



PATENT PORTFOLIO

ISTITUTO ROMAGNOLO PER LO STUDIO DEI TUMORI
"DINO AMADORI" - IRST IRCCS

LIPOSOMES COMPRISING ANTI-LOX ANTIBODY

ACRONYM: LIPO-EPI-LOX NANOPARTICLES

Background: Triple-negative breast cancer (TNBC) is the most aggressive subtype with limited treatment options, affecting over 2 million women worldwide each year. Since 1970, the standard therapy has included anthracyclines and taxanes, which are highly toxic and lack targeted molecular therapy.

Technical problem / Medical need: TNBC market currently lacks a molecular-targeted therapy to be used as a first-line treatment in metastatic cases. There is an unmet clinical need to improve therapeutic agents, which often have limited efficacy and systemic toxicity due to non-specific targeting. In this context, nanotechnology offers a promising approach, using nanotherapeutics designed to selectively deliver drugs to the tumor site, potentially overcoming these drawbacks and enhancing treatment outcomes.

Solution/Technology: The present invention describes a lipid-based nanocarrier functionalized with a LOX antibody and loaded with the therapeutic agent epirubicin, a standard treatment for breast cancer. The concentration of anti-LOX was significantly reduced to minimize in vivo toxicity and enhance translational outcomes. The in vivo analyses were designed to align with near-patient treatment regimens. This nano-drug effectively combines the therapeutic activity of the LOX antibody with its ability to selectively concentrate the drug at the tumor site, offering increased efficacy and reduced systemic toxicity.

Competitive advantages: Employing selective targeting through the binding of anti-LOX antibodies to PEG- based liposomes shows advantages over conventional chemotherapy. Targeting LOX inhibits tumor cell migration and metastatic growth, allowing for a synergistic effect with chemotherapeutics while minimizing systemic toxicity.

Looking for: We are looking for strategic partnerships and investors to support next phases of our product development.

TRL 4 – Patent: EP207807181; US17766123

Inventors:

Dr. Alessandro De Vita, Preclinic and Osteoncology Unit Biosciences Laboratory;

Dr. Chiara Liverani, Preclinic and Osteoncology Unit Biosciences Laboratory

TTO Contact:

Luca Battistelli; Giuliana Villari - TTO.urttf@irst.emr.it - +39 0543 739421 - www.irst.emr.it

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TRIBILIFE INNOVATIONS – ANTIBODY DISCOVERY PLATFORM ACRONYM: TRIBILIFE

Background: A major challenge in oncological immunotherapy is the lack of specific tumor targets for safe, selective treatment. This is critical for non-small cell lung cancer (NSCLC), metastatic melanoma, and pleural mesothelioma, which have significant unmet clinical needs. NSCLC accounts for 81% of U.S. lung cancer cases, with 238,340 diagnoses in 2023. Melanoma, highly aggressive at advanced stages, represents 4-5% of cancer cases in Europe and the U.S. Mesothelioma, though rare, has a poor 5-year survival rate of just 5%. Personalized therapies are urgently needed.

Technical problem / Medical need: Currently, no biomolecular alterations allow targeted therapies for mesothelioma (MP), making platinum-based chemotherapy the standard first-line treatment, with no accepted second-line guidelines. Immunotherapy shows promise in specific MP subtypes, with checkpoint inhibitors like nivolumab, ipilimumab, and pembrolizumab improving disease control in advanced cases. The role of antibody responses suggests MP is a strong candidate for isolating specific antibodies via the TriBILife Innovations platform.

Solution/Technology: TriBILife Innovations aims to revolutionize oncology treatment and diagnostics by identifying new targets and specific antibodies against cancer. Through advanced translational research, we have discovered fully human antibodies targeting metastatic melanoma and NSCLC. Our goal is to extend the TriBILife platform to other diseases, including pleural mesothelioma. Antibodies are reconstructed from sequences found in patients responsive to immune-checkpoint inhibitors (ICI) to create therapeutically potent antibodies.

Competitive advantages: The platform offers strategic and competitive advantages: no need for prior tumor antigen selection, allowing direct expression of human antibody sequences; patient-derived, biocompatible antibodies enhance tolerability; broad patient applicability aids diagnosis and treatment decisions. Its personalized antibody reconstruction optimizes efficacy while reducing side effects, integrating therapeutic and diagnostic solutions for comprehensive patient management.

Looking for: We are looking for strategic partnerships and investors to support next phases of our product development and to implement novel technologies to higher the throughput of screening of TriBILife.

TRL 3 – Patent: WO2024/188790; WO2024/188786

Inventors:

Dr. Massimiliano Mazza, Advanced Cellular Therapies and Rare Tumors Unit;

Dr. Anna De Lucia, Advanced Cellular Therapies and Rare Tumors Unit

TTO Contact:

Luca Battistelli; Giuliana Villari - TTO.urttf@irst.emr.it - +39 0543 739421 - www.irst.emr.it

ADVANCING EARLY DIAGNOSIS AND PROGNOSIS IN NEUROENDOCRINE TUMORS ACRONYM: ZEBRA DX

Background: Neuroendocrine tumors (NETs) have been steadily increasing over the past decade. The global NET market was estimated to be valued at around \$2.5 billion in 2025, with a projected compound annual growth rate of 10% from 2018 to 2028. NETs have a diverse range of presentations, affecting multiple organ systems, and can be challenging to diagnose accurately. The prevalence of NETs is difficult to ascertain precisely due to their often indolent nature, the reason why they are diagnosed at a late stage when the tumors have already spread to other parts of the body.

Technical problem / Medical need: The increasing incidence of NETs and the demand for more accurate and timely diagnostics still stands as an unmet clinical need for early diagnosis and accurate prognosis in this specific patient population frequently misdiagnosed or detected too late and clinicians lack of tool to guide their treatment decisions into this complex disease, towards personalized medicine approaches and tailored therapeutic decisions to avoid overtreatment, minimizing drugs toxicity.

Solution/Technology: Zebra Dx technology innovative non-coding (nc) RNA-based liquid biopsy detects specific molecular signatures associated with these rare tumors and stand as a non-invasive and highly accurate diagnostic tool enabling early detection of NETs, addressing the current clinical need for timely intervention. The assay is a powerful prognostic tool, predicting treatment responses and guiding personalized therapeutic decisions.

Competitive advantages: Zebra Dx's addresses the clinical need for early diagnosis, prognosis, and treatment response monitoring of neuroendocrine tumors (NETs) providing early, accessible, and accurate diagnosis and prognosis of NETs through non-invasive advanced ncRNA-based in vitro diagnostics, reducing potential complications associated with invasive procedures for patients.

Looking for: We are looking for strategic partnerships and investors to support next phases of our product development.

TRL 3 – Patent: PCT/EP2023/073631

Inventors:

Dr. Massimiliano Mazza, Advanced Cellular Therapies and Rare Tumors Unit;

Dr. Patricia Borges de Souza, Advanced Cellular Therapies and Rare Tumors Unit

TTO Contact:

Luca Battistelli; Giuliana Villari - TTO.urtf@irst.emr.it - +39 0543 739421 - www.irst.emr.it

CVL

DETECTION AND CHARACTERIZATION OF CIRCULATING TUMOR CELLS USING THE MEDICAL DEVICE CLEAR EVOLUTION. ACRONYM: CLEAR EVOLUTION

Background: Liquid biopsy (LB) represents a promising, non invasive tool to predict the primary and acquired resistance to treatments early and to monitor the molecular evolution of the disease, modulating the therapeutic choice. LB is currently recommended in clinical practice for the molecular determination in advanced non- small-cell lung cancer (NSCLC) patients. In clinical practice, LB is used for the identification of driver mutations carried by the circulating tumor DNA (ctDNA).

Technical problem / Medical need: ctDNA analysis can only detect the presence or absence of alterations on the DNA of specific tumor genes. The analysis of circulating tumor cells (CTCs), which are tumor cells that released from the tumor tissue and then migrate through the blood vessels, would allow to obtain more complete information on the patient's tumor, in terms of DNA, RNA and proteins. The detection of CTCs would represent an essential component of cancer and could serve to personalize cancer therapy.

Solution/Technology: CLEAR EVOLUTION therefore arises in response to the need of improving tumor molecular characterization via CTCs isolation. It's an in vitro device, based on Raman spectroscopy, capable of recognizing, isolating and characterizing CTCs, in a non invasive, rapid and accurate way.

Competitive advantages: The process requires no sample pretreatment, significantly thus reducing costs and time compared to traditional methods; highest quality of extracted biological material, ensuring superior results for our patients.

Looking for: We are looking for strategic partnerships and investors to support next phases of our product development.

TRL 4 – Patent: PCTEP2017059626 (GE; SP; FR; UK; HU; ITA; LI); USA 16096466; 17099069

Inventors:

Dr. Paola Ulivi, Lead Researcher CLEAR EVOLUTION | Translational Oncology Biosciences Laboratory;

Dr. Giorgia Marisi, Lead Researcher CLEAR EVOLUTION | Translational Oncology Bioscience Laboratory

TTO Contact:

Luca Battistelli; Giuliana Villari

TTO.urttf@irst.emr.it - +39 0543 739421 - <https://www.irst.emr.it/en/home>

METHOD TO IDENTIFY DISEASE LINKED GENETIC FUSIONS; ACRONYM: ALL-FUSIONE

Background: B-cell acute lymphoblastic leukemia (B-ALL) is an aggressive hematological cancer marked by the proliferation of undifferentiated B-cell precursors. Patients are classified into subgroups based on genomic alterations, particularly translocations, which are vital for clinical outcomes and targeted therapies. About 40% of adult B-ALL patients belong to three main subtypes, while 60% fall into a heterogeneous category. Research has enhanced molecular classification, improving risk assessment and treatment options, though routine diagnostics still face challenges.

Technical problem / Medical need: Gene fusions have a causative, prognostic and therapeutic role in onco-hematology. However, their diagnostic identification is limited to few translocations. The classification of B-cell acute lymphoblastic leukemia (B-ALL) into subgroups is essential for determining clinical outcomes and guiding genomic-based therapies. Improved molecular classification offers better risk assessment and treatment options for patients.

Solution/Technology: We collected of a robust pipeline for fusion detection settled mainly on B-cell acute lymphoblastic leukemia (B-ALL) data (RNA-seq large panel). Our in-house RNA-seq pipeline, integrates different fusion-mining tools integrated by a multistep filtering strategy that interrogates an exhaustive internal database (copyright) allowing us to retain the most reliable transcripts via the crucial "literature filter" highlights fusions documented in over 900 B-ALL studies, resulting in a detailed list of 749 fusions linked to various B-ALL ages and subtypes.

Competitive advantages: ALL-FusiONE is designed to resolve the unmet need of genomic-based diagnostic in ALL, making genomic analysis immediately scalable at single-patient level providing reliable results. Eliminating false positive results, ALL-FusiONE provide a method that allow immediate prognostication and drug prescription basing on test results.

Looking for: We are looking for strategic partnerships and investors to support next phases of our product development.

TRL 3 - Patent: TPF4857/WO-EP 2021; IPF4857/WO-US 2021; SIAE n 2022/00102

Inventors:

Dr. Anna Ferrari, Lead Researcher - Translational Hematology Unit, Biosciences Laboratory;

Dr. Eugenio Fonzi, Lead Bioinformatic Researcher - Unit of Biostatistics and Clinical Trials.

TTO Contact:

Luca Battistelli; Giuliana Villari

TTO.urttf@irst.emr.it - +39 0543 739421 - <https://www.irst.emr.it/en/home>

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TTO.URTTF@IRST.EMR.IT