Actively-targeted intracellular delivery of monoclonal antibodies to change the paradigm of cancer treatment

MARIA J. ALONSO (CSO)

Libera Bio

Libera Bio® at a Glance

Spin-off of the USC in Spain

USC UNIVERSIDADE DE SANTIAGO DE COMPOSTELA

BIOINCUBATECH

+20

years of international research in cancer

European Commission

GOBIERNO DE ESPAÑA MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES

XUNTA DE GALICIA

continuous support from Regional, National and EU funds

Positive External Validation

OXENTIA Oxford's Global Innovation Consultancy

Healthtech TAB Healthtech Translation Advisory Board

BIOEXPERT NETWORK

MedCity INVEST JULY 20-24, 2020 • VIRTUAL • National Healthcare Investing Event

Awards

QUICKFIRE CHALLENGE

Johnson & Johnson INNOVATION | JLABS

US, Jan 2020

AIM HI ACCELERATOR FUND

US, Sep 2020

innovatia 8.3

Spain, Oct 2020

Leadership Team

Prof. Maria J. Alonso Ph.D | CSO

Worldwide leader in drug delivery
30-year experience: formulation of biological drugs

- 300 research papers, >31,000 cites, H Index 93
- Member US National Academy of Medicine
- Past President of the Controlled Release Society
- Pharmacology Top 10
- Most Influential Researcher Power List
- Inventor of 22 patent families. 3 start-up ventures.

Leadership Team

Olivier Jarry, MS, MBA | CEO

NOVARTIS · BAYER · Bristol-Myers Squibb

Executive with Novartis, Bayer and Bristol-Myers Squibb

- CEO, President, CCO of small companies from preclinical stage to commercialization stage
- Experience in business development in large pharma
- Investment banking training. Contacts at approx. 1500 investors. Fundraising: up to 45m $
- Launched products on 4 continents in oncology, and other areas

Desirée Teijeiro, Ph.D | COO

USC Universidade de Santiago de Compostela · University of Copenhagen · Fénix Biotech · AdvanCell

>18 years scientific management experience in academic and private sectors

- Numerous translational and industry collaborative projects in Nanomedicine
- Inventor of several patents
- Experience in Technology Transfer , IP strategy and Regulatory issues

Advisory Board

TECHNOLOGY

Robert Langer

MIT

MOLECULAR BIOLOGY

Silve Vicent

cima

Stanford University

Manuel Hidalgo

Weill Cornell Medicine

HARVARD UNIVERSITY

CLINICAL ONCOLOGY

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UNIVERSITY OF CAMBRIDGE

Teresa Macarulla

VHIO VALL D'HEBRON Institute of Oncology

Rafael López

USC UNIVERSIDADE DE SANTIAGO DE COMPOSTELA

REGULATORY

VBC Team

Evidera

PPD

Unmet Need

The two well-established anticancer drug modalities, small molecules and biologics, have saved millions of lives, but they are not a universal solution:

Small molecules:

Minimal accumulation in tumor and metastatic cells; important side effects

Engage only about 10 percent of all targets

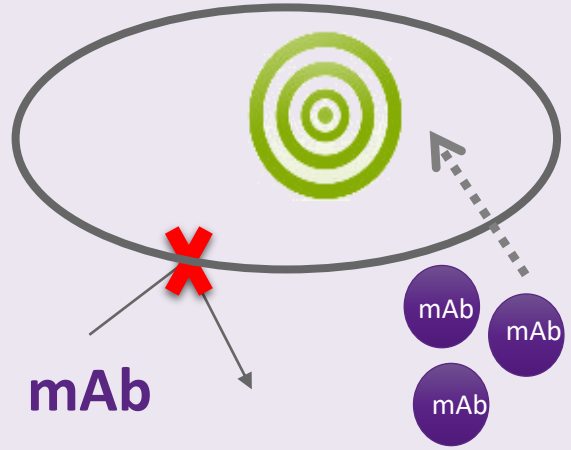
Monoclonal antibodies:

Strongly engage targets, but are too large (150 kDa) and polar to be internalized by the cells if no specific receptors are present at the cell membrane

Many desirable targets, such as the widely known RAS cancer drivers, **fall into the category of 'undruggable'**

Addressing 'undruggable' intracellular targets:

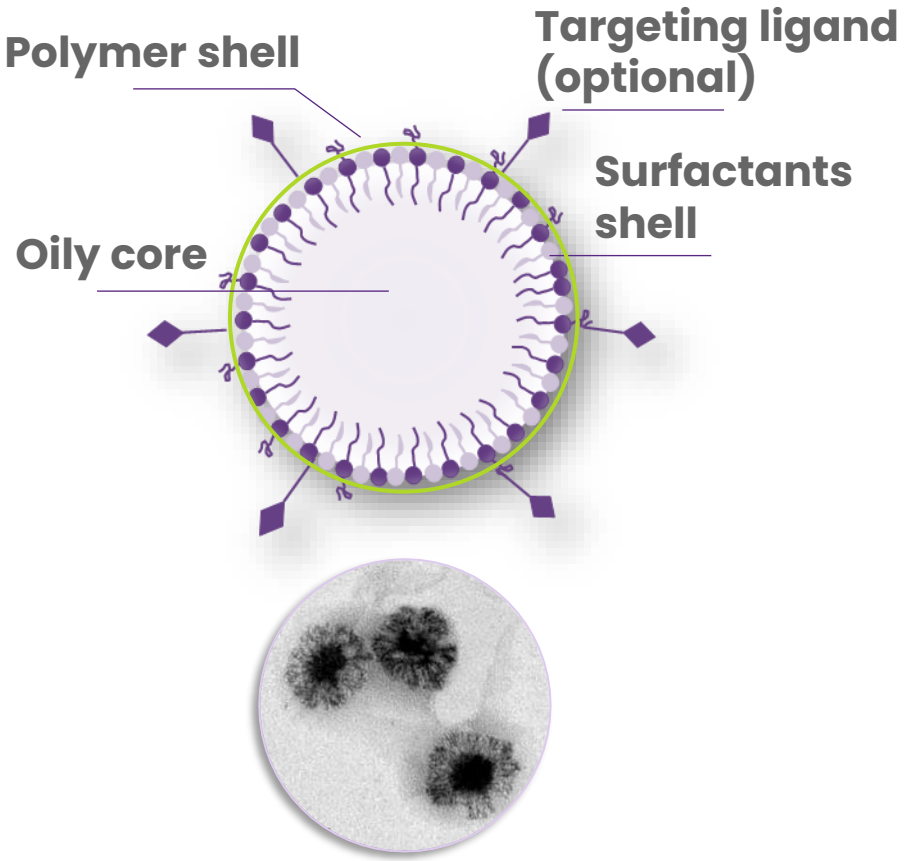
'The Holy Grail' in oncology



Our solution: The MPN Technology®

Allows to encapsulate anticancer compounds **(biologics such as mAbs and/or small molecules)** and to **selectively deliver them to and into the tumor and metastatic cells after IV administration** ("targeting").

It is the **first nanotechnology proven *in vivo* for the intracellular delivery of whole antibodies**

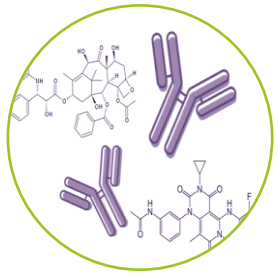


journal of controlled release

CLINICAL CANCER RESEARCH

MPN Technology® Key Pharmaceutical Features

Versatility



Validated for 6 mAbs and 10 small molecules

May combine mAb and small molecule

Safety

FDA/EMA approved ingredients

Favorable safety record in preliminary toxicology studies

Manufacturability

Simple & Scalable manufacturing process

Lyophilisable

Lead Target: Mutated KRAS

KRAS is the Most Frequently Mutated Gene in Human Cancer:

Over 30% of cancers are driven by mutant RAS

Medical Unmet Need:

› 3 decades of failures in the development of small anti-RAS molecules

	KRAS G12V	KRAS G12D
Pancreatic	45155 **(22%)**	48870 **(24%)**
Colorectal	36852 **(8%)**	53805 **(12%)**
Lung	31327 **(5%)**	22994 **(3.6%)**
Total addressable/ year (only US & EU)	113334	125669

Libera Bio estimates based on epidemiology data reported in Globocan 2025 (accessed April 2020) and frequencies by mutation (mycancergenome.org)

Addressing KRAS G12V+/G12D: a Potential Blockbuster Drug Market Opportunity

MPN-anti-KRAS mAb: Precision Medicine in Cancer

Patient Selection

Tumors Expressing Mutated KRAS

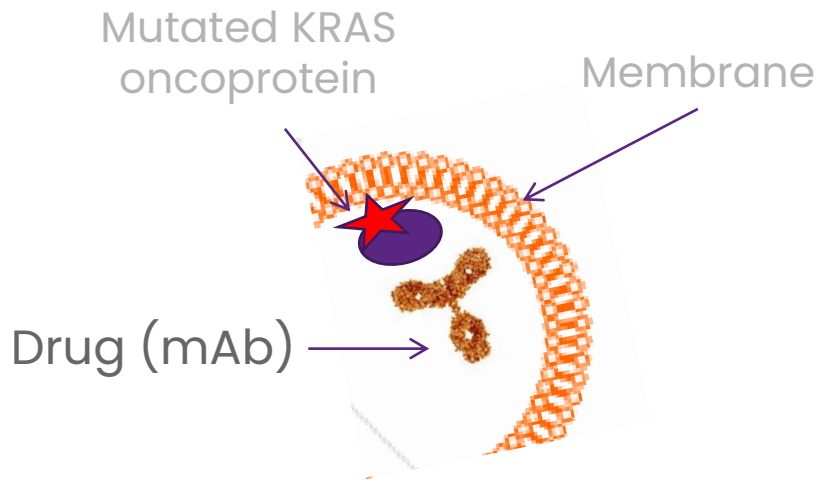
Already available routine tools for patient screening

Smart Delivery

MPN Technology® delivers the drug (mAb) into tumor/metastatic cancer cells

Drug Specificity

Anti-KRAS mAb only recognizes mutated KRAS oncoproteins

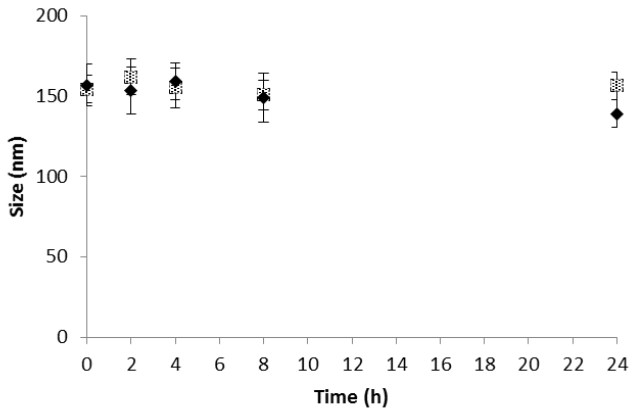


Minimal off-target toxicity

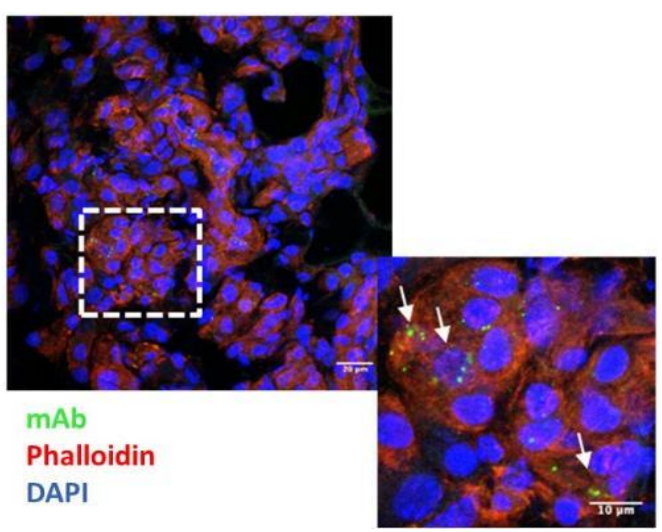
Intracellular mAbs *in vivo* Biodistribution

MPN™ Technology remains stable in Plasma and Facilitates:

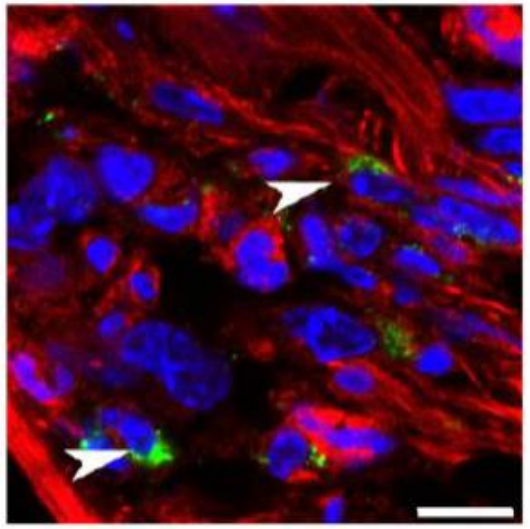
Accumulation of Antibodies in Tumor Tissue and Internalization of mAbs in Cancer Cells



PLASMA STABILITY



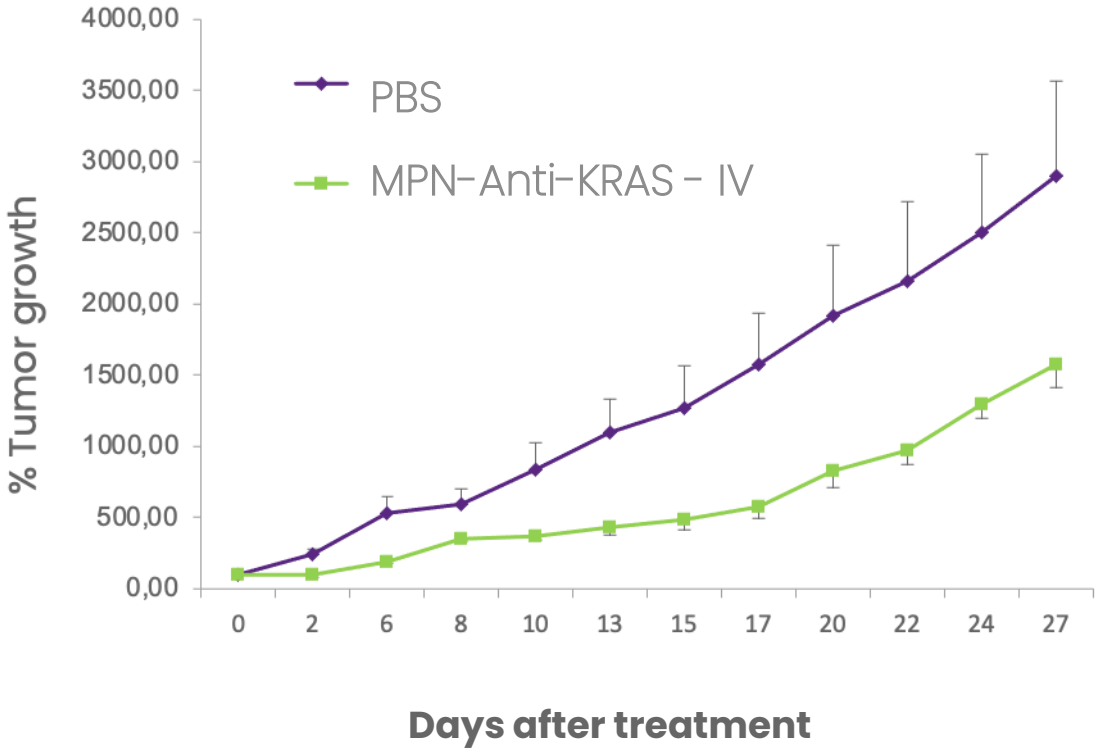
Immunofluorescence



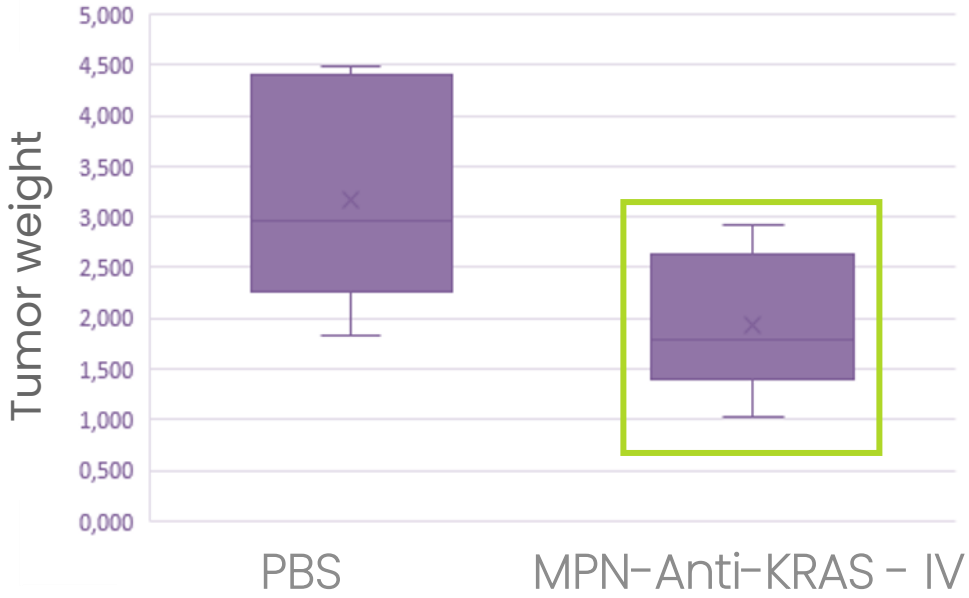
FITC-labeled mAb

Intracellular mAbs: efficacy POC studies (KRAS+)

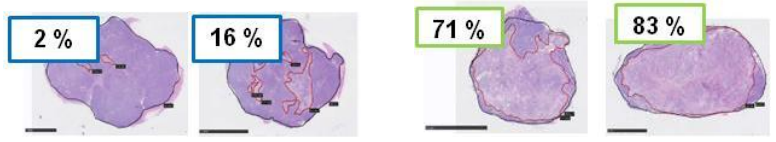
LUNG CANCER S.C ALLOGRAFT MODEL



COLORECTAL CANCER ORTHOTOPIC MODEL

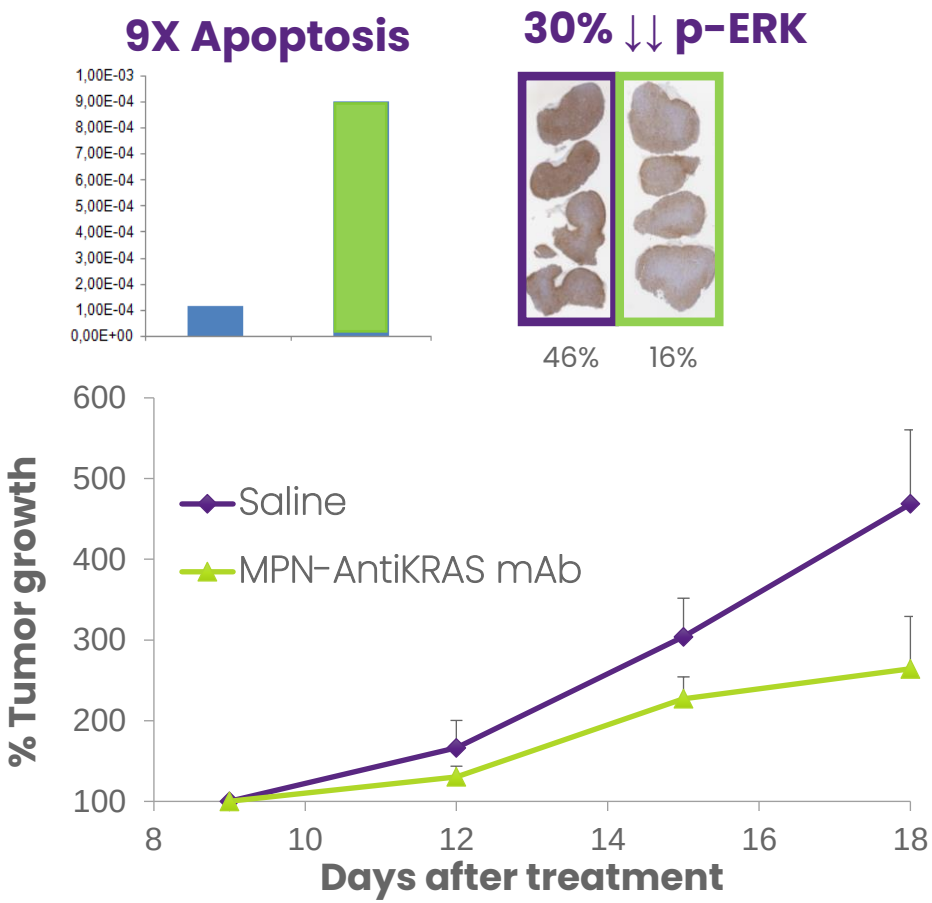


Necrosis →

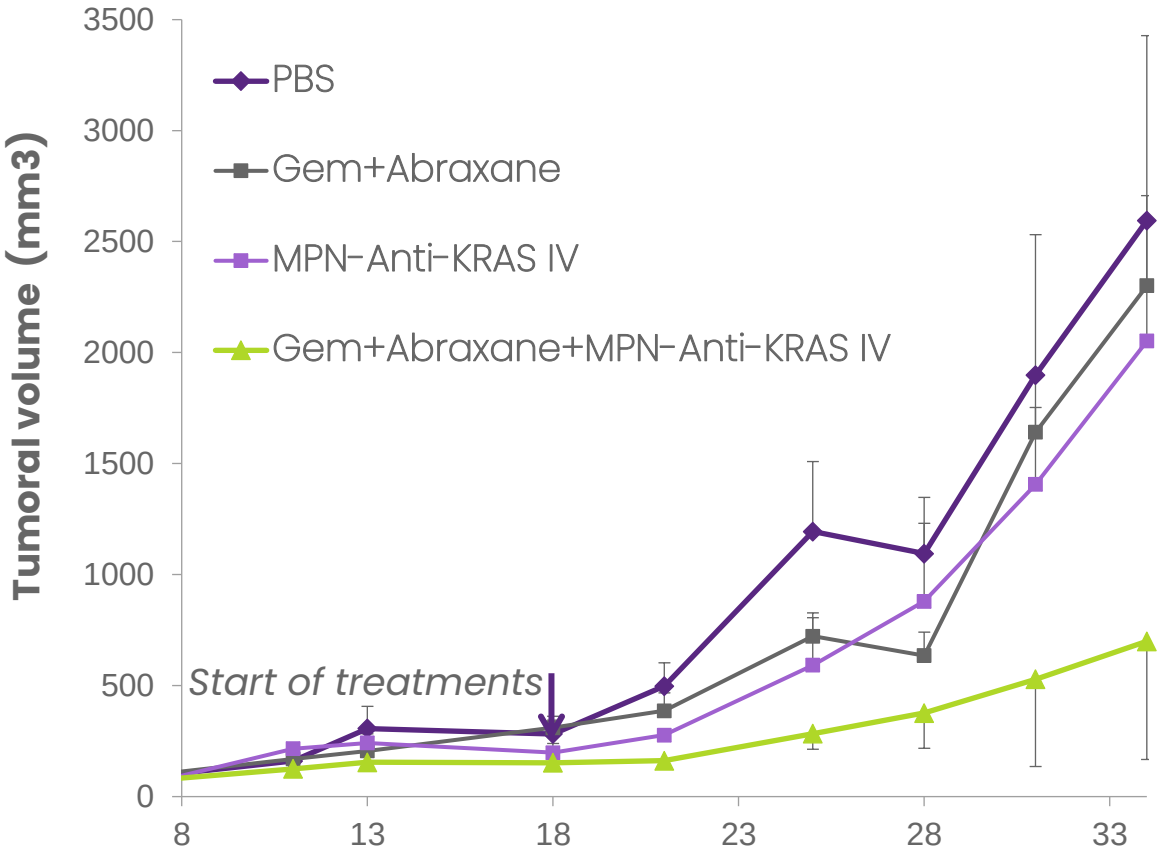


Intracellular mAbs: efficacy POC studies (KRAS+)

PANCREATIC S.C. XENOGRAFT MODEL



PATIENT DERIVED PANCREATIC XENOGRAFT MODEL (PDX)



Patent Portfolio

Libera Bio holds exclusive licenses to USC patents and intends to create new IP as it develops new therapeutic candidates

9 patents issued worldwide

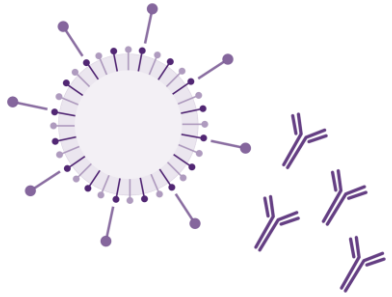
7 pending applications worldwide

1 PCT

Patent claims cover:

- MPN for drug delivery
- MPN for intracellular mAb delivery
- Pharmaceutical use of MPN to treat cancer
  - MPN-Anti-KRAS mAbs

- Combination therapies
- Methods for MPN manufacturing

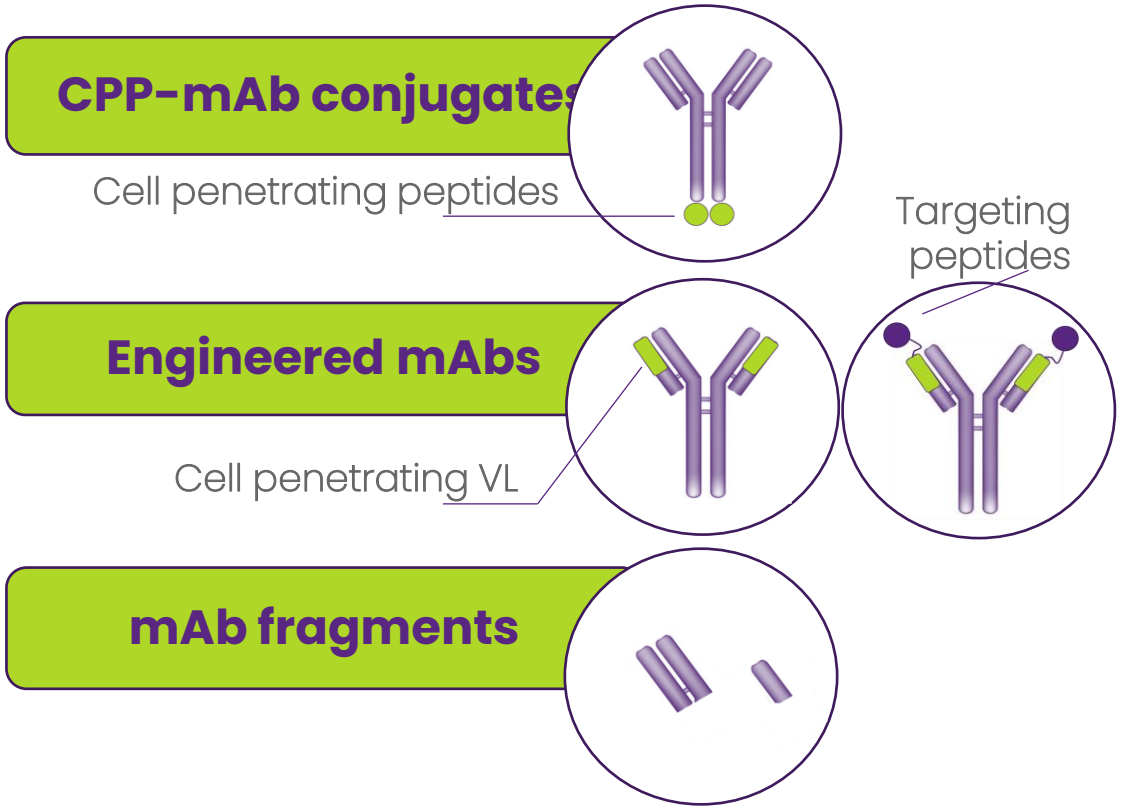


Wolf Greenfield INTELLECTUAL PROPERTY LAW

ZBM : PATENTS & TRADEMARKS

Competitive Advantages

Other companies are aiming at intracellular targets, but they are lacking key features that the MPN Technology® combines



Libera Bio

- No mAb manipulation (e.g. conjugation)
- Selective biodistribution to tumor and metastatic cells
- Intravenous administration
- mAbs protected in plasma
- Low doses required for efficacy
- Feasible co-encapsulation of actives

CPP-mAbs: Entrada Ther., Cellivery, Sorrento/City of Hope; **Engineered mAbs:** Orum Therap.; **mAb fragments:** Singh Biotech, Complix/MSD/Amgen/Feldan Therap. **Other:** Targovax/Oblique Therap. (mAb-adenovirus)

Business Approach

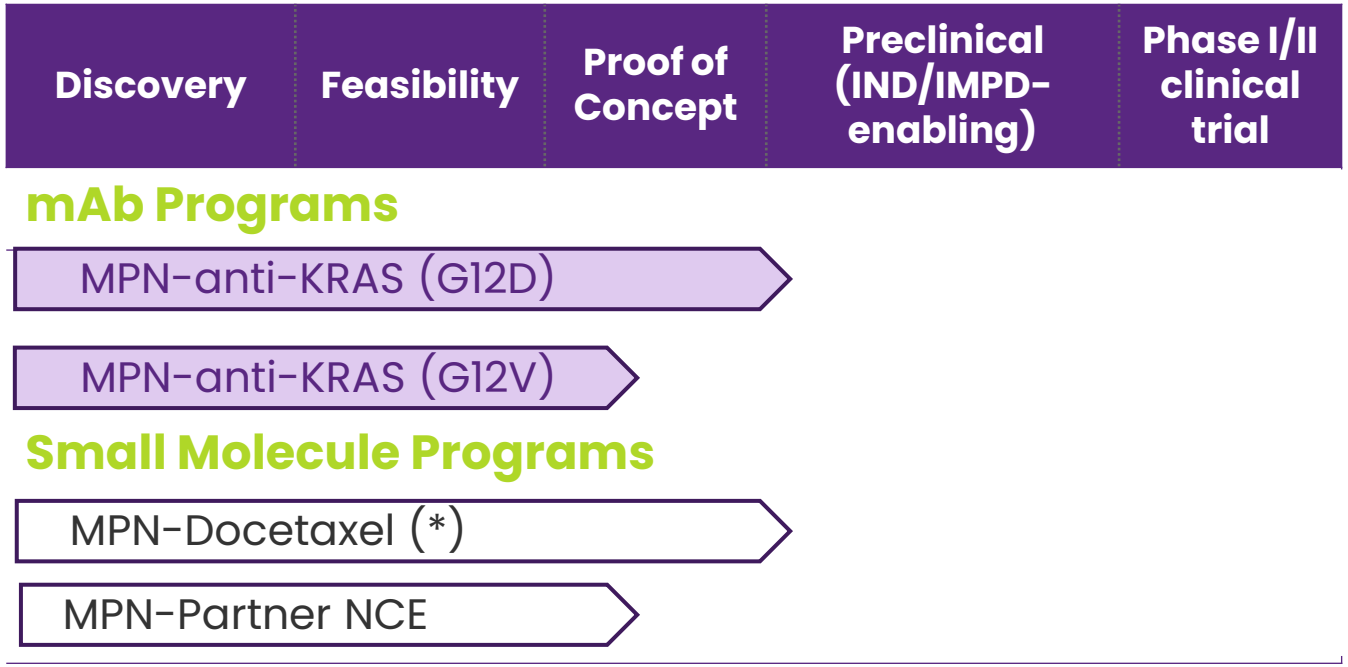
Libera Bio is developing treatments based on the intracellular delivery of mAbs, known to be safe and highly specific toward their targets.

LICENSING STRATEGY

- Libera Bio aims at licensing its first MPN-anti-KRAS as early as possible (e.g. IND/IMPD approval/ Phase 1/2A) to a biopharma company (contacts already established) **and pursues addressing other intracellular targets**

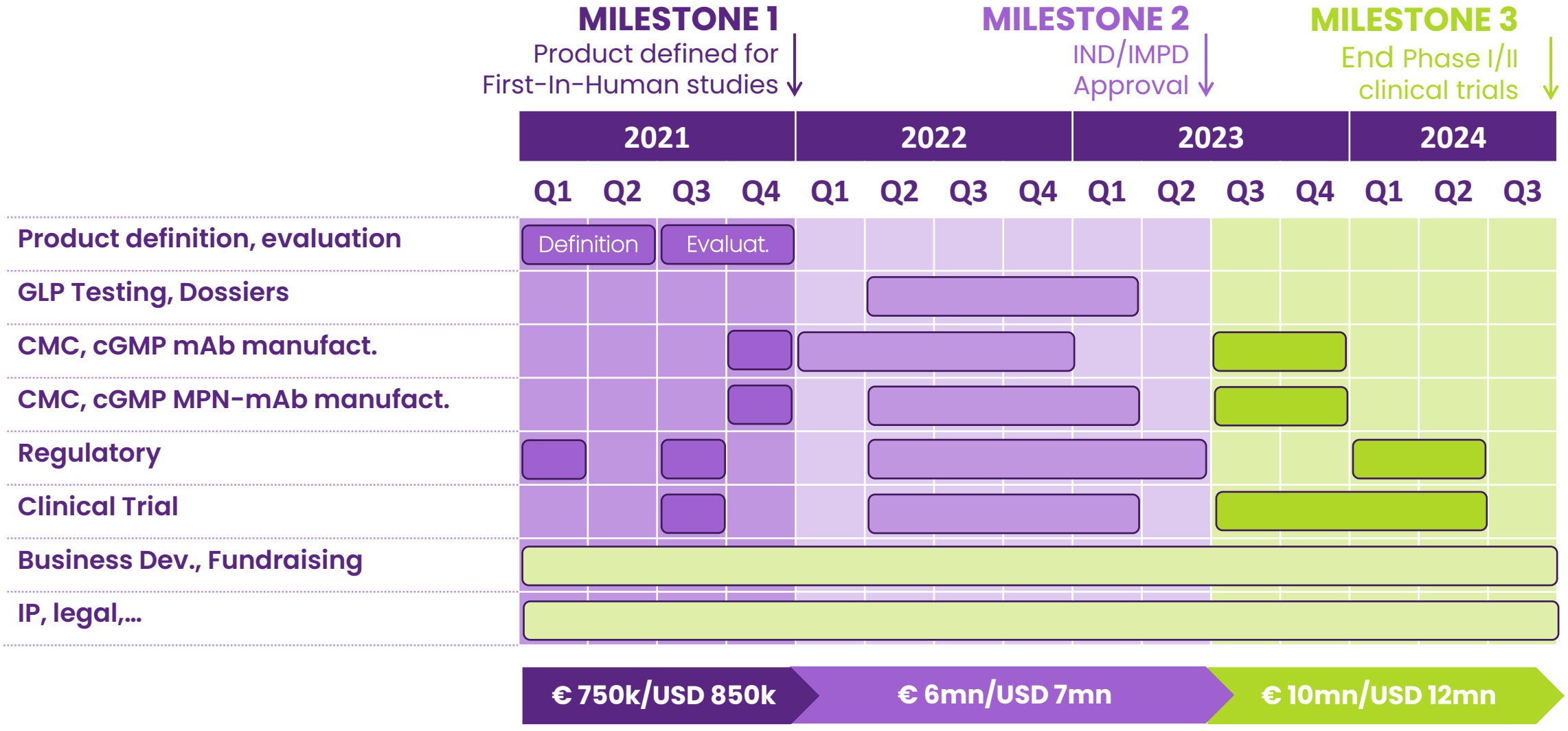
- Libera Bio is open to license the MPN **technology itself** to deliver biologics or small molecules developed by the pharma partner

PIPELINE



(*) program available for out-licensing

Development Plan



In Summary…

- Patented technology to deliver whole mAbs to **intracellular targets**
- **Evidence** of internalization and tumor shrinkage
- **Simple, scalable** manufacturing
- Dedicated, **experienced team**
- Currently looking for **USD 850k**
    - to optimize MPN-Anti-KRAS and prepare for enabling studies and CMC
- Open to **alliances** and out-licensing

Thank you!

You may contact us as follows

Olivier Jarry
Contact@LiberaBio.com
+1 914 703 1073

Libera Bio