- RUTI® has been well tolerated and safe. Promising results in terms of efficacy are expected.
- RUTI® has received orphan drug designation from the EMA.

INNOVATIVE ASPECTS

- Several vaccines are being developed for tuberculosis treatment and relapse prevention, but no efficacy results have been reported.
- The main competitors are H56:IC31, which failed to prevent recurrence in a Phase 2b trial; Vaccae, which is safe but has limited evidence for relapse prevention; and VPM1002, a recombinant BCG that completed a Phase II/III study in adults for preventing TB recurrence.
- Despite the VPM 1002 trial's completion in 2023, no results have been publicly released.

IPR

Four active patents cover RUTI® for tuberculosis vaccines. The patents WO/2008/053055 and WO/2010/031883 covers a prophylactic TB vaccine use; the patent WO/2012/093137 covers the product for TB treatment or prevention, and WO/2023/062066 covers the treatment of active tuberculosis. And 1 active patent for immunotherapies, PCT/EP2025/057265 RUTI for potential cancer applications.

PARTNERING OPPORTUNITIES

We are seeking a licensee or strategic partnerships with pharmaceutical companies and/or investors to advance the clinical development of the RUTI® vaccine and accelerate its market entry, aiming to improve the treatment of TB, the world's leading infectious disease.

PROFILE

Dual Dynamics Influence SL (Commercial name: Debios Diagnostics) is a spin-off created from the Institut de Recerca Germans Trias i Pujol (IGTP) dedicated to the development of noninvasive diagnostic tests for the detection and monitoring of chronic diseases. Its main project is FIBROKIT, an in vitro diagnostic device for the detection of renal fibrosis through urinary biomarkers. Debios Diagnostics combines translational research, clinical validation, and technological development.

SPEAKER

Marta Clos *is a PhD in Advanced Immunology from the Universitat Autònoma de Barcelona. Currently CTO and co-founder of Debios Diagnostics, a spin-off focused on the development of non-invasive in vitro diagnostic tests. Her expertise lies in extracellular vesicles, urinary biomarkers, and renal fibrosis. mclos@debiosdx.com*

PRODUCT

FIBROKIT: non-invasive diagnostic platform for renal fibrosis

MECHANISM OF ACTION

FIBROKIT is an innovative diagnostic platform composed of two complementary formats: a quantitative ELISA and a semi-quantitative lateral flow test, both targeting urinary vitronectin detection. The test is designed to discriminate between patients with and without renal fibrosis and to monitor fibrosis progression, in a non-invasive way and with the sensitivity of a renal biopsy. It is suitable for both clinical settings and home-monitoring programs, aligning with trends in personalized and patient-centered care. In addition, it has strong potential as a companion diagnostic (CDx) in the development of antifibrotic therapies, as well as for the evaluation of drug-induced renal toxicity, broadening its clinical and pharmaceutical applications.

FIBROKIT development is based on the direct correlation between urinary vitronectin levels and the degree of renal fibrosis confirmed by biopsy. Vitronectin plays a key role in extracellular matrix remodeling and fibrosis progression in the kidney. Its quantification in urine allows the detection of early pathological changes, offering a dynamic and sensitive measure of renal status without invasive procedures. Moreover, the platform relies on the detection of vitronectin using proprietary, highly specific monoclonal antibodies, ensuring robustness, reproducibility, and intellectual property protection of the assay.

TARGET INDICATIONS

The main therapeutic area of FIBROKIT is nephrology, with application in patients with chronic kidney disease, kidney transplant recipients, and individuals at risk of developing the disease. It enables the detection and monitoring of renal fibrosis in a non-invasive manner, overcoming most of the limitations of renal biopsy. Additional applications include supporting the development of antifibrotic drugs and monitoring personalized therapies, including the evaluation of drug-induced renal toxicity.

CURRENT STATUS

- FIBROKIT is supported by solid experimental results demonstrating a significant correlation between urinary vitronectin levels and biopsy-confirmed renal fibrosis.
- A clinical study with the ELISA is currently underway, designed to validate its diagnostic performance in patient cohorts, after showing high sensitivity and specificity in preliminary studies.
- The lateral flow (LF) test is in the industrial development phase, following a successful homemade prototype that yielded highly satisfactory results as a screening tool.
- The project is progressing toward the preparation of the regulatory dossier under the European IVDR framework (Class C for ELISA and Class B for the rapid test). It is patentprotected and has generated strong clinical interest from multiple nephrology reference centers.

INNOVATIVE ASPECTS

- FIBROKIT goes beyond measuring kidney function, unlike current biomarkers already assessed routinely in hospitals, which only detect disease in advanced stages. Instead, it opens a new category as the only non-invasive liquid biopsy capable of identifying renal fibrosis before functional signs appear, with greater diagnostic power and better costefficiency.
- It even enables detection and monitoring in patient stages where biopsies are not currently performed.
- By being the only test that directly measures renal fibrosis, FIBROKIT becomes a key tool for the development and follow-up of antifibrotic therapies currently in clinical trials.

IPR

FIBROKIT is protected by an international patent (PCT) covering the use of urinary vitronectin as a biomarker of renal fibrosis and its application in diagnostic devices, including ELISA and lateral flow formats. The patent has already entered the national phase in Europe, ensuring strong intellectual property protection and reinforcing the project's competitive advantage.

PARTNERING OPPORTUNITIES

We seek strategic alliances with the pharmaceutical industry for the joint development of companion diagnostics (CDx) in antifibrotic programs and for evaluating drug-induced renal toxicity. Partnerships will also help facilitate the clinical implementation of FIBROKIT in multicenter trials.

PROFILE

PlusVitech is a Spanish biotech SME founded in 2013 in Seville, specializing in drug repurposing and precision medicine for oncology, particularly non-small cell lung cancer (NSCLC). The company focuses on innovative solutions like PVT-1, combining repurposed drugs, nanotechnology formulations, and non-invasive diagnostics to improve patient outcomes. Key work lines include developing NK1R antagonists for cancer treatment, liquid biopsy companion diagnostics, and decision support software for personalized therapy. The team blends medical, business, and tech expertise to advance scalable, side-effect-free treatments.

SPEAKER

Fran Guillen *serves as General Manager at PlusVitech, bringing his background as an engineer and his expertise in business development. Guillen has contributed to PlusVitech's growth by overseeing strategic initiatives, funding efforts, and operational efficiency. His expertise in investment and entrepreneurship supports the company's mission to advance innovative cancer treatments. Under his management, PlusVitech has successfully raised funds, awards and forged key partnerships.*

franguillen@plusvitech.com

PRODUCT

PVT-1: NK1R Antagonist with Nanoformulation for NSCLC Treatment

MECHANISM OF ACTION

PVT-1 is an innovative oncology solution repurposing aprepitant, an FDA/EMA-approved antiemetic, as an anticancer drug via NK1R antagonism. It features a nanotechnologyenhanced formulation for improved solubility, bioavailability, and efficacy, reducing daily pill burden. The product includes a non-invasive liquid biopsy Companion Diagnostic Test (CDT) to monitor tumor molecular profiles. A Decision Support Software (DSS) predicts patient responses and guides personalized treatment adjustments. PVT-1 induces selective apoptosis in cancer cells without harming healthy ones, minimizing side effects. The integrated system enables frequent, non-invasive monitoring for better outcomes in advanced NSCLC.

PVT-1 acts as a specific antagonist of the Neurokinin-1 receptor (NK1R), which is overexpressed in cancer cells and promotes growth and metastasis. By blocking NK1R, it disrupts signaling pathways, inducing selective apoptosis (programmed cell death) in tumor cells while sparing healthy cells. This mechanism halts tumor proliferation and metastasis without the toxicity of traditional therapies. The nanoformulation enhances absorption, allowing higher effective doses with fewer capsules. Integrated CDT analyzes biomarkers like NK1R isoforms, ERK, AKT, K-ras, and TAC1R mutations via liquid biopsy. DSS correlates these profiles with drug response data to predict sensitivity and adjust treatments.

TARGET INDICATIONS

PVT-1 targets advanced non-small cell lung cancer (NSCLC), which accounts for 84% of lung cancer cases, focusing on patients with no mutations (EGFR-/ALK-/ROS1-). It addresses unmet needs in oncology by providing a safer, oral alternative to invasive treatments like chemotherapy and immunotherapy. Additional indications include potential expansion to breast cancer and lymphoma, where complete remissions have been observed in off-label studies. Future scalability may extend to other solid tumors with NK1R involvement.

CURRENT STATUS

- Ongoing Phase II trial recruiting advanced NSCLC patients to evaluate safety and efficacy.
- Preclinical: Over 100,000 in vitro tests across 38 cancers; 80% tumor reduction in vivo (mice); molecular characterization with 19,540 DNA markers.
- Off-label human studies: Complete remissions in NSCLC, breast cancer, lymphoma and others.
- Nanoformulation: Partnership with Nanoform using CESS® technology.
- CDT and DSS: MVP developed with 5M+ in vitro records; pre-validation using Phase II samples for biomarker correlation.
- Funding: €7M raised; €3,5M public funding.
- Regulatory: Phase II approved; FTO report by JA Kemp; meetings with EMA/FDA planned.
- Experimental results: Tumor shrinkage in vivo; full remissions in terminal cancer patients; no toxicity observed.
- Milestones: Patent families granted; collaborations with Nanoform, CROs. Bioequivalence studies upcoming. Next: Complete Phase II, GMP batch production, and licensing negotiations.

INNOVATIVE ASPECTS

- Unlike chemotherapy, PVT-1 is non-toxic, oral, and avoids severe side effects like hair loss or myelosuppression.
- It outperforms immunotherapies by targeting all NSCLC patients, not just subsets, with no immune-related adverse events. In addition, it has demonstrated a synergistic effect with immunotherapy.
- Compared to targeted therapies, PVT-1's NK1R antagonism addresses a novel pathway, reducing resistance development.
- The nanoformulation boosts bioavailability 10-fold, enabling optimal concentrations in tumor tissues and better patient adherence.
- Non-invasive CDT and DSS provide real-time, personalized monitoring, unlike sporadic invasive biopsies in current practices.
- PVT-1 achieves complete remissions in off-label cases where others fail, positioning it as a premium option for advanced patients.
- No other NK1R antagonists are in cancer trials; PVT-1 fills this gap with repurposed safety data.

IPR

PlusVitech holds seven patent families covering cancer indications, composition of matter, and CDT, with grants in USA, Europe, and pending in multiple territories. Exclusive licensing from Andalusian Health Service; FTO confirmed by JA Kemp; nanoformulation patent pending post-Nanoform PoC. Trademarks and DSS algorithms protected as trade secret, vigilant monitoring for infringements. Strategy: License to big pharma for commercialization while retaining exploitation rights.

PARTNERING OPPORTUNITIES

PlusVitech's business model focuses on licensing PVT-1 to big pharma for manufacturing, distribution, and commercialization, leveraging their channels for upfront, milestone, and royalty payments, while also considering sponsorship agreements. Collaboration via partnerships for Phase III trials and regulatory approvals, with expert Jörg Landwehr (ex-Roche) leading negotiations. Target: Secure agreements with interim data of the Phase II clinical trial.

PROFILE

IBIMA Plataforma BIONAND is a biomedical research institute based in Málaga, Spain, specializing in translational medicine and nanotechnology. The Endocrinology and Nutrition, Diabetes and Obesity research group focuses on advancing diagnostic and therapeutic approaches for metabolic disorders. Their work integrates clinical research with innovative technologies to improve patient outcomes. The group collaborates closely with healthcare and research institutions and contributes to regional and national biomedical initiatives.

SPEAKER

Dr. Rajaa El Bekay *is a Senior Researcher at IBIMA Plataforma BIONAND (Málaga, Spain) and Principal Investigator of the Endocrinology and Nutrition, Diabetes and Obesity research group. With extensive experience in translational research, she has led competitive national and international projects, published over 60 peer-reviewed articles, and is co-inventor of several patents. Her research focuses on nanomedicine and molecular therapies for obesity and metabolic diseases.*

elbekay@gmail.com

PRODUCT

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

MECHANISM OF ACTION

BRITE-A is an advanced nanosystem developed at IBIMA Plataforma BIONAND for the precision treatment of obesity. It integrates gold nanoparticles, a gemini surfactant, and a therapeutic microRNA to selectively target white adipose tissue. Once delivered, the microRNA induces adipose browning and activates thermogenesis in beige and brown fat, increasing energy expenditure and reducing fat accumulation. Preclinical studies in dietinduced obese mice have demonstrated robust efficacy and safety. BRITE-A represents a firstin-class therapeutic strategy that combines molecular specificity with nanotechnology for the treatment of obesity and related metabolic diseases.

BRITE-A acts through targeted delivery of a microRNA-21 mimic to adipose tissue. This triggers adipose browning, converting white fat into thermogenically active beige fat. The activation of thermogenesis in beige and brown adipocytes increases energy expenditure and reduces lipid storage. Preclinical studies also revealed a local paracrine effect that amplifies its therapeutic action. Furthermore, BRITE-A can be combined with an adipose tissue targeting system based on opposing electric fields, enhancing localization and retention while minimizing systemic exposure and ensuring more precise action.

TARGET INDICATIONS

BRITE-A is primarily intended for the treatment of obesity, specifically targeting adipose tissue to promote weight loss. It also shows potential to improve metabolic parameters associated with type 2 diabetes. The technology addresses a major global health challenge where effective therapeutic options remain limited.

CURRENT STATUS

- BRITE-A has undergone extensive preclinical validation in both human samples and animal models.
- In adipose tissue from obese individuals, elevated endogenous levels of miR-21 were observed compared to lean or insulin-resistant subjects, supporting its relevance as a therapeutic target.
- In vitro, adipocytes treated with synthetic miR-21 mimic showed increased expression of browning and thermogenic genes. In vivo, BRITE-A significantly prevented weight gain in diet-induced obese mice and promoted a brown-like adipocyte phenotype across multiple depots, with dose–response studies confirming efficacy at 0.2–0.3 µg.
- Integration with a targeting system based on opposing electric fields improved localization and retention within adipose tissue, confining effects to the injection site and minimizing systemic spread.
- Toxicity assessments revealed no adverse effects, and gene expression analyses showed no activation of oncogenes commonly associated with tumorigenesis.
- In parallel, ongoing studies are evaluating potential effects on skeletal muscle integrity; preliminary ultrastructural analyses indicate preserved sarcomere organization, suggesting no induction of sarcopenia.
- Collectively, these results demonstrate BRITE-A's safety, tissue specificity, and readiness for translational development (TRL 4–5).

INNOVATIVE ASPECTS

- BRITE-A stands out from existing anti-obesity treatments by offering a tissue-specific, molecularly targeted approach.
- Unlike current drugs—mainly appetite suppressants or absorption inhibitors—BRITE-A induces browning and thermogenesis directly within adipose tissue.
- Its nanosystem ensures precise delivery, minimizing systemic side effects.
- The integration of microRNA adds a layer of biological specificity, and its dual action on obesity and type 2 diabetes positions it as a truly next-generation therapeutic candidate.

IPR

BRITE-A is protected under two patent families. Family 1, with priority date of September 15, 2019, covers the nanosystem and its use in treating metabolic diseases. It has been extended via PCT to Europe and the United States (applications: P201930118, PCT/ES2020/070104, EP20755751.3, US17/599,463). Family 2, focused on the targeting system using electric fields, was filed on October 4, 2023, and extended via PCT in 2024 (applications: P202330831, PCT/ES2024/070605). New results are under evaluation for further protection (internal code: FIMABIS-25024).

PARTNERING OPPORTUNITIES

IBIMA Plataforma BIONAND seeks strategic partnerships with pharmaceutical companies through co-development or licensing agreements. The goal is to accelerate clinical translation and market access for BRITE-A.

PROFILE

Lifesome Therapeutics is a Spanish biotech startup currently in the pre-clinical phase of development of an innovative and patented cancer drug delivery and therapeutic agent known as Ohmline. The anti-tumor properties of Ohnmline position this nanoparticle as the only therapeutic lipidic drug delivery system for cancer, but also applicable to many other indications. Ohmline is also being tested for treatment of AMR infections.

SPEAKER

Ana Bouchet *is co-founder and CEO of Lifesome Therapeutics. Her academic career has been focused on lipid biophysics (Biophysics PhD, UBA, Argentina). After being granted a Prestige Marie Curie Fellowship, she joined Prof. Christophe Vandier's group for investigating the dysregulation of ion channels in cancer. She pursued Innovation Managing studies at IESE Business School and took a main role in registering Lifesome Therapeutics.*

anabouchet@lifesometx.com

PRODUCT

Ohmline therapeutic nanocarrier for treatment of metastatic cancer

MECHANISM OF ACTION

Ohmline is a glycolipid able to form either liposomes or nanotubes in aqueous solutions. The liposome can deliver systemically polar and apolar drugs, antibiotics and nucleic acids. The surface sugar of the liposome allows targeting of the payload to tumor areas and immune activated tissues. Also, specific blocking activity of SK3 allows personalised therapeutical approaches based on Ohmline glycolipid formulated as nanocarrier.

The molecular target of Ohmline is SK3, potassium ion channel (KCNN3 gene). SK3 is overexpressed in a wide range of cancer cell types, whereas SK3 expression level in normal tissues is low. Inhibition of mitochondrial SK3 disrupts tumor cell's ability to proliferate. Furthermore, the activity of SK3, when located at migrating cell membrane domains lipid rafts, is key for cancer cells metastasis to other tissues. Ohmline nanoparticles are fused with cancer cell membranes at those lipid rafts, disturbing their structure and inhibiting the activity of SK3, thus impairing cell migration and metastatic processes. Notably, Ohmline impairs the SK3 function without almost no blockade of other ion channels activity, thus leaving non-cancer cells unharmed.

TARGET INDICATIONS

Ohmline is being progressed as a therapy for castration resistant prostate cancer, in combination with taxanes. However, it has shown so far in vitro efficacy at a wide range of cancer types: prostate, lung, colon, melanoma, breast, rhabdomyosarcoma and also haematological cancers. Other developments in our pipeline include testing Ohmline as antibiotic, therapy for parasites infections and also gene therapy applications.

CURRENT STATUS

- Ohmline combination with docetaxel has been extensively validated in prostate cell lines, showing Ohmline as stand-alone agent efficacy, and clear synergistic cell growth inhibitory capabilities.
- In vivo xenograft (PC3 cell line) studies are being carried out for confirming the potential of the combination.
- In vitro standard toxicity tests have shown no toxicity of Ohmline. In house maximum tolerated dose studies in mice has been carried out, reaching 1000 mg/kg doses with no effect.
- A preliminary meeting with EMA Innovation Task Force (16th December 2024) confirmed the external experts support for the development of the Ohmline-taxane therapy for the treatment of castration resistant prostate cancer.

INNOVATIVE ASPECTS

- Ohmline stands out among other drug delivery systems because of its ability to target tumors and inhibiting properties of tumor growth: disaccharide groups exposed on its surface recognise and interact with aberrantly expressed sugars in tumor areas, improving its biodistribution and allowing very precise drug delivery to its intended site of action.
- Furthermore, the anti-tumor properties of Ohmline glycolipid position this nanoparticle as the only therapeutic lipidic drug delivery system, able to mediate synergistic efficacy improvement of the therapeutic effect of authorised drugs.

IPR

Lifesome Therapeutics SL remain the solely owner of Ohmline technology and its applications. These are protected by 2 proprietary patents: PCTWO2011/101408A1 and PCTEP WO 2024/126812 A1. Main territories (Europe unitary area, non-adhered to Euro PCT European states, USA, China) are covered (as for September 2025) or in the process of.

PARTNERING OPPORTUNITIES

Lifesome Therapeutics is aiming to arrange co-development agreements with pharmaceutical companies focused on highly aggressive metastatic cancer types with no current available treatment.

PROFILE

Highlight Therapeutics

Highlight is a private, clinical-stage biotechnology company dedicated to unlocking the full potential of dermato-oncology. HTL is developing a novel anti-tumor immunotherapy drug called BO-112, a non-coding double-stranded RNA based on poly I:C, for the treatment of skin tumors.

SPEAKER

Marisol Quintero *is the CEO of Highlight Therapeutics, where she leads the company's scientific and clinical development, as well as manages funding rounds. She has a strong background in innovation and technology transfer, with experience at institutions such as CNIO and the Botín Foundation. She is a Partner at Columbus Venture Partners and actively participates in boards of directors and specialized forums. Marisol holds a degree in Pharmacy from the University of Valencia, a Ph.D. in Pharmacology from University College London, and an MBA from IE Business School.*

mquintero@highlighttherapeutics.com

PRODUCT

BO-112: a non-coding double-stranded ribonucleic acid (dsRNA)

MECHANISM OF ACTION

BO-112 is a non-coding double-stranded ribonucleic acid (dsRNA) based on Polyinosinic Acid Polycytidylic Acid (Poly I:C) formulated with polyethyleneimeine (PEI). It is an analog of double-stranded viral RNA thereby mimicking effects of a viral infection.

Mechanism of Action includes innate and adaptive immune system activation mediated by TLR3, MDA5, RIG-I, and PKR and direct tumor cell death creating a long-lasting immune response.

TARGET INDICATIONS

Dermatology, oncology.

CURRENT STATUS

- Phase IIb in Basal Cell Carcinoma on going, with recruitment expected to be completed within H2 2025

INNOVATIVE ASPECTS

- The approach of BO-112 is unique; there is no other solution on the market that, when administered locally, has curative potential for high-risk basal cell tumors.
- BO-112 is ideal for the treatment of localized diseases such as basal cell carcinoma (BCC).

IPR

Several patents filed and granted with protection well ahead in the commercialization phase.

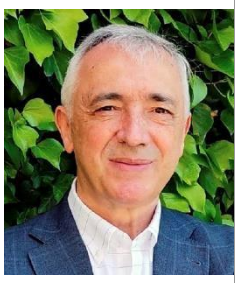
PARTNERING OPPORTUNITIES

Seeking partners post Phase IIb

PROFILE

Servatrix Biomed S.L. is a spin-off of the Universidad Autónoma de Madrid whose main goal is to develop compounds that activate the transcription factor NRF2 to treat chronic diseases. It focuses particularly on non-alcoholic steatohepatitis (NASH/MASLD), aiming to slow liver damage through regulation of lipid metabolism and protection against inflammation and fibrosis.

SPEAKER



Antonio Cuadrado *is a Full Professor of Biochemistry at the Universidad Autónoma de Madrid and co-founder, as well as Chief Scientific Officer (CSO), of Servatrix Biomed S.L. Specialist in the molecular mechanisms regulating metabolism, oxidative stress, and inflammation, he focuses his research on the development of innovative therapies to halt chronic diseases.*

antonio.cuadado@uam.es

PRODUCT

NRF2 Activation: Pharmacological Innovation against Fatty Liver Disease

MECHANISM OF ACTION

The product is a mild and controlled activator of NRF2 - the master regulator of cellular defense mechanisms - designed to modulate this master regulator of cellular defense precisely and selectively in the liver. Unlike other approaches, its action avoids excessive activation, allowing an optimal therapeutic balance that enhances antioxidant and antiinflammatory defense without adverse effects. Its main application is advanced fatty liver disease (NASH/MASLD), where it helps reduce inflammation, fibrosis, and metabolic damage.

NRF2 strengthens redox balance, reduces inflammation, and protects against chronic metabolic damage. In the liver, this mechanism protects hepatocytes against lipotoxicity, inflammation, and fibrosis, acting on the drivers of progression in advanced fatty liver disease (NASH/MASLD). The controlled nature of this activation ensures therapeutic efficacy with a strong safety profile.

TARGET INDICATIONS

The product is primarily aimed at the treatment of chronic liver diseases, particularly advanced fatty liver disease (NASH/MASLD), a condition with a high unmet medical need and a rapidly expanding market. Thanks to its innovative mechanism of NRF2 activation, it also holds potential for addressing other chronic diseases linked to oxidative stress and inflammation, such as certain metabolic and neurodegenerative disorders.

CURRENT STATUS

- The project is currently in an advanced preclinical stage, having successfully completed proof-of-concept studies in animal models of advanced fatty liver disease (NASH/MASLD).
- Experimental results have shown that mild and controlled activation of NRF2 significantly reduces inflammation, oxidative stress, fat accumulation, and liver fibrosis, confirming the expected mechanism of action.
- Work is currently focused on pharmacological optimization and preclinical safety studies, with the goal of starting regulated preclinical trials in the near future.

INNOVATIVE ASPECTS

- Unlike current treatments for advanced fatty liver disease (NASH/MASLD), which are focused on specific metabolic or anti-inflammatory targets, our strategy strengthens natural defense mechanisms against oxidative stress, chronic inflammation, and fibrosis in an integrated manner.
- Other competitors acting on NRF2 use highly unspecific electrophilic compounds, which may cause overstimulation and toxicity.
- Our product stands out due to its mild and controlled NRF2 activation mechanism, capable of modulating this pathway effectively without inducing supra-physiological activation.

IPR

Servatrix holds exclusive license to PCT/EP2022/050657, already granted in Europe (priority; 17 countries) and extended to the United Kingdom, Switzerland, and Spain. Applications are also under review in the USA and Japan.

PARTNERING OPPORTUNITIES

The project aims to establish strategic alliances with the pharmaceutical industry to secure progress in clinical and regulatory development. The business plan foresees an exit after Phase IIa clinical trials, through the sale of patent or a development agreement with a pharmaceutical partner.