



Driving innovative therapeutics across the finish line

Corporate Presentation

December 2024

Forward-Looking Statements

This presentation contains “forward-looking statements,” including statements regarding expectations, beliefs, intentions or strategies for the future. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, the potential benefits of APHEXDA®, the potential success of license agreements with our collaboration partners to develop and commercialize motixafortide, expectations with regard to clinical trials of motixafortide and the plans and objectives of management for future operations and expectations and commercial potential of APHEXDA, as well as its potential investigational uses. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. You should not put undue reliance on any forward-looking statements. Factors that could our cause actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of our preclinical studies, clinical trials, and other therapeutic candidate development efforts; our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials; whether our collaboration partners will be able to execute on their development and commercialization plans and other collaboration goals in a timely manner; whether the clinical trial results for APHEXDA will be predictive of real-world results; our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of our therapeutic candidates, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients; whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors; our ability to establish, manage, and maintain corporate collaborations; our ability to integrate new therapeutic candidates and new personnel, as well as new collaborations; the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials; the implementation of our business model and strategic plans for our business and therapeutic candidates; the scope of protection that we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others; estimates of our expenses, future revenues, capital requirements and our need for and ability to access sufficient additional financing, including any unexpected costs or delays in the ongoing commercialization of APHEXDA; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and our industry; and statements as to the impact of the political and security situation in Israel on our business, including the impact of Israel’s war with Hamas and other terrorist organizations, which may exacerbate the magnitude of the factors discussed above. These and other factors are more fully discussed in the “Risk Factors” section of BioLineRx’s most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 26, 2024. In addition, any forward-looking statements represent BioLineRx’s views only as of the date of this presentation and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

Propelling the best ideas beyond the bench, all the way to the bedside

We develop ***life-changing therapies*** for certain cancers and rare disease. Our out-licensed FDA approved drug APHEXDA[®] is improving the cancer journey for patients with multiple myeloma. We are building a legacy of changing lives around the world.

Seeking near- and long-term value for shareholders, and developing important therapies for patients in disease areas with high unmet need



Two Phase 2b clinical trials in PDAC (one ongoing and one planned) with de-minimis investment by BioLineRx. **Interim readout from ongoing PDAC trial anticipated in ~2026**



Plan to onboard additional pipeline assets in 2025 and 2026 in the areas of oncology and/or rare diseases



Proven team of seasoned specialists comprising every area needed to successfully bring a drug from bench to market



Low operational expenses and **financial foundation supported by revenues** and commercial milestones from licensing agreements for APHEXDA, FDA approved therapy developed by BioLineRx

Ongoing license revenue to fund future growth and operational expenses



Announced November 2024

Exclusive license to develop and commercialize APHEXDA (motixafortide) across all indications except solid tumors, and all territories except Asia

- Up to \$87 million in commercial milestones
- Royalties on sales from 18%-23%



Announced October 2023

Exclusive license to develop motixafortide across all indications in Asia

- Up to \$200 million in commercial milestones
- Tiered double-digit royalties on sales

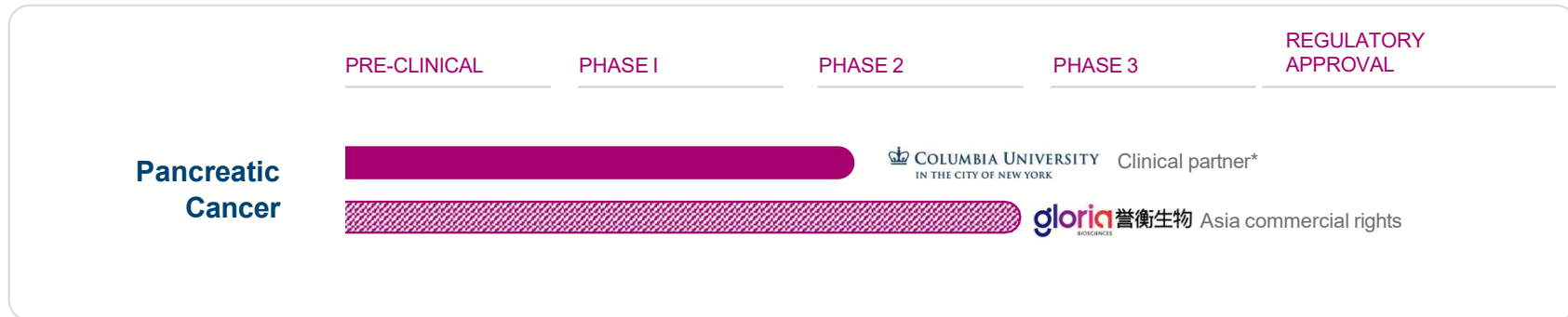
Value creation through program execution



PDAC Program—with additional solid tumor potential expansion

- Proof-of-mechanism and concept established in completed Phase 2 study in second-line metastatic pancreatic cancer
- Encouraging single-arm pilot phase data in first-line metastatic pancreatic cancer showed significantly expanded mPFS and mORR compared to historical data
- Two randomized Phase 2b studies in first-line metastatic pancreatic cancer in combination with PD-1 inhibitors cemiplimab and zimberelimab

Pipeline Programs



*Investigator Initiated Study



Studies in Planning

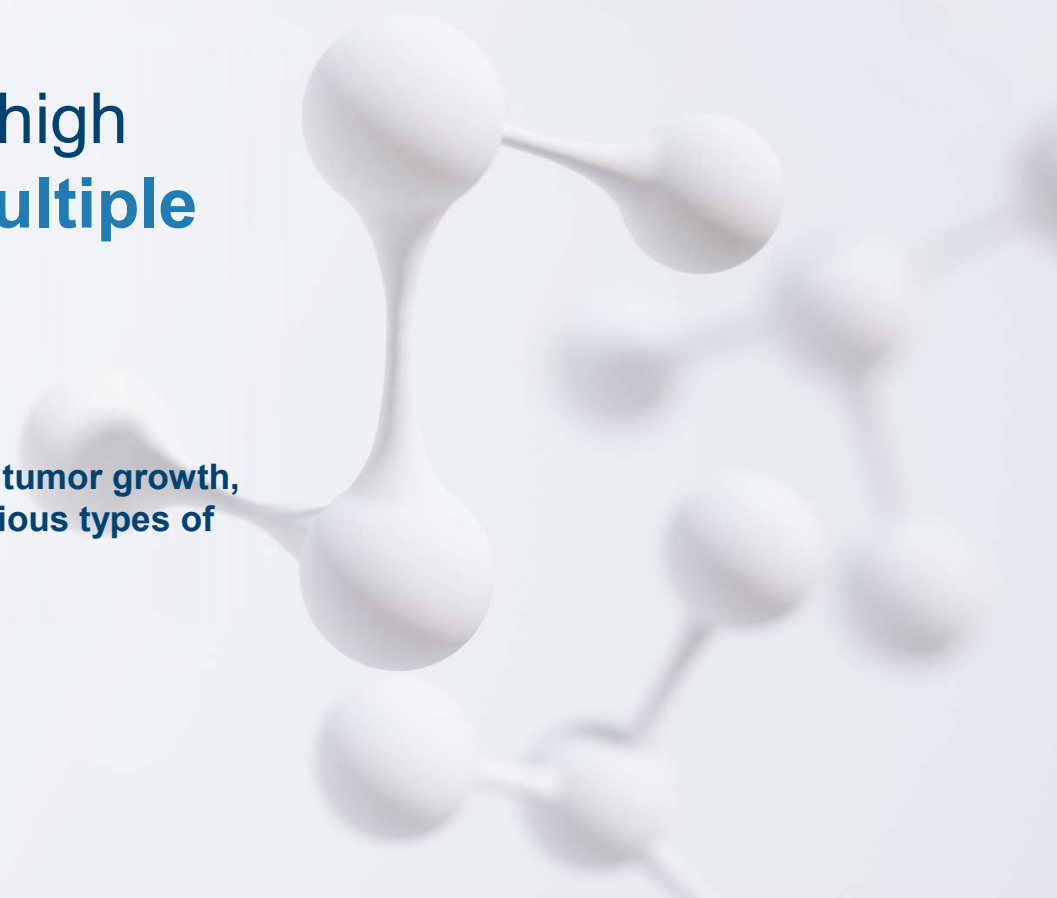
Company plans to onboard additional pipeline assets in 2025 and 2026



Motixafortide in Cancer Immunotherapy – Pancreatic Ductal Adenocarcinoma (PDAC) and Other Solid Tumors

Lead asset **motixafortide** is a high affinity CXCR4 inhibitor with **multiple potential anti-tumor therapy opportunities**

Elevated CXCR4 expression is associated with increased tumor growth, metastasis, invasion and poor patient survival across various types of cancers and can indicate a more aggressive cancer type.



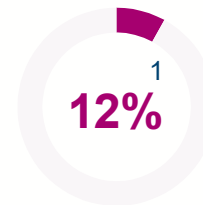
Significant unmet need and opportunity in PDAC

PDAC is associated with **poor patient outcomes** because efficacious therapies do not yet exist

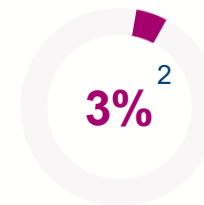


– the highest mortality rate among solid tumor malignancies – and globally, nearly a **half million** people were diagnosed in 2020 alone²

For all stages, the five-year **survival rate** in the US is only

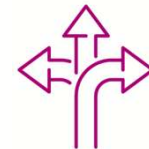


For **metastatic** PDAC (>50% of diagnosed cases), the five-year survival rate in the US is only



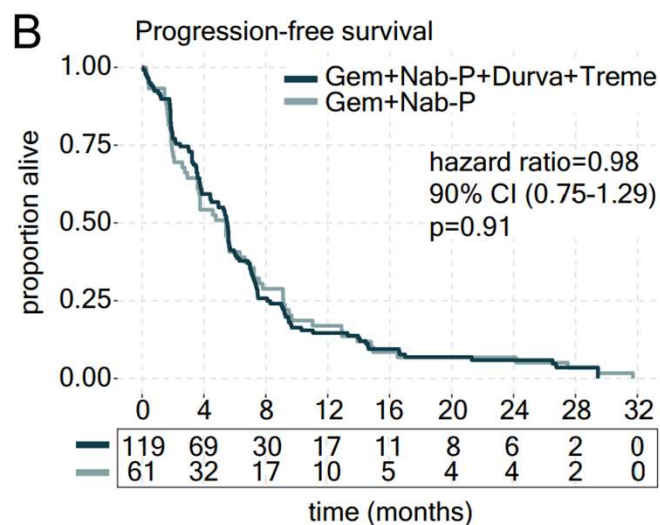
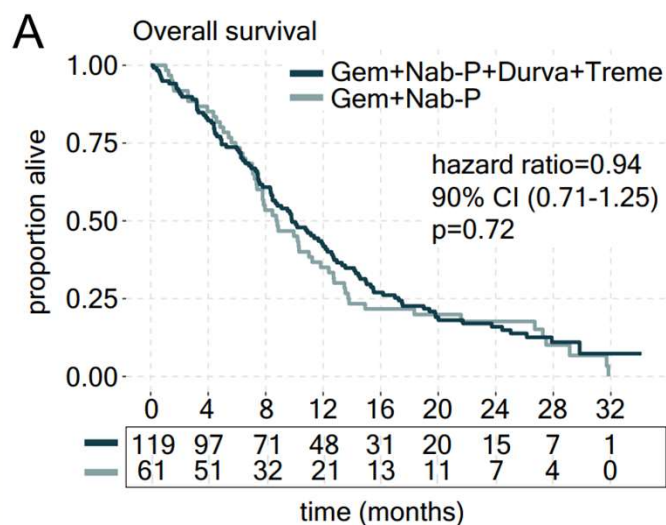
PDAC incidence is growing, and it is estimated that there will be **815,000 cases** by 2040³

Newer treatments like immunotherapy do not address all unmet needs, demonstrating a clear need to co-target **alternative pathways**



1. Pancreatic Cancer Action Network; 2. Cancer Net = Pancreatic Cancer Statistics; 3. The Global Cancer Observatory

Effectiveness of immunotherapy in PDAC remains limited



- Immune checkpoint inhibitors have demonstrated significant efficacy in multiple solid tumor types, **but effectiveness of ICIs in mPDAC remains limited¹**
- **No survival benefit found among the unselected patient population in phase 2 randomized trial with 180 patients comparing combination immunotherapy and standard-of-care chemotherapy vs standard-of-care chemotherapy alone²**

CCTG PA.7 Phase 2 Trial (2022): durvalumab (PD-L1) and tremelimumab (CTLA-4) with gemcitabine and nab-paclitaxel vs. gemcitabine and nab-paclitaxel alone in PDAC patients receiving first line therapy

1. O'Reilly, EM JAMA Oncol. 2019; Wainberg ZA Clin. Cancer Res. 2020; Renauf DJ Nat Commun. 2022; 2. Renauf DJ Nat Commun. 2022; 13: 5020.

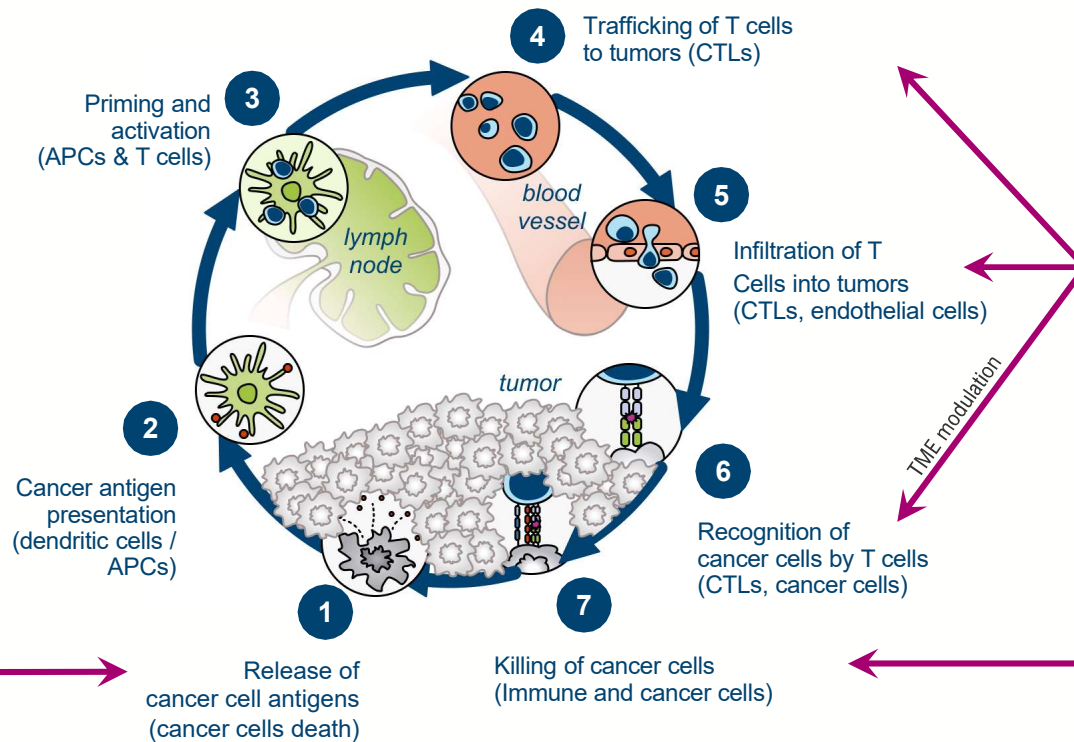
Rationale for motixafortide triple combination therapy

Solid tumors with low immune system visibility require a multi-pronged approach

Chemotherapy

- Chemotherapy induces tumor death, reducing tumor burden
- Chemotherapy induces immunogenic cell death, leading to activation & expansion of new tumor-reactive T-cell clones

Adapted from Chen, D. et al. Immunity Review 2013



Motixafortide + Checkpoint Inhibitor

- Motixafortide facilitates T cell trafficking and infiltration into tumor core; TME modulation

Checkpoint Inhibitor

- PD-1 maintains and restores activity of T cells within tumor

Unmet need in first-line metastatic PDAC

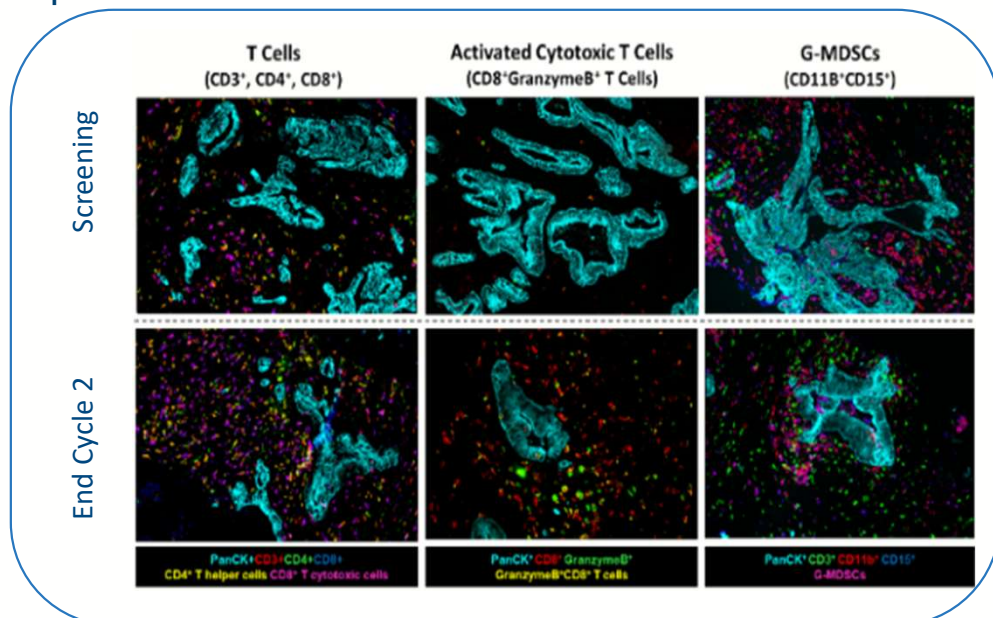
First Line Treatment	mOS (mos)	mPFS (mos)	cORR (%)
Gemcitabine ^{2,3}	5.6-6.7		7-9.4%
5FU ¹	4.4	1	0%
Gem / Abrax ³ (Van Hoff study)	8.5	5.5	23%
Gem / Abrax ⁴ (NAPOLI 3 study)	9.2	5.6	36.2%
NALIRIFOX ⁴ (NAPOLI 3 study)	11.1	7.4	41.8%
mFOLFIRINOX ²	11.1	6.4	31.6%

mPFS values in graphic; mPFS varies between studies due to study design, inclusion/exclusion criteria and patient demographics. 5-FU=5-fluorouracil.

1. Burris HA et al. J Clin Oncol. 1997; 2. Conroy T et al, NEJM 2011; 3. Von Hoff et al. NEJM 2013/ 4 NAPOLI-3 Study ASCO 2023

Proof of mechanism & concept from COMBAT Phase 2 PDAC study (2nd Line)

Cohort 1: Dual combination of motixafortide + pembrolizumab



*Representative MultiOmyx™ data taken from SD patient with long treatment duration (11 combo cycles ~34 weeks). Data shown before treatment vs. after ~7w of treatment (end of cycle 2)

- **Increased activated cytotoxic T cells**
- **Decreased suppressor cells** in tumor microenvironment
- **Reduction in tumor cell numbers**

Cohort 2: Triple combination of motixafortide + pembrolizumab + chemo (Onivyde, 5FU, Leucovorin)

	COMBAT	HISTORICAL DATA [#]
mOS	6.5 months	4.7 months ¹
mPFS	4.0 months	2.7-3.1 months ^{2,3}
cORR	13.2%	7.7% ³
DCR	63.2%	29-52% ^{2,4}

- COMBAT results suggest **motixafortide + PD-1 inhibitor + chemotherapy benefit in second-line PDAC setting**
- **Improvements were seen across all study endpoints**, including overall survival, progression-free survival, and overall response rate in patients with very advanced disease
- **Favorable safety and generally well tolerated**

These encouraging results prompted the initiation of a triple combination study in earlier line of treatment to maximize PoS

¹ Macarulla Mercade et al, Pancreas 2020; ² Petrelli et al Eu J Cancer 2017; ³ Onivyde SMPC; ⁴ Wang Gillam Eu J cancer 2019

Chemo4MetPanc Phase 2 clinical trial pilot Phase (1st Line)

Pilot Trial Design

Simon Optimal 2-Stage Design

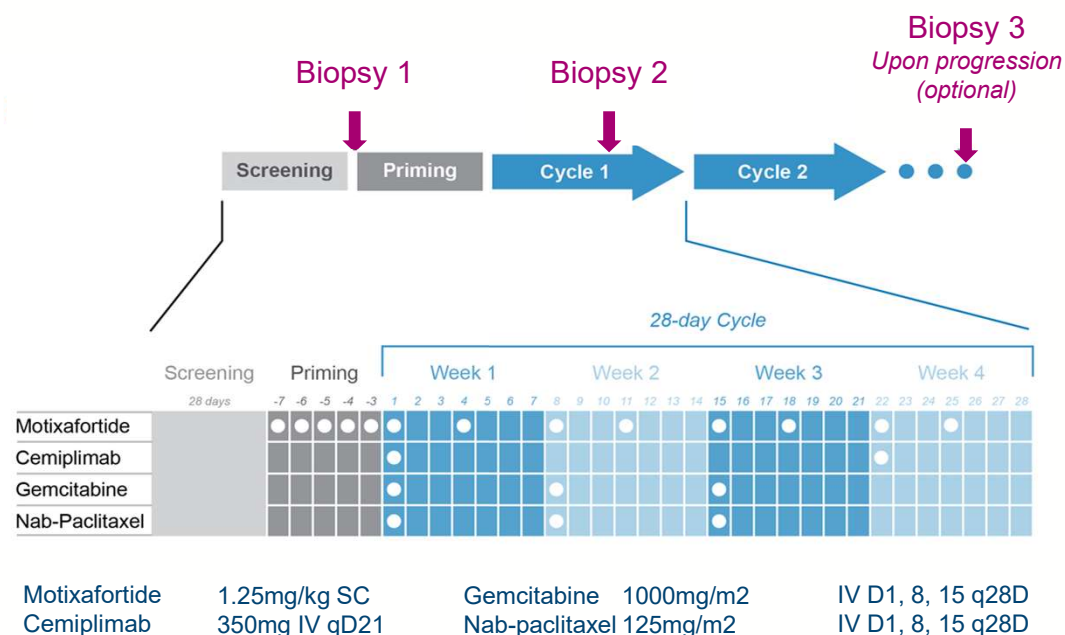
- 1st Stage – 6 patient safety run-in
- 2nd Stage – 4 additional patients
- Expansion Stage

Primary Endpoint

- Response rate by week 16
- RR > 45% promising
- RR < 23% not promising

If ≥ 3 PR → expand study to recruit additional 30 patients (amended 2023*)

*Based on encouraging pilot phase data, Chemo4MetPanc trial was amended in 2023 to become a randomized study with planned enrollment increasing from 30 to 108 patients



Baseline characteristics

Pilot Phase

Multicenter Investigator-Initiated

11 enrolled (11/09/2020 – 3/3/2023)

Columbia University 9 patients
Brown University 2 patients



Characteristic	N = 11
Age	60 y (46–69)
Sex	
Female	2 (18%)
Male	9 (82%)
Race	
Black or African American	3 (27%)
White	8 (73%)
Site of Pancreas Primary	
Head	2 (18%)
Neck/Uncinate/Body	3 (27%)
Tail	4 (36%)
Metastatic Sites at Baseline	
1	9 (82%)
Site of Metastasis at Baseline	
Liver	10 (91%)
Peritoneum	1 (9%)
Lung	1 (9%)
Osseous	1 (9%)

Safety

Pilot Phase Findings



Motixafortide (>3)	N = 11
Chills	3
Flushing	7
Hypotension	3
Injection site reaction	8
Nail discoloration	3
Pruritis	8
Rash maculo-papular	3
Skin hyperpigmentation	10
Urticaria	3

Motixafortide G3	N = 11
Allergic Reaction	1
Bone Pain	1
Hypertension	1
Hypotension	1
Pain	1
Rash Maculo-popular	1
Urticaria	2

Cemiplimab G3	N = 11
Hypotension	1
Anemia	1
Thrombocytopenia	1
Myalgia	1

Gemcitabine / Nab-P G3	N = 11
Anemia	5
Capillary leak syndrome	1
Edema limbs	1
Febrile neutropenia	1
Generalized edema	1
Heart failure	1
Hypertension	2
Hypotension	1
Infections and infestations	1
Platelet count decreased	2
Rash Maculopapular	1
White blood cell decreased	1

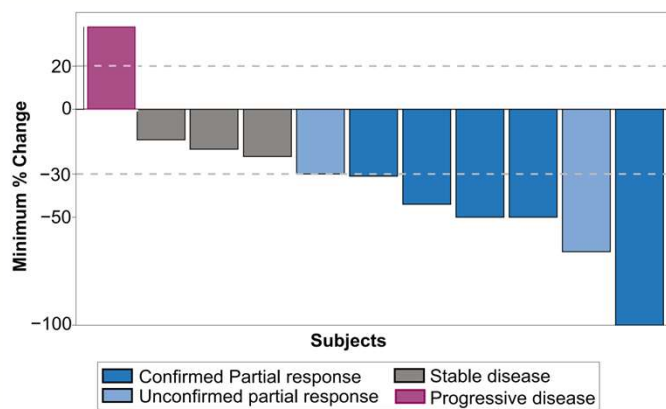
AACR Special Conference on: Pancreatic Cancer

Chemo4MetPanc Phase 2 clinical trial pilot phase at AACR (1st Line)

Pilot Phase Findings



Radiological Response¹



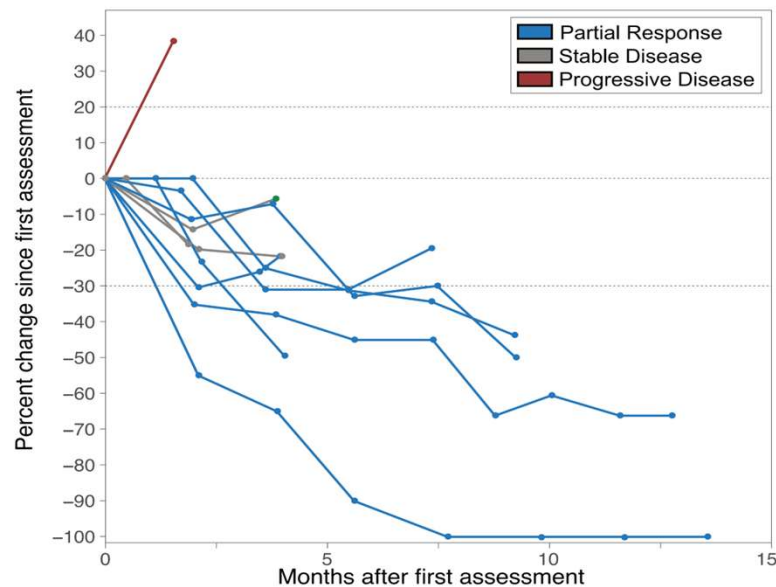
*N = 11 (%)

Disease Progression	1 (9%)
Stable Disease	3 (27%)
**Partial Response	7 (64%)
**Disease Control Rate	(91%)

*90% of patients had liver metastasis at baseline

**Compares favorably to historical PR (23%) and DCR (48%) with gemcitabine and nab-paclitaxel alone

Radiological Response Duration¹



1. Manji, GA AACR Pancreatic Cancer 2023 (Sensor Date – July 20, 2023)

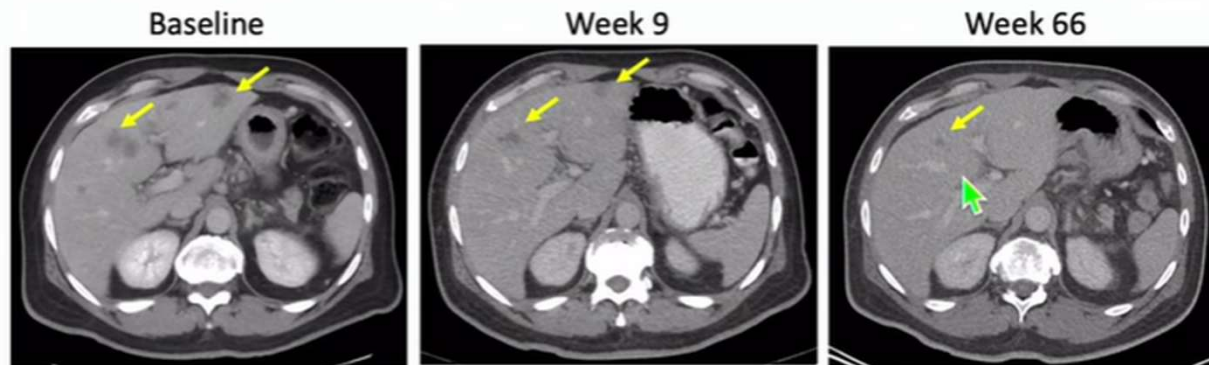
Responses in primary and metastatic sites

Pilot Phase Findings

Pancreas
001-18

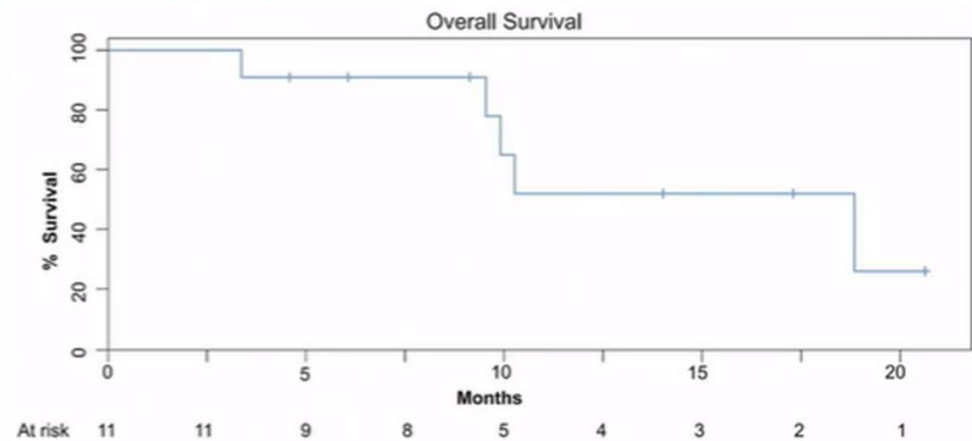
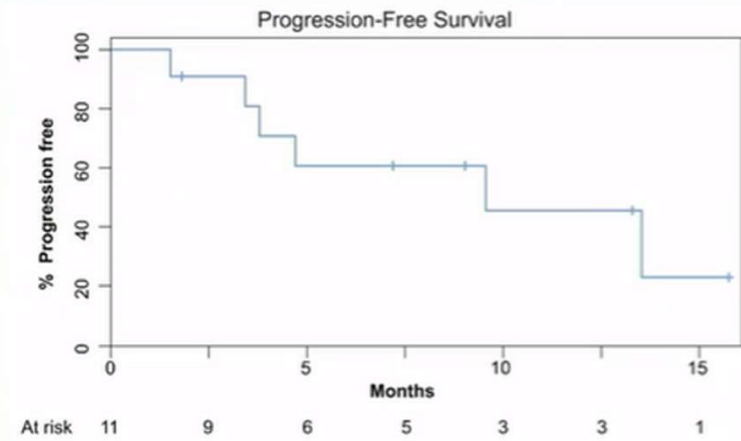


Liver Metastasis
001-06



Survival outcome

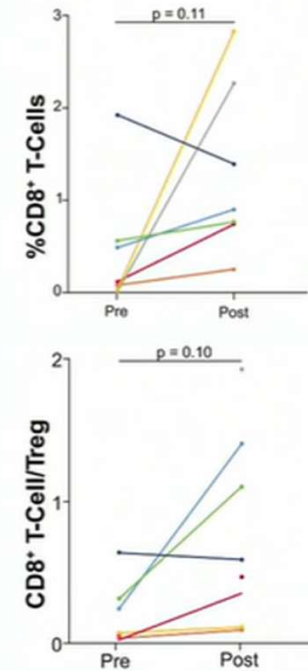
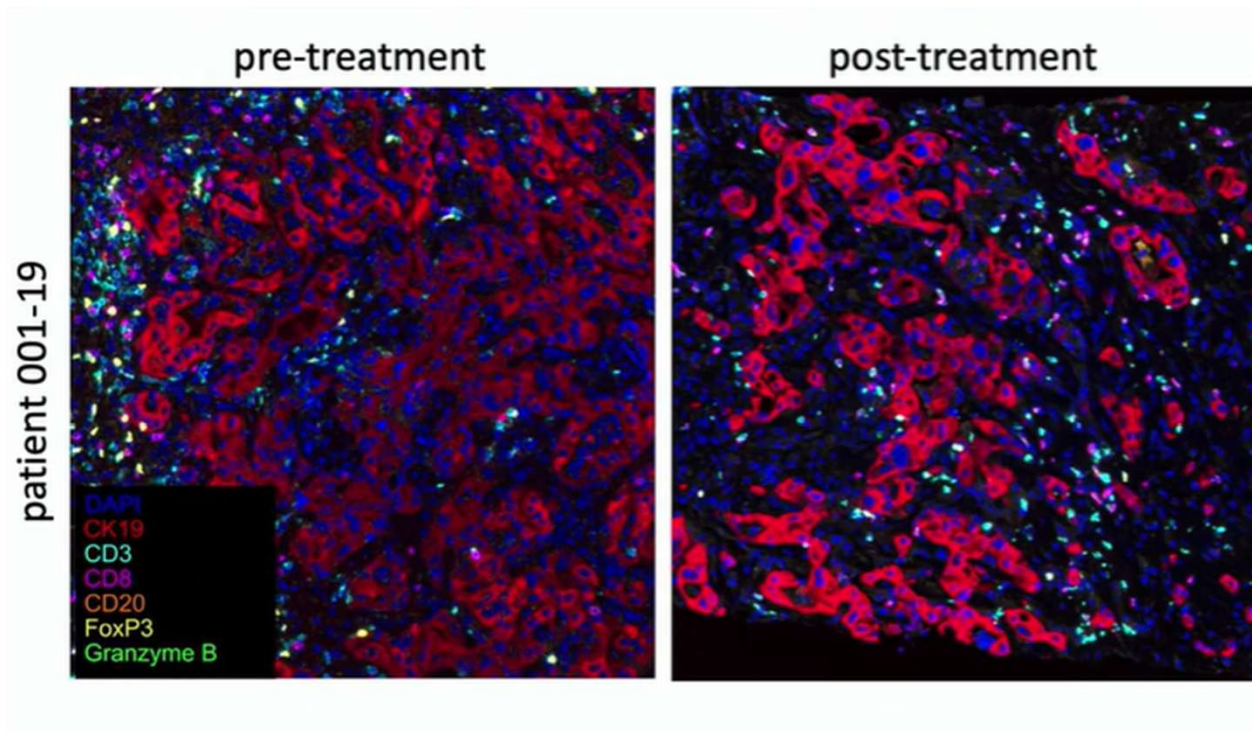
Pilot Phase Findings



Median follow-up 13.4 m
Median PFS 9.6 m (95% CI: 3.78 – NA)

Change in tumor immune-microenvironment

Pilot Phase Findings



Chemo4MetPanc Phase 2 clinical trial pilot phase at AACR (1st Line)

Pilot Phase Conclusions



Gemcitabine, nab-paclitaxel, motixafortide and cemiplimab resulted in

Overall Response Rate **64%**

Median Progression Free Survival **9.6 months**

One patient experienced **resolution of hepatic (liver) metastatic** lesion as of July 20, 2023.

The combination demonstrated a **tolerable safety profile**

No unexpected Grade 4 or 5 treatment related adverse events

Correlative analysis on paired tumor biopsies on all patients are ongoing

The encouraging preliminary efficacy prompted a change in clinical trial design to a **randomized phase 2 trial (Chemo4MetPanc; NCT NCT04543071)**

Manji, GA AACR Pancreatic Cancer 2023 (Censor Date – July 20, 2023)

Chemo4MetPanc randomized Phase 2b clinical trial in first-Line PDAC

IIS currently enrolling, equally funded by Regeneron and BioLineRx

Randomized Trial Recruiting

Primary Endpoint
median PFS

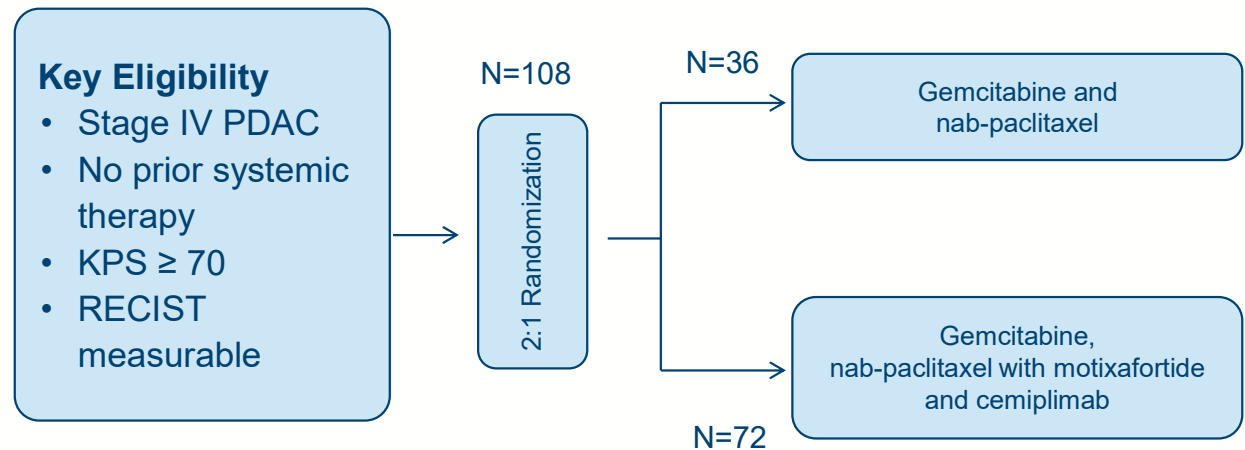
Secondary Endpoints
OS, RR

Correlates
mIF, snRNAseq, cytokine

Trial Sites

- Columbia University (PI Dr. Manji)
- Brown University
- University of California - San Francisco
- Medical College of Wisconsin
- Northwell Health

Study Design



Key Milestones*

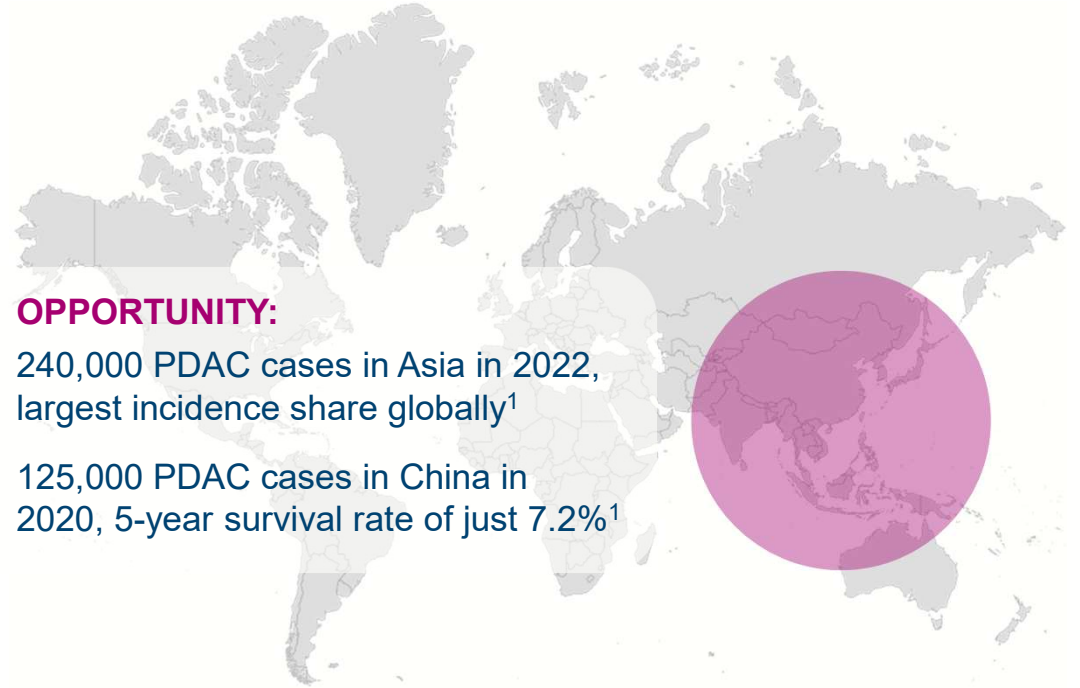
- ✓ Pilot phase (promising findings reported at AACR Pancreas 2023)
- Prespecified interim futility analysis (when 40% of PFS events observed) expected in 2026
- Full enrollment projected in 2027

*Independent Investigator Study (IIS) timelines, as well as other study related decisions, are ultimately controlled by the independent investigator-sponsor and are, therefore, subject to change.

Additional randomized study in first-line PDAC in China



- GloriaBio will execute a randomized first-line PDAC trial in China evaluating motixafortide in combination with PD-1 inhibitor *zimberelimab and standard of care combination chemotherapy
- Zimberelimab is a fully human anti-PD-1 monoclonal antibody. GloriaBio is developing and commercializing zimberelimab in Greater China, including mainland China, Hong Kong, Macao and Taiwan, where zimberelimab is approved for R/R classical Hodgkin's lymphoma and recurrent or metastatic cervical cancer



1. Datamonitor Healthcare; the National Central Cancer Registry of China (NCCR); United Nations, 2022; China CDC Weekly, 2022, 4(24): 527-531

*Arcus Biosciences, and development partner Gilead Sciences, have the exclusive rights to develop and commercialize zimberelimab throughout the world except in Greater China and certain territories



Summary and Upcoming Milestones



Focused vision for growth

- Continued execution of Phase 2b clinical trials of motixafortide in combination with PD-1 inhibitors in pancreatic cancer
 - Accelerate ongoing trial in U.S. through addition of three new sites over next two quarters
 - Support IND submission to regulatory authorities in China
 - Potential evaluation of motixafortide in other solid tumor indications where CXCR4 overexpression is implicated
 - Broaden pipeline via in-licensing of selected assets in 2025 and 2026
-

Expected major pipeline milestones over next 18 months

Addition of 3 new clinical trial sites for U.S. based Ph 2b PDAC Trial**

2Q 2025

Motixafortide approval in China for SCM*

2025

Interim data from U.S. based Ph 2b PDAC trial**

2026

Submission of Ph 2b PDAC trial IND to China regulatory authorities*

1H 2025

Onboard additional pipeline asset

2025

Onboard additional pipeline asset

2026

Independent Investigator Study (IIS) timelines: IIS timelines, as well as other study related decisions, are ultimately controlled by the independent investigator-sponsor and are, therefore, subject to change.

*Clinical development with GloriaBio
**IIS with Columbia University



biolinerx

Thank You