

# 1Q 2024 INVESTORS' CONFERENCE

## 2024/04/30

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## AGENDA

1. 1Q24 Operational Highlights
2. 1Q24 Operational Overview
3. Research and Development
  - ONIVYDE®
  - Pipeline
4. Vision for 2024
5. Q&A

# 1Q24 Operational Highlights: Sustainable Growth and Enhanced Pipeline

## COMMERCIAL

### ONIVYDE® new indication expansion

1. **Feb. 2024:** received US FDA sNDA approval (IPSEN)
2. **Mar. 2024:** received sNDA approval from Australia TGA and EMA's CHMP gave positive opinion on ONIVYDE® Type II Variation (Servier)
3. **Mar. 2024:** received sNDA approval from Taiwan FDA (PharmaEngine)

## PIPELINE

### New project R&D progress accelerated

1. Phase 1 clinical trial of PEP07 for **hematologic cancers** continues
2. Phase 1 clinical trial of PEP07 for **solid tumors** began and first patient dosed
3. Multiple projects meet expectations with external AI/CADD collaboration
4. R&D investment for new drugs continues to grow

## OPERATION

### Operation with sustainable growth

1. 1Q24 cash and cash equivalents and current financial assets (>3 months time deposits) at amortized cost: **NT\$37 bn**
2. Kicked off the initial phase of scope 3 GHG inventory, scheduled to be completed before end of 2024



# 1Q24 OPERATIONAL OVERVIEW

# Sales and Royalties Drive Long-term Growth

NT\$(000)

Items \ Year	2018	2019	2020	2021	2022	2023	1Q24 YoY (%)
Taiwan Sales	87,384	180,389	214,828	235,469	277,594	278,547	65,271 (-10.9%)
Royalties from Europe and Asia	109,825	133,651	271,584	419,366	376,789	426,652	99,200 (+4.3%)
Milestone	96,221	0	569,600	0	0	62,470	0
<b>Total</b>	<b>293,430</b>	<b>314,040</b>	<b>1,056,012</b>	<b>654,835</b>	<b>654,383</b>	<b>767,669</b>	<b>164,471 (-2.3%)</b>

Taiwan Sales belongs to PharmaEngine, Inc.  
Tiered royalties (high single-low double digit) in Europe/Asia (excl. TW) from Servier/IPSEN

# 1Q24 Financial Results

NT\$(000)	1Q24	1Q23	Amount Change	% Change
<b>Operating revenue</b>	<b>164,471</b>	<b>168,333</b>	<b>(3,862)</b>	<b>(2%)</b>
<b>Operating costs</b>	<b>11,045</b>	<b>13,628</b>	<b>(2,583)</b>	<b>(19%)</b>
<b>Gross profit</b>	<b>153,426</b>	<b>154,705</b>	<b>(1,279)</b>	<b>(1%)</b>
<b>Sales expenses</b>	<b>7,152</b>	<b>9,676</b>	<b>(2,524)</b>	<b>(26%)</b>
<b>G&amp;A expenses</b>	<b>22,375</b>	<b>24,326</b>	<b>(1,951)</b>	<b>(8%)</b>
<b>R&amp;D expenses</b>	<b>56,521</b>	<b>39,611</b>	<b>16,910</b>	<b>43%</b>
<b>Total operating expenses</b>	<b>86,048</b>	<b>73,613</b>	<b>12,435</b>	<b>17%</b>
<b>Operating income</b>	<b>67,378</b>	<b>81,092</b>	<b>(13,714)</b>	<b>(17%)</b>
<b>Total non-operating income and expenses</b>	<b>35,367</b>	<b>21,360</b>	<b>14,007</b>	<b>66%</b>
<b>Income before income tax</b>	<b>102,745</b>	<b>102,452</b>	<b>293</b>	<b>0%</b>
<b>Income tax expense</b>	<b>21,019</b>	<b>21,072</b>	<b>(53)</b>	<b>(0%)</b>
<b>Profit for the period</b>	<b>81,726</b>	<b>81,380</b>	<b>346</b>	<b>0%</b>
<b>EPS(NT\$)</b>	<b>0.57</b>	<b>0.57</b>	<b>0</b>	<b>0%</b>

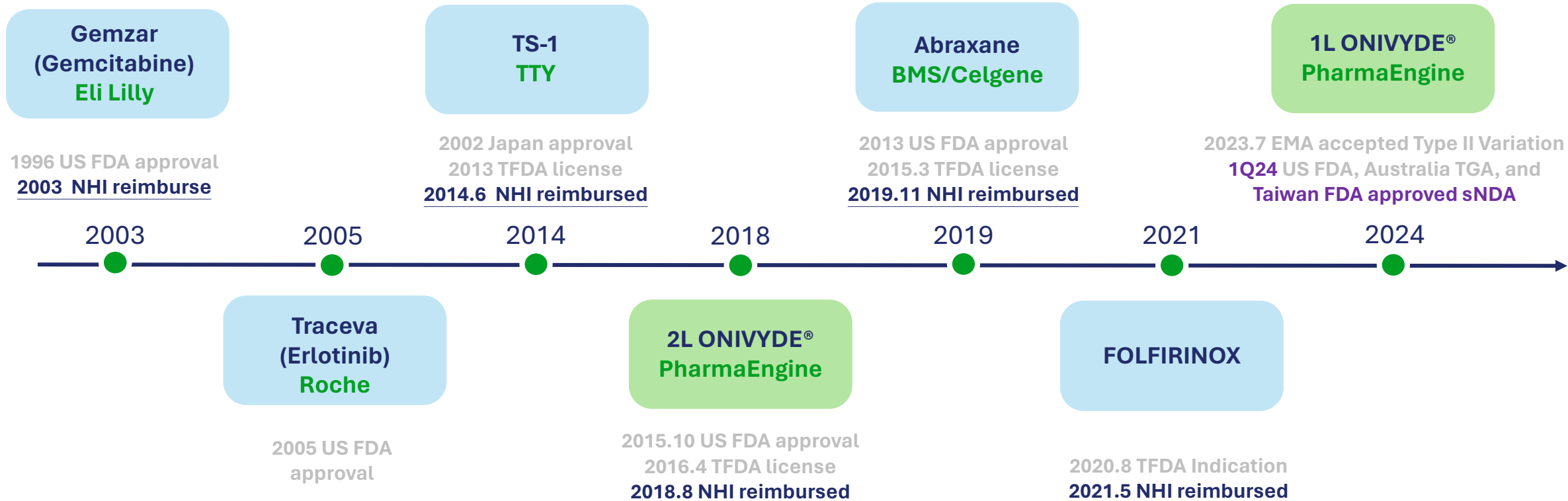


## ONIVYDE® STATUS & MARKET ANALYSIS

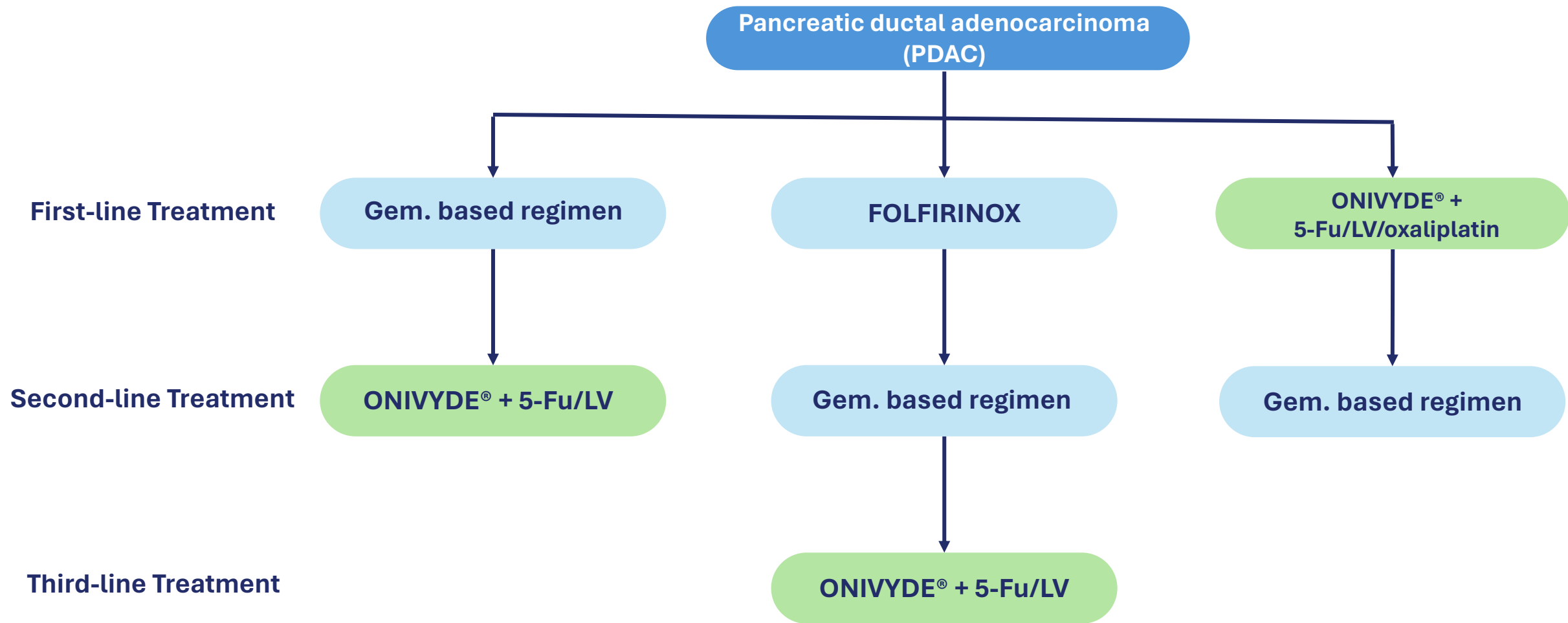
- ONIVYDE® 1L PDAC received sNDA from US FDA, Australia TGA, and Taiwan TFDA and received positive opinion from Europe EMA's CHMP



# Development of Pancreatic Cancer Therapy in Taiwan





# Taiwan PDAC Therapy Market Analysis



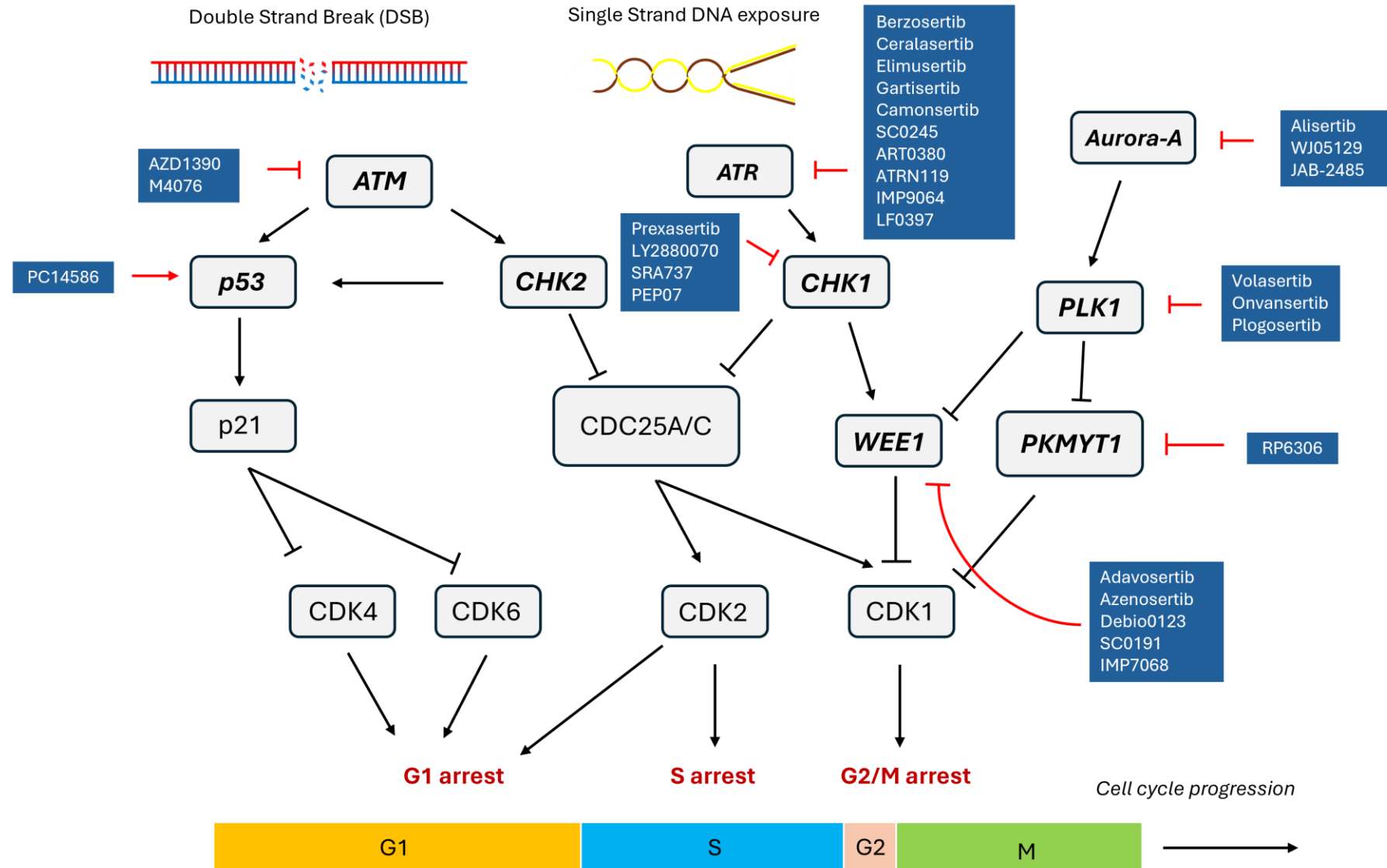


# R&D PIPELINE

# Pipeline Portfolio Focus on Precision Oncology

Program	Indications	Lead	Preclinical	Phase I	Phase II	Phase III	Approval	Commercial Rights	Partner
ONIVYDE® (liposomal irinotecan)	2L PDAC	[Green bar spanning Lead, Preclinical, Phase I, Phase II, Phase III]					Approval	EU/Asia	 Innovation for patient care
	1L PDAC	[Green bar spanning Lead, Preclinical, Phase I, Phase II, Phase III]					Approval		
DNA Damage Response (DDR) & Precision Oncology	PEP07 (CHK1i)	Hematologic Cancers/Solid Tumors	[Blue bar spanning Lead, Preclinical, Phase I]					Global	
	PEP08	Undisclosed (Predictive Biomarker)	[Blue bar spanning Lead, Preclinical, Phase I]					Global	PEI Owned
	PEP09	Undisclosed	[Blue bar spanning Lead, Preclinical]					Global	Undisclosed
	PEP10	Undisclosed (Predictive Biomarker)	[Blue bar spanning Lead]					Global	PEI Owned

# A New Wave of Innovations within the DNA Damage Response (DDR)



# PEP07 Phase 1 Clinical Trials



dose escalation/expansion in **hematologic cancers**  
(first patient dosed in 2023/08)



dose finding/expansion in selected **hematologic cancers**,  
e.g., **AML or MCL**



dose escalation/expansion in advanced or metastatic **solid tumors**  
(first patient dosed in 2024/04)




dose finding/expansion in selected **solid tumors**



# VISION FOR 2024

# 2024年營運目標

**1** ONIVYDE® 1L PDAC sNDA certification obtained in US, AU, and Taiwan 

**2** ONIVYDE® 1L PDAC sNDA certification in EU (1H24)

**3** PEP07 Phase 1 studies in hematologic cancers and solid tumors continue 

**4** One project in pipeline may reach IND ready stage (2H24)

**5** Continue to advance pipeline progress toward preclinical stage

**6** Complete initial scope 3 emissions data collection and analysis





THANK YOU

**PharmaEngine, Inc.**