IHI Call Days | Call 9

Therapeutic anti-CDH17 & **anti-IL13Ra2** monoclonal antibodies for cancer therapy

(colorectal, gastric, glioblastoma, neuroendocrine…)

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Member of IHI industry partner: No

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Link to the IHI brokerage platform →

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Challenges and objectives

- Problem to address: **Metastatic colorectal cancer: an unmet need**

Colorectal cancer (CRC) → **Liver metastasis** → **High mortality rates**

Colorectal cancer (CRC)	Liver metastasis	High mortality rates
4th leading cause of cancer-related deaths worldwide	**Metastases cause ~90% of overall CRC related deaths**	**900,000 deaths (47%)** in 2022 [1]
1.9 million new cases in 2022[1]	~39% of diagnosed cases undergo liver metastasis	Low survival of mCRC patients → **5-years survival <15%**
Yearly increasing rates	>30% of the total economic budget dedicated to late/metastatic stages	Proven low efficacy of current treatments
individuals >50 years old		

→ URGENT NEED TO DEVELOP NOVEL AND MORE EFFECTIVE THERAPIES!

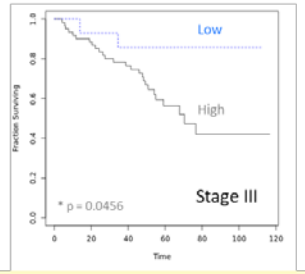
[1] WHO: World Health Organization

- IHI specific objective being addressed: **Objective #2. Improved treatments and management of diseases**

Proposed solution #1

- **PA-661 (anti-CDH17) first-in-class monoclonal antibody**

~80% of CRC tumors overexpress **CDH17** protein[1]



86%

41%

Overall Survival (OS)
Kaplan-Meier curve

High expression levels of **CDH17** protein correlates with lower overall survival (OS)

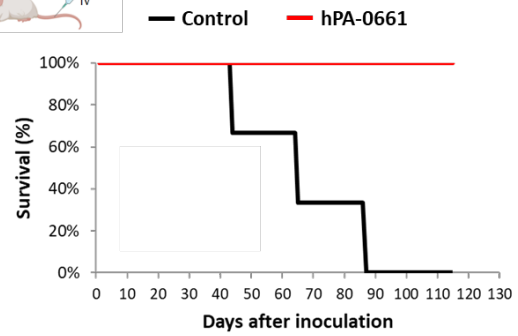
[1] Source: GSE17538-GPL570 data base

Main indication: **metastatic colorectal cancer**

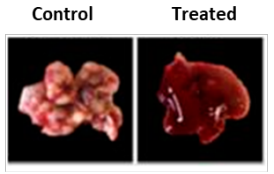
Other indications: **Pancreatic & Gastric Cancer**

LIVER METASTASIS MOUSE MODEL BY INTRASPLENIC INJECTION

ROA: intravenous (IV)



Representative images



Organ: Liver

Kaplan-Meier analysis indicated survival of all treated animals

Target patient: well differentiated and moderately differentiated epithelial tumors (‘cold' tumors).

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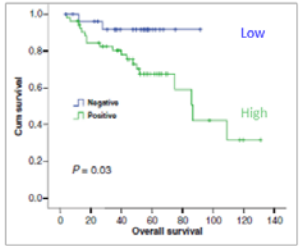
Proposed solution #2 (complimentary to #1)

- **PA-554 (anti-IL13Ra2) first-in-class monoclonal antibody**

~55% of CRC tumors overexpress **IL13Ra2** protein[2]



92%

32%

Overall Survival (OS)
Kaplan-Meier curve

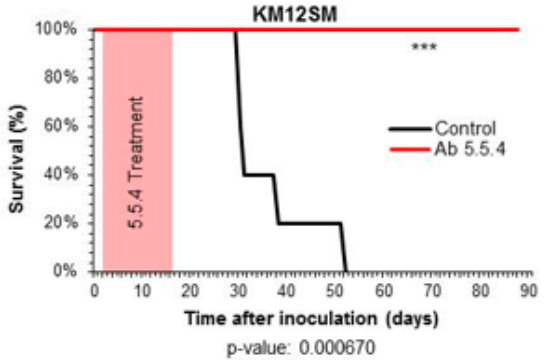
High expression levels of **IL13Ra2** protein correlates with lower overall survival (OS)

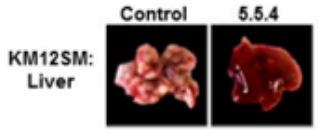
[2] Source: **GSE17538, GSE39582** and **COADREAD** data bases

Main indication: **metastatic colorectal cancer**

Other indications: **Glioblastoma**

LIVER METASTASIS MOUSE MODEL BY INTRASPLENIC INJECTION





Target patient: poorly differentiated tumors (immune cell infiltration in the tumor microenvironment; 'hot' tumors)

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Project suitability for IHI call 9

- Health innovation

Need of a public-private collaboration **to develop highly effective new therapies.**

- Contribution from industry

Need of collaboration and/or support of key health industry players (pharma, biotech, *in vivo* models, radiotherapy, medical imaging) to develop anti-CDH17 and/or anti-IL13Ra2-based biological drugs with the final goal of providing clinicians with improved treatments solutions for highly aggressive tumors like:

  - Metastatic Colorectal Cancer (mCRC)
  - Glioblastoma (GBM)
  - Gastric cancer
  - Neuroendocrine (pancreatic cancer)

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Expected Outcomes and Impact

- Expect Tx product pipeline and impacts:
  - ❑ anti-CDH17 (PA-661)
  - ❑ anti-IL13Ra2 (PA-554)

+

Contribution from IHI partners:

Antibody Drug Conjugates (ADC)
Radioligands (Lutetium; Lu^{177})
Bispecific

- Integration into the healthcare system:
  Pharma partner recommended

- Contribution to strengthen EU competitiveness:
  Biological drugs = High added value products (e.g.: the Ozempic effect in Denmark)

- Expected benefits for patients:
  Novel and highly efficacious medicines → **improve Overall Survival (OS) rates**

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Expertise and resources

Partner seeking for a consortium / coordinator

- We have:
  - **Therapeutic drugs: PA-661 (anti-CDH17)** & **PA-554 (anti-IL13Ra2)** monoclonal antibodies in preclinical stage.
  - **Network of collaborators** (academic, hospitals, CDMOs…) in Spain and EU.
  - **Experience in previous EU projects**: Eurostars, SME Instrument…

- We are looking for:
  - **Collaboration with Pharma partners** to:
  (1) Conduct preclinical and clinical trials of PA-661 & PA-554 (alone or in combination)
  (2) To co-develop 2nd generation products from PA-661 and PA-554 like ADCs, radiopharmaceuticals, bispecifics…

In-kind contributions (IKOP* and IKAA): NO**

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* IKOP - in-kind contributions to operational activities

** IKAA - in-kind contribution to additional activities

Thanks!

Dr Juan Ignacio Imbaud

CEO

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Participant profile:

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Proposal:

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