

PharmaEngine

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4Q 2023 Financial Results

2024/03/05

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Agenda

1. 2023 Operational Highlights
2. 2023 Operational Overview
3. Research and Development
 - ONIVYDE®
 - PEP07
4. Vision for 2024
5. Q&A



2023 Operational Highlights- Keep Delivering Sustainable Growth and Enhanced Value

Commercial

ONIVYDE® market and new indication expansion

1. Taiwan FDA sNDA submission (PharmaEngine)
2. EMA Type II Variation submission (Servier)
3. **US FDA sNDA approval received on February 13, 2024 (IPSEN)**



Pipeline

New project R&D progress accelerated

1. Phase 1 clinical studies of PEP07 for hematologic and solid tumor cancers continue.
2. Multiple projects meet expectations with external AI/CADD collaboration
3. >20% regular operation revenue as R&D expense



Operation

Operation with a sustainable growth

1. Approved by the Ministry of Economic Affairs as a “Biotech and Pharmaceutical Company”
2. FY 2023 cash and cash equivalents and current financial assets at amortised cost: NT\$36.3 bn
3. Completed the scope 1&2 emissions data collection, analysis and third-party assurance



2023 Operational Overview



Sales and Royalties Drives Long-term Growth



NT\$(000)

Items \ Year	2017	2018	2019	2020	2021	2022	2023 YTD YoY (%)
Taiwan Sales	40,651	87,384	180,389	214,828	235,469	277,594	278,547 (0%)
Royalties from Europe and Asia	63,526	109,825	133,651	271,584	419,366	376,789	426,652 (+13)
Milestone	749,500	96,221	0	569,600	0	0	62,470 (+100%)
Total	853,677	293,430	314,040	1,056,012	654,835	654,383	767,669 (+17%)

2023 Financial Results



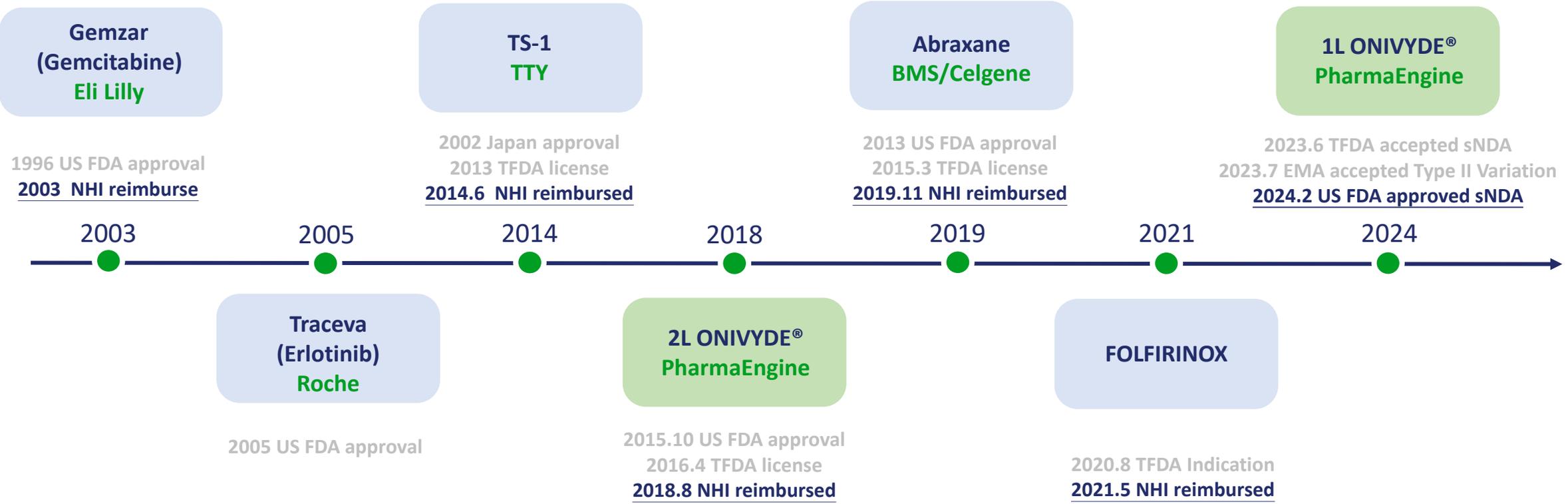
NT\$(000)	FY2023	1Q-3Q 2022	Amount Change	% Change
Operating revenue	767,669	654,383	113,286	17%
Operating costs	48,697	49,699	(1,002)	(2%)
Gross profit	718,972	604,684	114,288	19%
Sales expenses	38,538	45,104	(6,566)	(15%)
G&A expenses	92,970	94,960	(1,990)	(2%)
R&D expenses	310,281	181,881	128,400	71%
Total operating expenses	441,789	321,945	119,844	37%
Operating income	277,183	282,739	(5,556)	(2%)
Total non-operating income and expenses	60,791	109,726	(48,935)	(45%)
Income before income tax	337,974	392,465	(54,491)	(14%)
Income tax expense	63,324	73,682	(10,358)	(14%)
Profit for the period	274,650	318,783	(44,133)	(14%)
EPS(NT\$)	1.91	2.22	(0.31)	(14%)

Research and Development

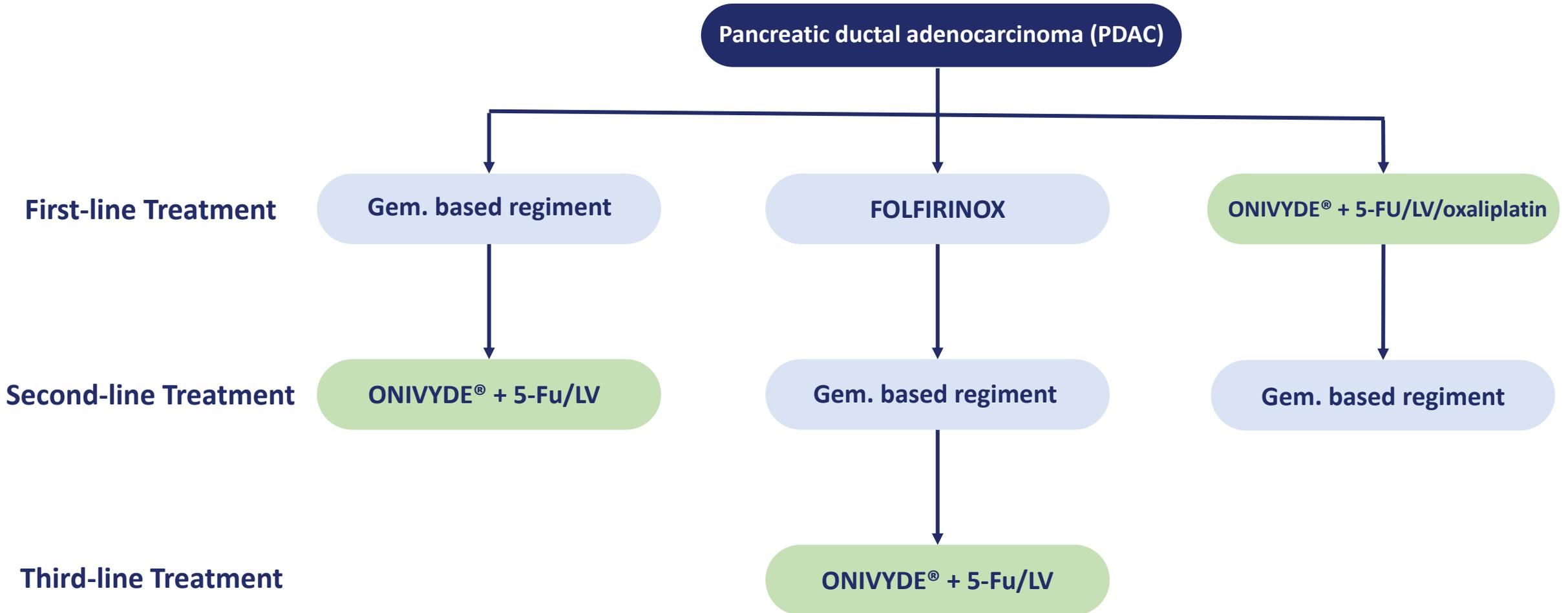
- ONIVYDE® 1L PDAC NDA submission status
- **First patient dosed** in PEP07 phase 1 for hematologic cancers
- PEP07 phase 1 for **solid cancer** approved by TFDA
- Multiple projects in collaboration with external AI/CADD



Development of Pancreatic Cancer Therapy in Taiwan



Taiwan PDAC Therapy Market Analysis



PEP07 – Potential Best in Class CHK1 Inhibitor

PEP07 is a brain penetrating oral inhibitor which is more potent and selective than the competitors.

	Drug	Stage	Potency	Selectivity	Oral Bioavailability
Acrivon (Eli Lilly)	Prexasertib	Ph II	●	●	●
Genetech	GDC-0575	Discontinued	●	●	●
GSK (Sierra Oncology)	SRA-737	Ph I / II (Complete)	●	●	●
Esperas Pharma	LY2880070	Ph I / II (Complete)	●	●	●
PharmaEngine	PEP07	Ph I	●	●	●



Excellent



Good



Fair

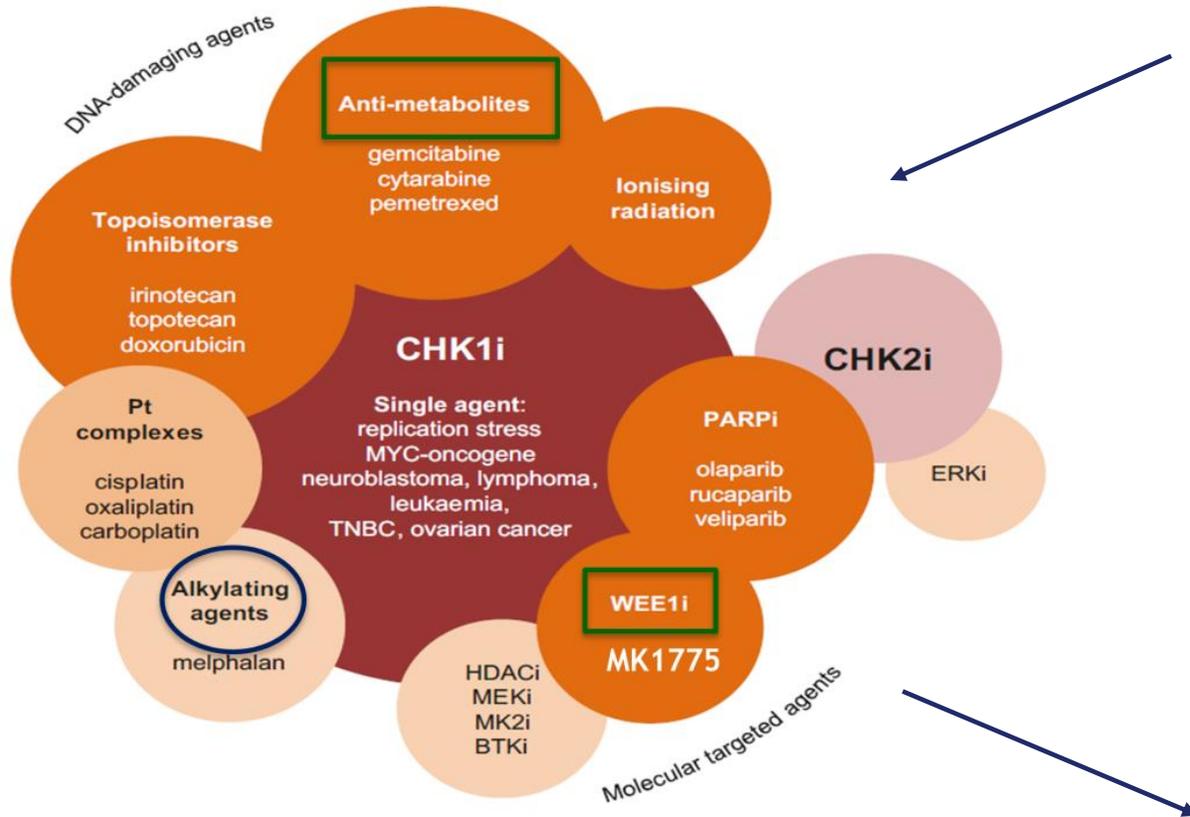


Poor



Unknown

PEP07 for Potential Combination Therapies



Synergistic effect verified in PEP07

Additive effect observed in PEP07

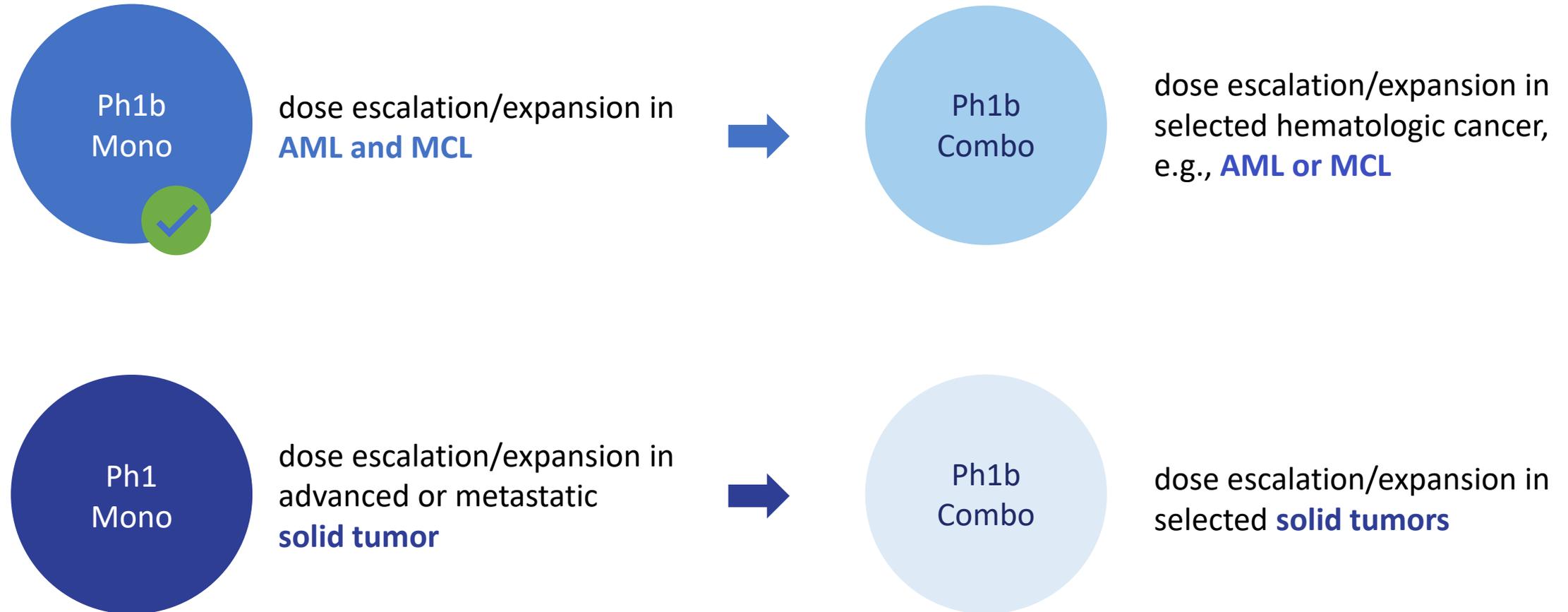
In vitro Combo Treatment

SoC agents	Indication	Cell line
Ara-C	AML	MV4-11 / THP-1
Gemcitabine	NSCLC	NCI-H1703
5-Fu	Esophagus	KYSE-270
5-Fu	Stomach	MKN-45, SNU-16, SNU-5,
5-Fu	CRC	DLD-1, HT-29, SW480
TMZ	Brain	IMR-32
Sorafenib	RCC	A498

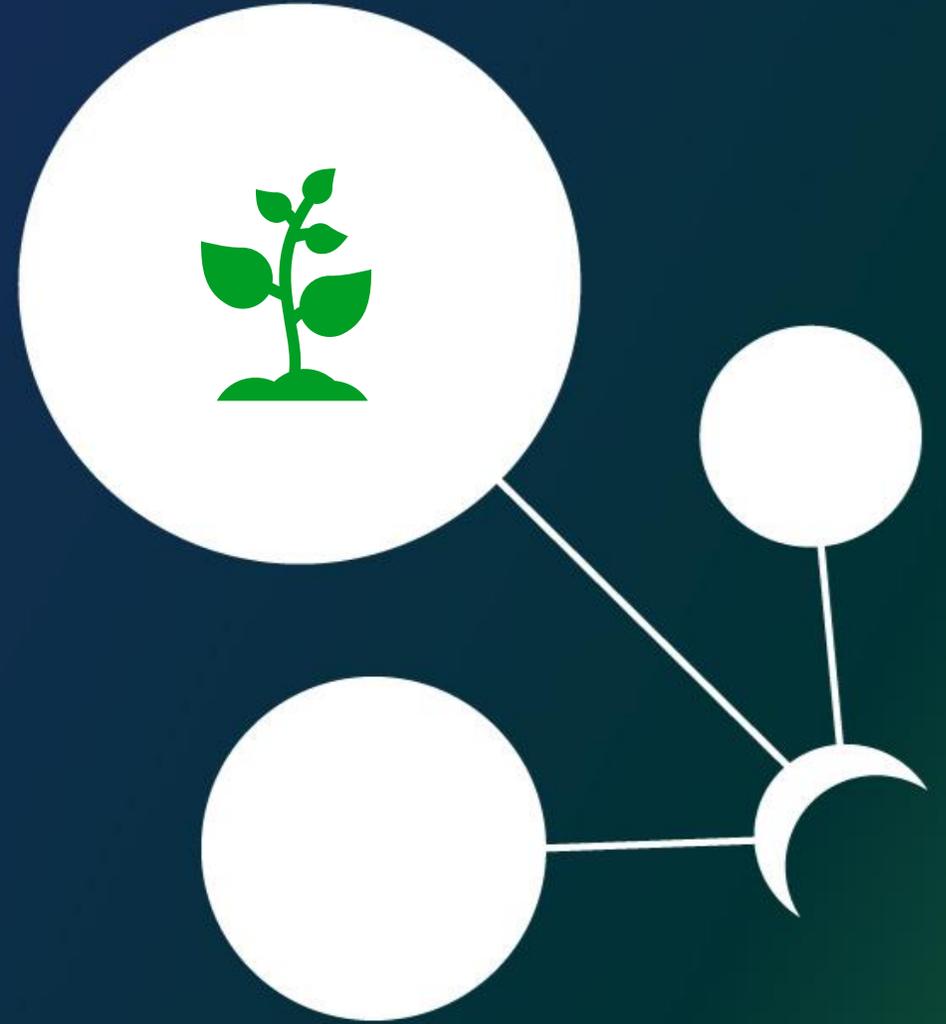
Green: Synergism; Blue: Additivity

Clinical Trial Designs and Indications Guidance

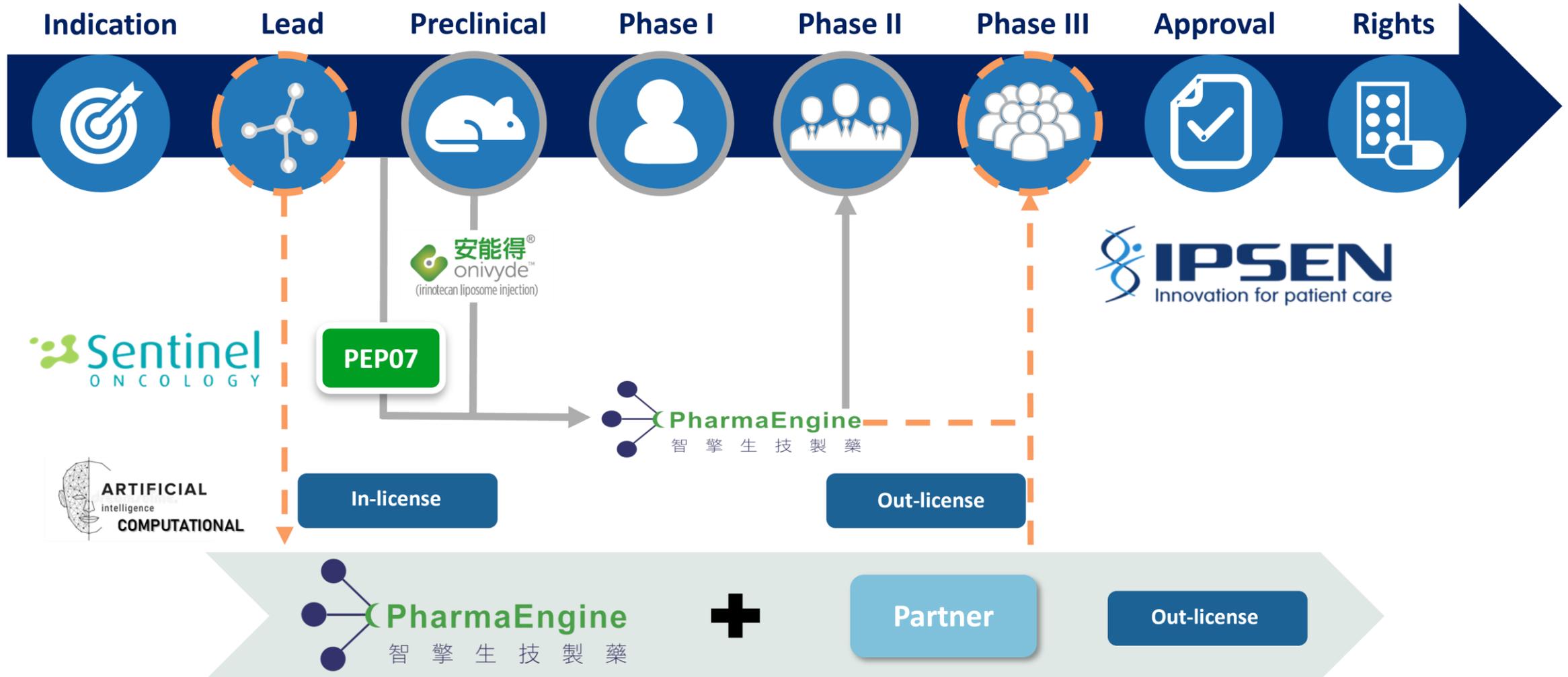
PEP07 Early-Stage Clinical Development Strategy



Vision for 2024



Virtual Pharmaceutical Company Business Model

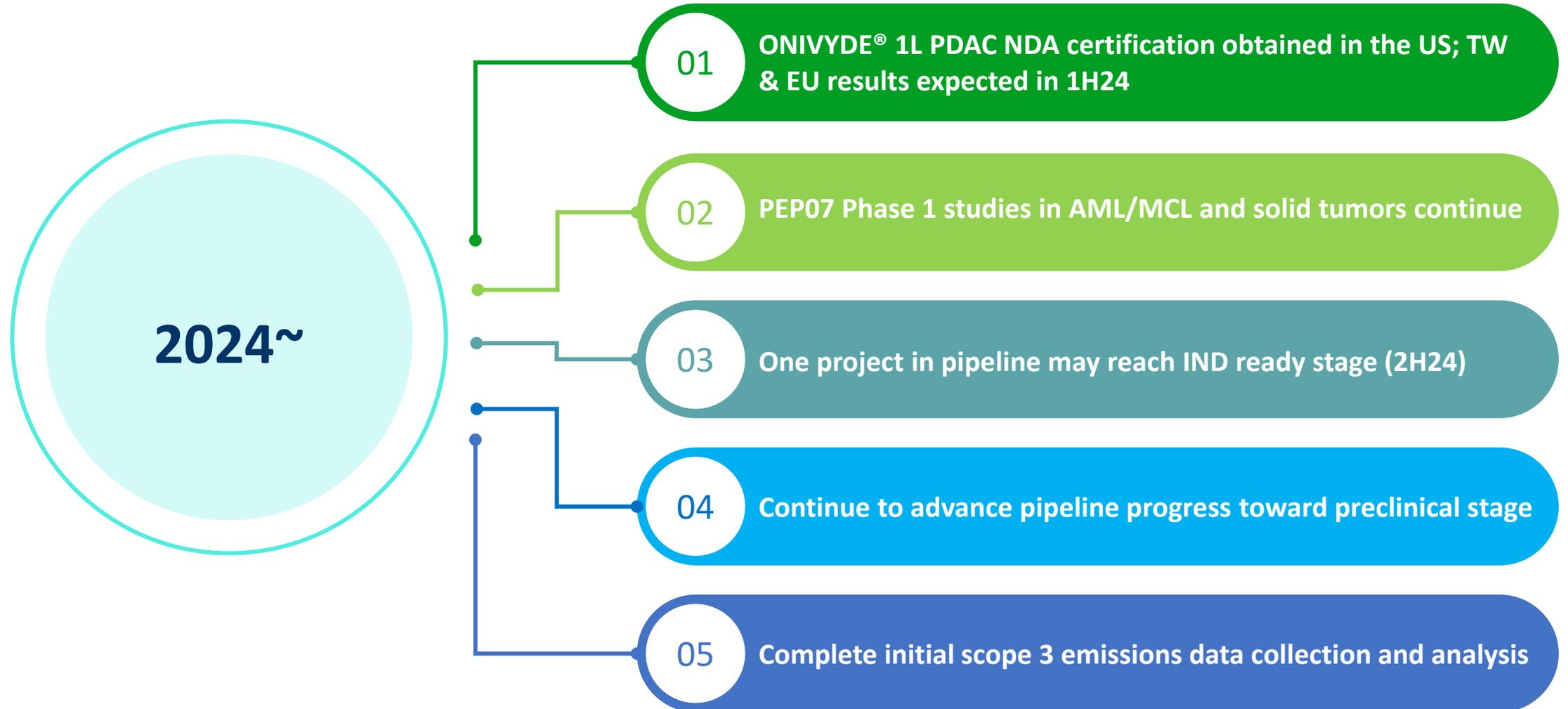


Pipeline Portfolio Focus on Precision Oncology

Program	Indications	Lead	Preclinical	Phase I	Phase II	Phase III	Approval	Commercial Rights	Partner
ONIVYDE® (liposomal irinotecan)	2L PDAC		Approval					EU/Asia	
	1L PDAC		Primary Endpoint met (2022/11)						
DDR	PEP07 (CHK1i)	AML/Solid Tumors						Global	
DNA Damage Response	PEP09	Undisclosed						Global	Undisclosed
	PEP10	Undisclosed (Predictive Biomarker)						Global	PEI Owned
Precision Oncology	PEP08	Undisclosed (Predictive Biomarker)						Global	PEI Owned

DDR: DNA Damage Response (BRCA ½, CHK ½, Wee1, etc...)

Continuous Advancement of Pipelines and ESG Activities





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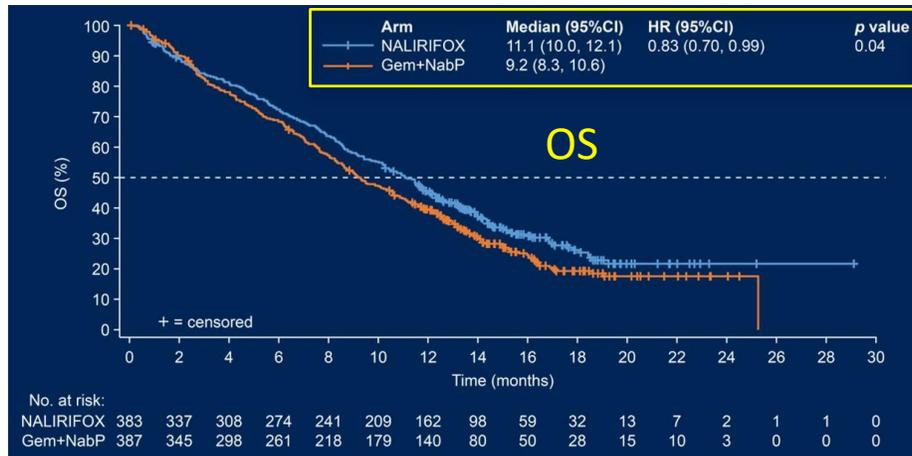
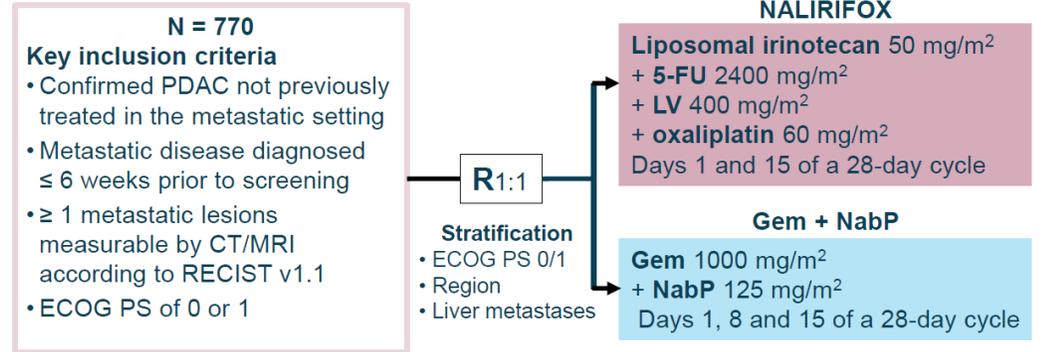
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NAPOLI-3

A randomized, Open Label Phase 3 Study of Liposomal Irinotecan + 5-FU/LV + Oxaliplatin (NALIRIFOX) versus Nab-Paclitaxel + Gemecitabine in Treatment-naïve Patients with Metastatic Pancreatic Ductal Adenocarcinoma



- ◆ NALIRIFOX (n = 383) vs. Gem + NabP (n = 387), 770 patients enrolled
- ◆ Study endpoints:
 - Primary endpoint – OS (Overall Survival)
 - Secondary endpoints – PFS (Progression Free Survival), ORR (Objective Response Rate)
- ◆ First Patient Enrolled: Feb. 2020; Data cut-off: July 23, 2022
- ◆ Topline results presented in 2023 ASCO GI



Conclusion

- The NALIRIFOX regimen met its primary endpoint demonstrating a statistically significant improvement in OS of 11.1 in months compared to 9.2 months for patients treated with Gem + NabP (HR 0.83 [95% CI 0.70–0.99]; p=0.04).
- The trial met its secondary endpoint showing patients treated with NALIRIFOX had a statistically significant improvement in mPFS of 7.4 months versus 5.6 months for Gem + NabP (p < 0.0001); ORR was 41.8% (36.8%-46.9%; 95% CI) for patients treated with the NALIRIFOX versus 36.2% with Gem + NabP (31.4%-41.2%; 95% CI).
- Overall, the safety profile of NALIRIFOX in NAPOLI 3 was manageable. No new safety concerns with the NALIRIFOX regimen were identified.