

PharmaEngine

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Cathay investor conference 4162.TWO

2022/05/03

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President and CEO

Disclaimer

This presentation contains certain forward-looking statements.

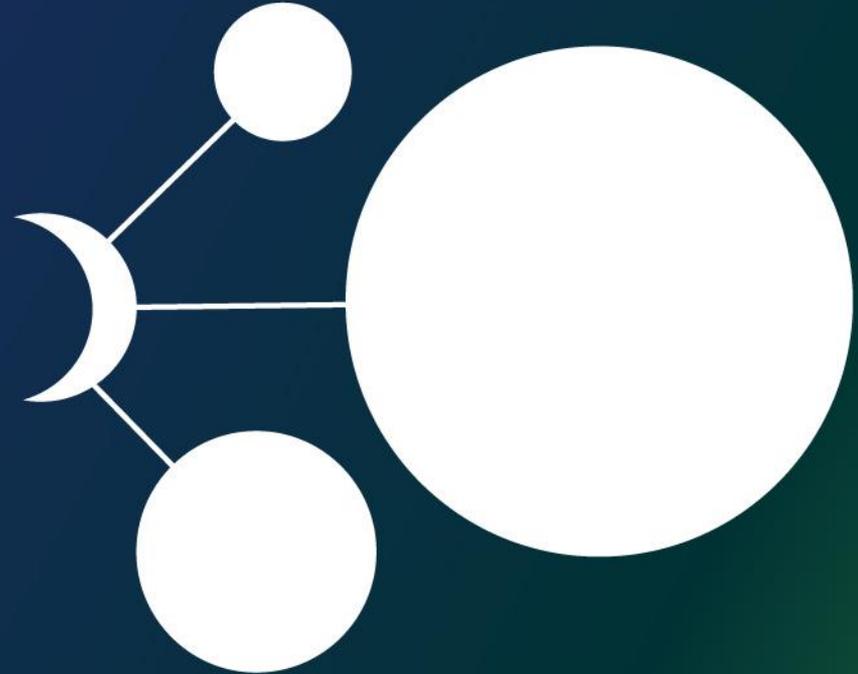
These forward-looking statements may be identified by words such as 'believes,' 'expects,' 'anticipates,' 'projects,' 'intends,' 'should,' 'seeks,' 'estimates,' 'future,' or similar expressions or by discussion of, among other things, strategy, goals, plans, or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

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Agenda

1. 1Q22 Operational Highlights
2. 1Q22 Operational Overview
3. Research and Development
 - ▣ ONIVYDE®
 - ▣ PEP07 (SOL-578)
4. Vision for 2022
5. Q&A



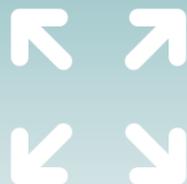
Commercial



ONIVYDE[®] market and new indication expansion

1. ONIVYDE[®] 2L PDAC treatment got China NMPA approved.
2. ONIVYDE[®] EU/Asia Royalties with strong growth momentum.
3. ONIVYDE[®] 2L SCLC/1L PDAC phase III trial ongoing.

Pipeline



New project licensing and RD progress accelerated

1. PEP07 preclinical progress meets expectation
2. Early stage projects under evaluation

Operation

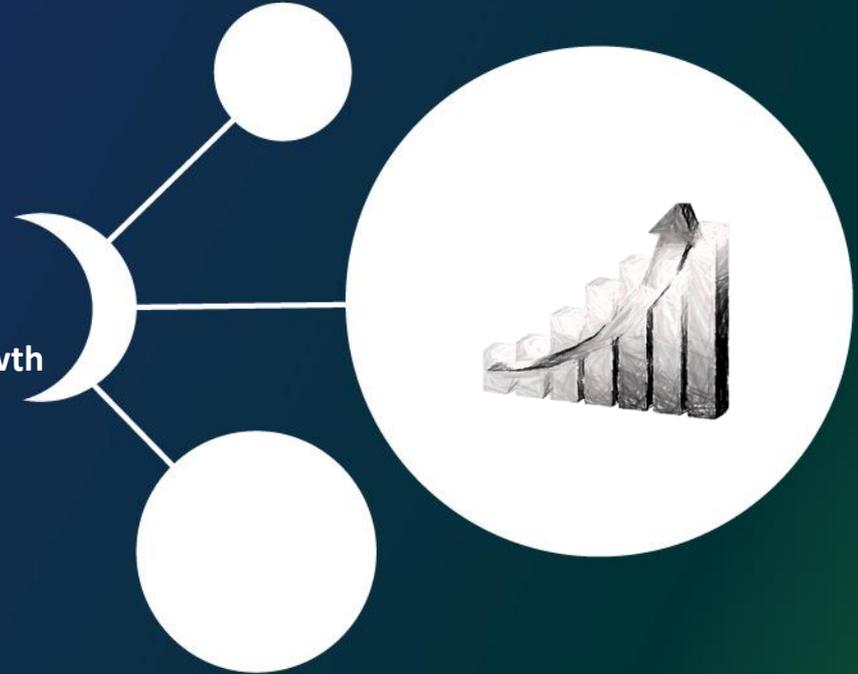


Operation with a sustainable growth

1. 1Q22 Cash and cash equivalents:
 - NTD\$3.8 bn
2. Long-lasting dividend payout :
 - NTD\$ 2.7/share (+8% YoY) 2021

1Q22 Operational Overview

ONIVYDE® Revenue with Double-Digit Growth



Sales and Royalties Drives Long-term Growth

NTD \$(000)

Items \ Year	2017	2018	2019	2020	2021	1Q21/1Q22 YoY (%)
Taiwan Sales	40,651	87,384	180,389	214,828	235,469	67,169 (25%)
Royalties from Europe and Asia	63,526	109,825	133,651	271,584	419,366	106,960 (72%)
Milestone	749,500	96,221	0	569,600	0	0
Total	<u>853,677</u>	<u>293,430</u>	<u>314,040</u>	<u>1,056,012</u>	<u>654,835</u>	174,129 (51%)

5 yr CAGR. 42% (ex. milestone)

Taiwan Sales belongs to PharmaEngine, Inc.

Tiered royalties (high single – low double digit) in Europe/Asia (excl. TW) from Servier/IPSEN

1Q22 Financial Results

NTD\$ (000)	1Q22	1Q21	Amount Change	% Change
Operating revenue	174,129	115,645	58,484	51
Operating costs	11,638	9,188	2,450	27
Gross profit	162,491	106,457	56,034	53
Sales expenses	7,793	5,977	1,816	30
G&A expenses	19,792	20,698	(906)	(4)
R&D expenses	18,274	45,435	(27,161)	(60)
Total operating expenses	45,866	71,898	(26,032)	(36)
Operating income	116,625	34,559	82,066	237
Total non-operating income and expenses	5,499	59,949	(54,450)	(91)
Income before income tax	122,124	94,508	27,616	29
Income tax expense	25,090	18,823	6,267	33
Profit for the period	97,034	75,685	21,349	28
Common stock	1,455,968	1,465,968	(10,000)	(1)
EPS(NT\$)	0.68	0.52	0.16	31

Research and Development

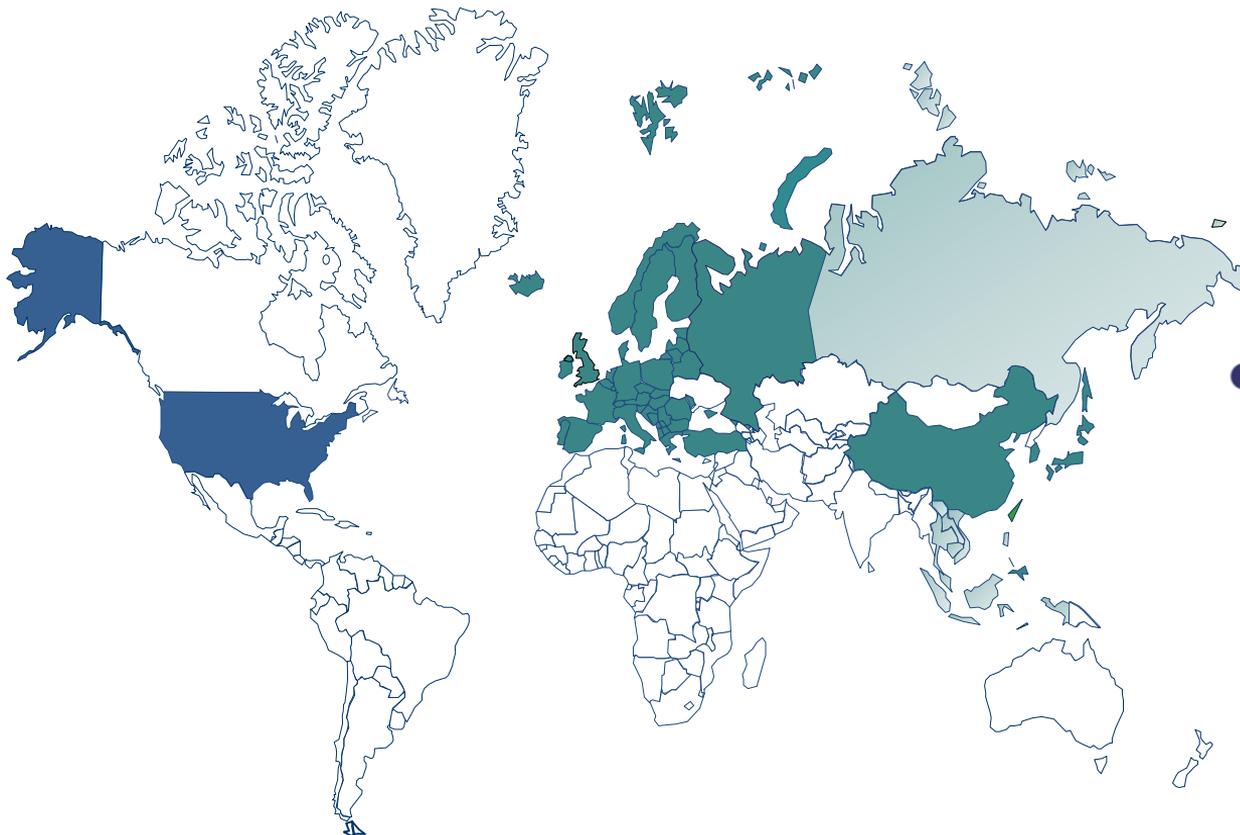
ONIVYDE® launched in China 2L PDAC market

PEP07 (SOL-578) preclinical progress meets expectation

Multiple projects under evaluation



ONIVYDE® Keep Global Market Expansion at 2L PDAC



Approved

Yet approved

Spotlight of ONIVYDE® 2L PDAC Approval in China

- ✓ **The first 2L PDAC new drug approved in the past 23 years**
- ✓ **ONIVYDE® has been recommended by China major treatment guidelines**
 - THE NATIONAL HEALTH COMMISSION 'PANCREATIC CANCER DIAGNOSIS AND TREATMENT SPECIFICATIONS (2018 EDITION)
 - THE CHINESE SOCIETY OF CLINICAL ONCOLOGY (CSCO) "PANCREATIC CANCER DIAGNOSIS AND TREATMENT GUIDELINES 2020",
 - THE CHINESE ANTI-CANCER ASSOCIATION PANCREATIC CANCER PROFESSIONAL COMMITTEE "CHINESE PANCREATIC CANCER COMPREHENSIVE DIAGNOSIS AND TREATMENT GUIDELINES (2020 EDITION)",
 - "GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF PANCREATIC CANCER IN CHINA (2021)" OF THE PANCREATIC SURGERY GROUP OF THE SURGERY BRANCH OF THE CHINESE MEDICAL ASSOCIATION
- ✓ **ONIVYDE® has been approved and get special reimbursement as an urgently needed clinical import drug in 2021**
 - Beijing universal health insurance (Government)
 - Lecheng special drug insurance (Commercial)
- ✓ **KoL Opinion**

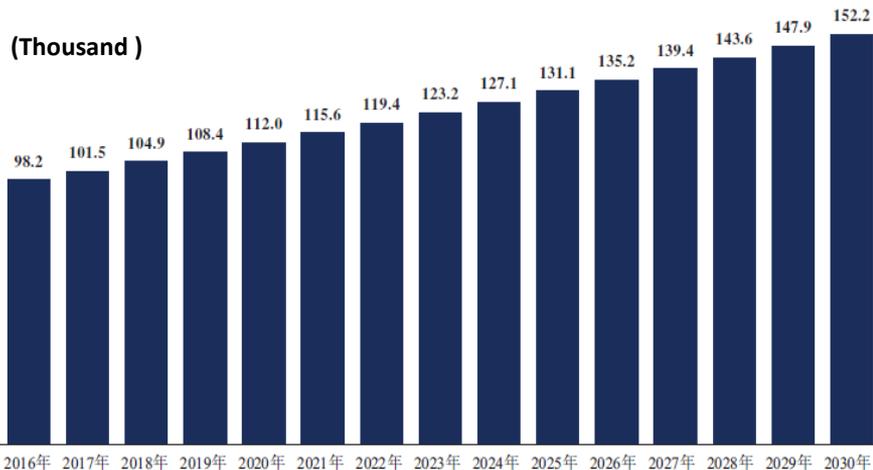


Professor Shen Lin from Peking University Cancer Hospital said: "The treatment of metastatic pancreatic cancer faces a huge and urgent unmet clinical need, especially the options for second-line and follow-up treatments are very limited, and patients with metastatic pancreatic cancer after failure of first-line chemotherapy are faced with the dilemma of 'no drug available' which seriously affects the overall survival of patients, and is a difficult point for clinical treatment to be broken through. The approval of ONIVYDE® in China fills the current gap in the treatment of pancreatic cancer and can bring more effective, A safe treatment plan brings new hope for patients to prolong their survival and improve their quality of life."

ONIVYDE® 2L PDAC Target Addressable Market (TAM)

The estimation of China PDAC Incidence No.
(2016-2030)

Period	CAGR
2016-2019	3.3%
2019-2024	3.2%
2024-2030	3.0%

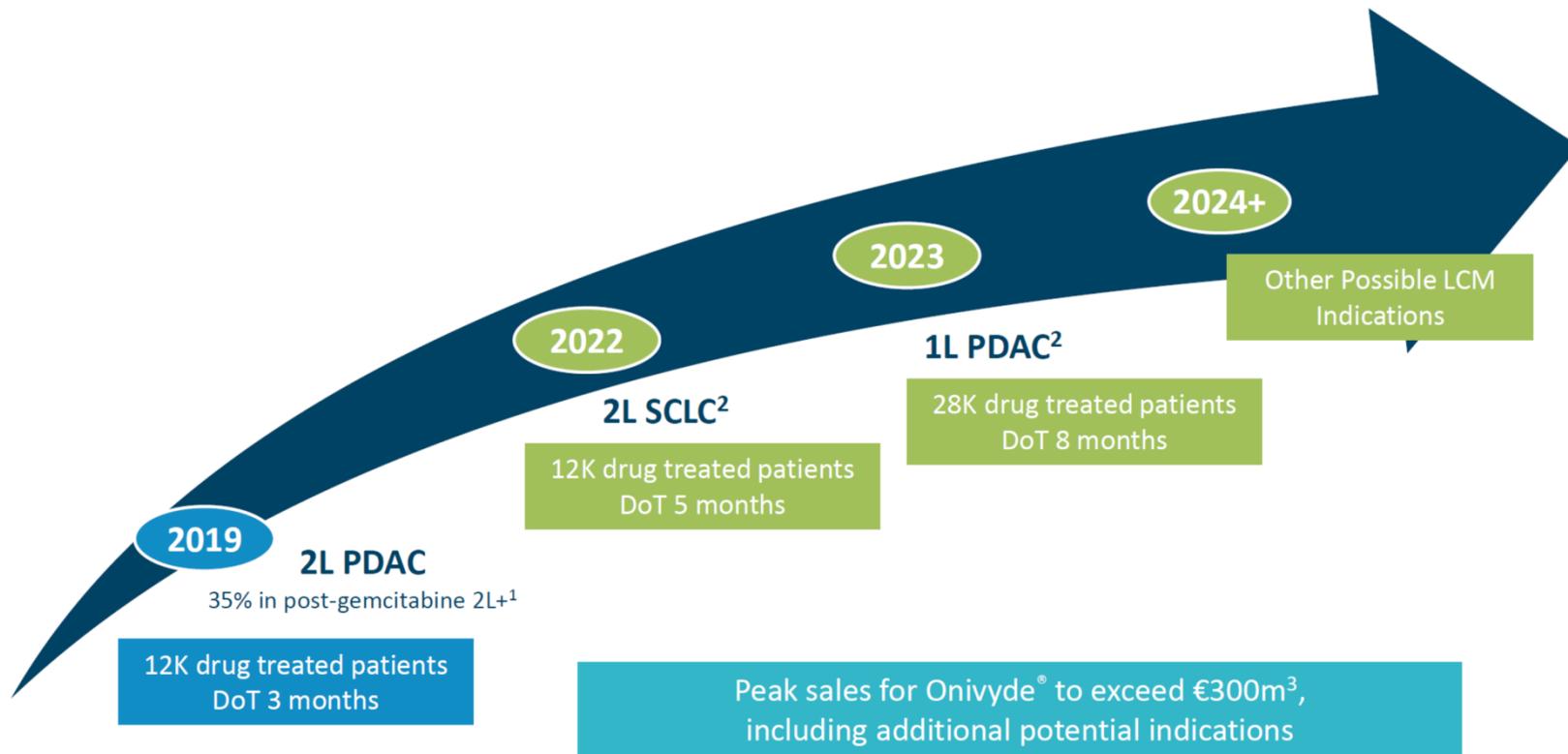


Indication	2L PDAC
Incidence No.	120K
Diagnose at stage IV (%)	60%
Potential to treat %	35%
2022E Potential to Treat No.	25.2K

- *Patients are prescribed 3-4 vials of Onivyde every two weeks, with an average four-month regimen.*

Source : WHO · NCCN · IPSEN FY21 Result · Frost & Sullivan

ONIVYDE® LCM: Expansion into New Tumor Types Globally



LCM: Life cycle management; PDAC: Pancreatic ductal adenocarcinoma; SCLC: Small cell lung cancer; DoT: Duration of treatment; 1L: First line; 2L: Second line; 1. IQVIA APLD claims, September 2020 ; 2. Expected submission dates ; 3. Risk adjusted; IPSEN Capital Market Day 2020

ONIVYDE® : Potential to Establish Standard of Care in Hard to Treat Cancers

1L PDAC



5Y survival rate only **7%**



Significant need for more effective therapies with reduced toxicity



Ability to build on successful approvals for 2L PDAC & leverage our global partners to establish new SoC



Existing commercial infrastructure & medical capabilities by our global partners

2L SCLC



5Y survival rate only **6%**



Very few FDA approved therapies, highlighting need for new options



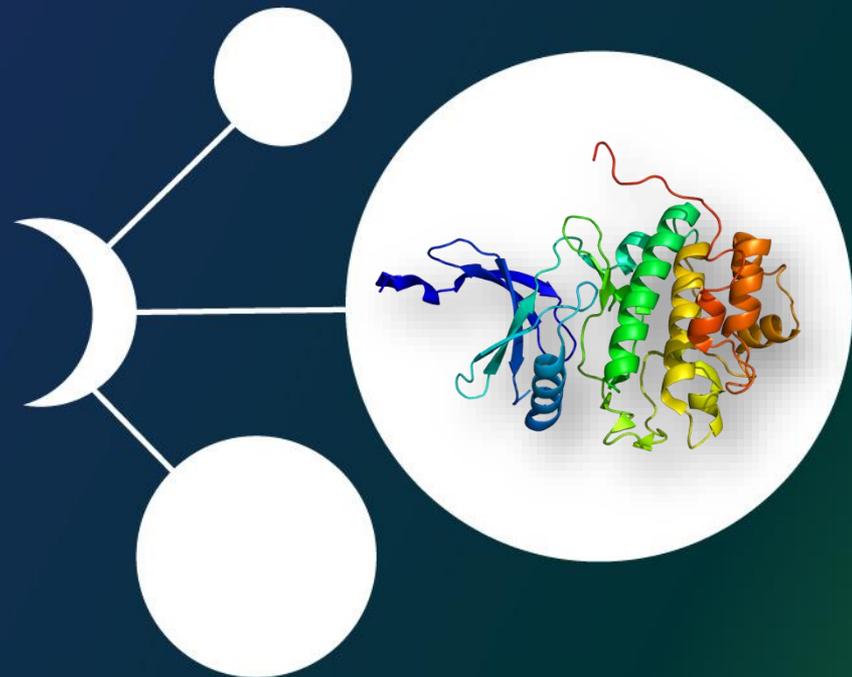
Improved toxicity profile versus SoC chemotherapies with severe side effects



Strong leverage of current organization by our global partners

PEP07 (SOL-578)

Preclinical Progress Meets Expectation



PEP07 (SOL-578) – Best in Class CHK1 Inhibitor

PEP07 (SOL-578) is a brain penetrating oral inhibitor which is more potent, selective and specific.

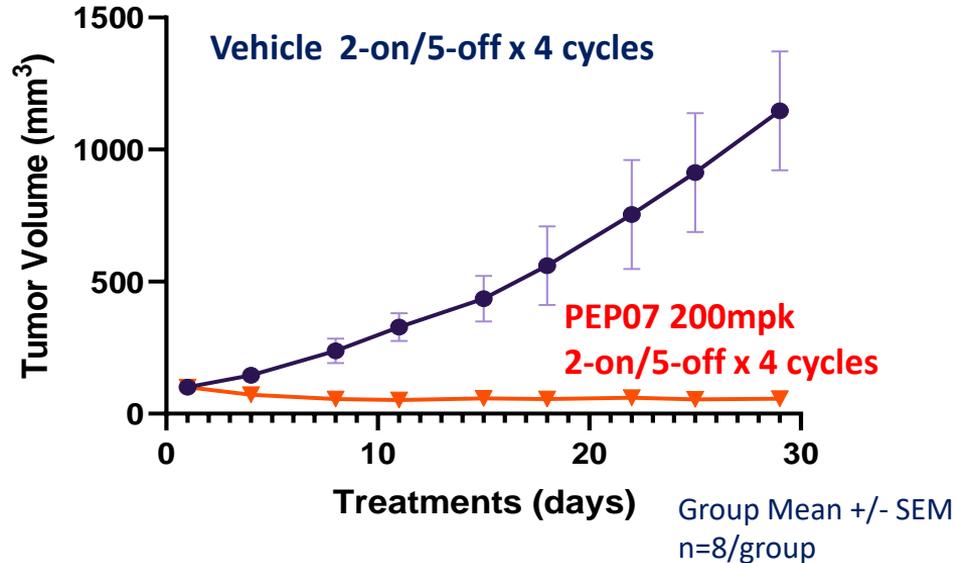
	Drug	Potency	Selectivity	Specificity	Oral Bioavailability
Eli Lilly	LY2606368	●	●	●	●
Genetech	GDC-0575	●	●	●	●
Sierra Oncology	SRA-737	●	●	●	●
Esperas Pharma	LY2880070	●	●	●	●
PEI/Sentinel	PEP07/SOL-578	●	●	●	●

●	Excellent	●	Good	●	Fair	●	Poor	●	Unknown
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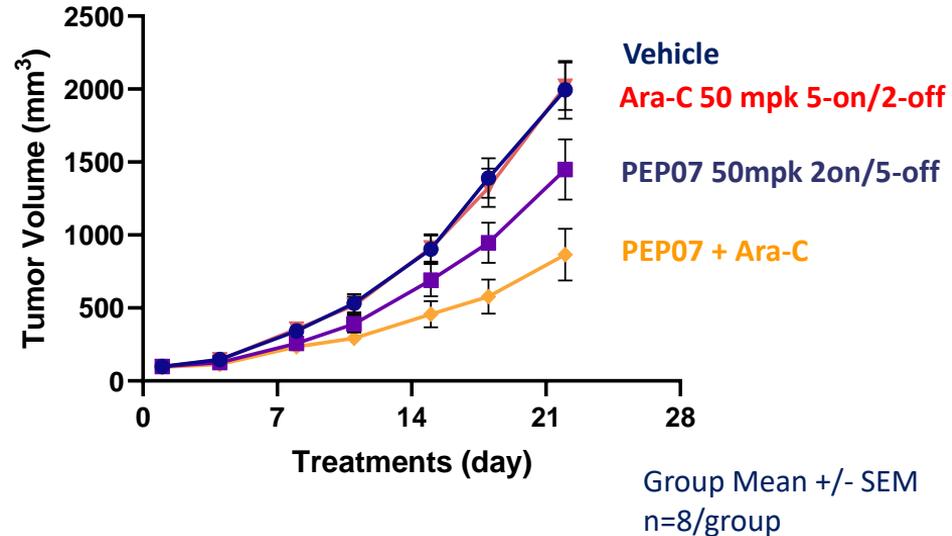
PEP07 (SOL-578) : Significant Efficacy in Hematologic Malignancies as Monotherapy and Combination Therapy

Acute Myeloid Leukemic (AML)

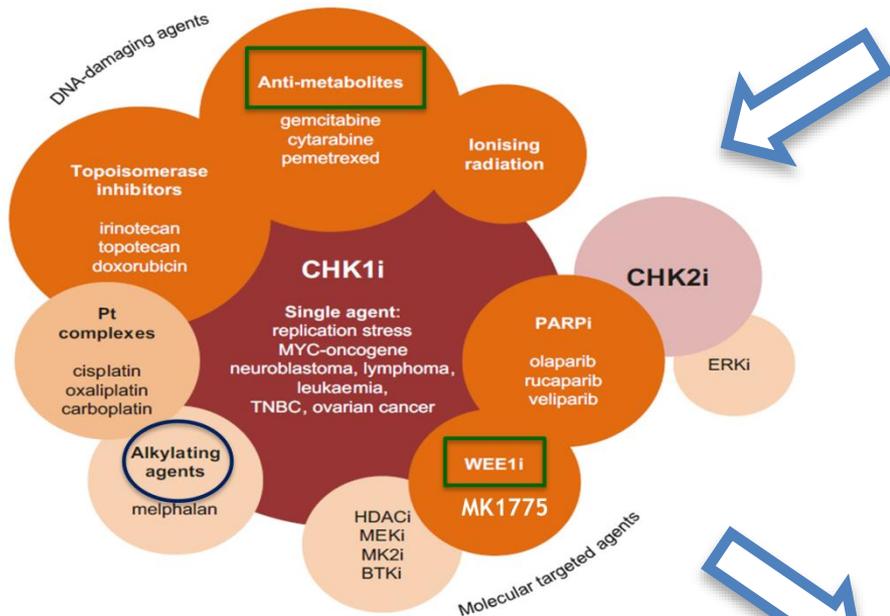
Ara-C Sensitive



Ara-C Resistant



PEP07 (SOL-578) 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 (SOL-578) IND Development Plan

Development Plan	2021												2022											
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10		
Preclinical Development	Active																							
CMC Development	Active																							
Toxicology Development																								
IND Preparation/ Submission																								

May of 2022

Preclinical

Anti-tumor efficacy in two AML models and MCL model
 Synergistic with Ara-C including Ara-C resistance model
 Efficacy study for solid tumors ongoing
 Biomarker evaluation ongoing

CMC

Identified novel salts
 Kg-scale ready for GMP production

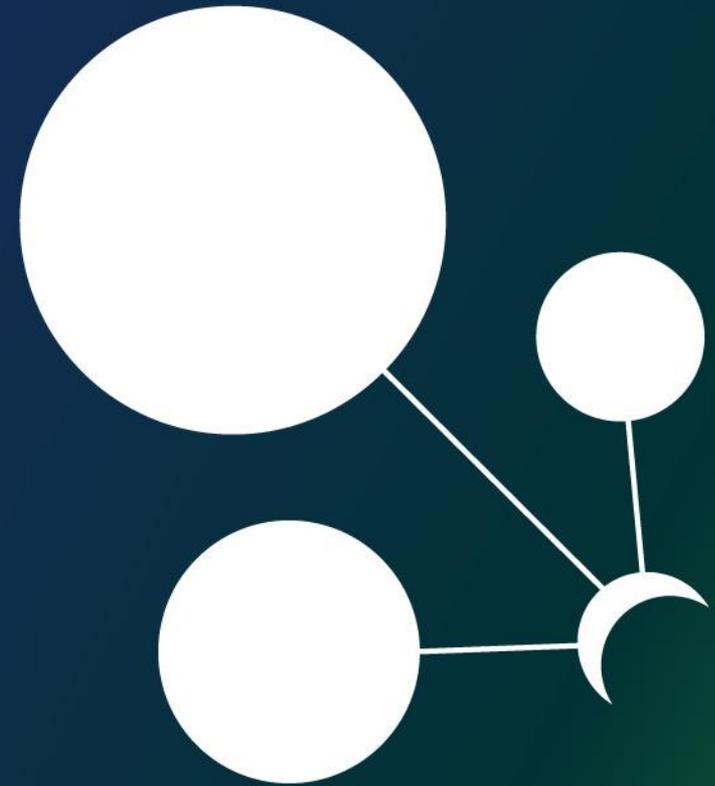
Toxicology

GLP study initiated

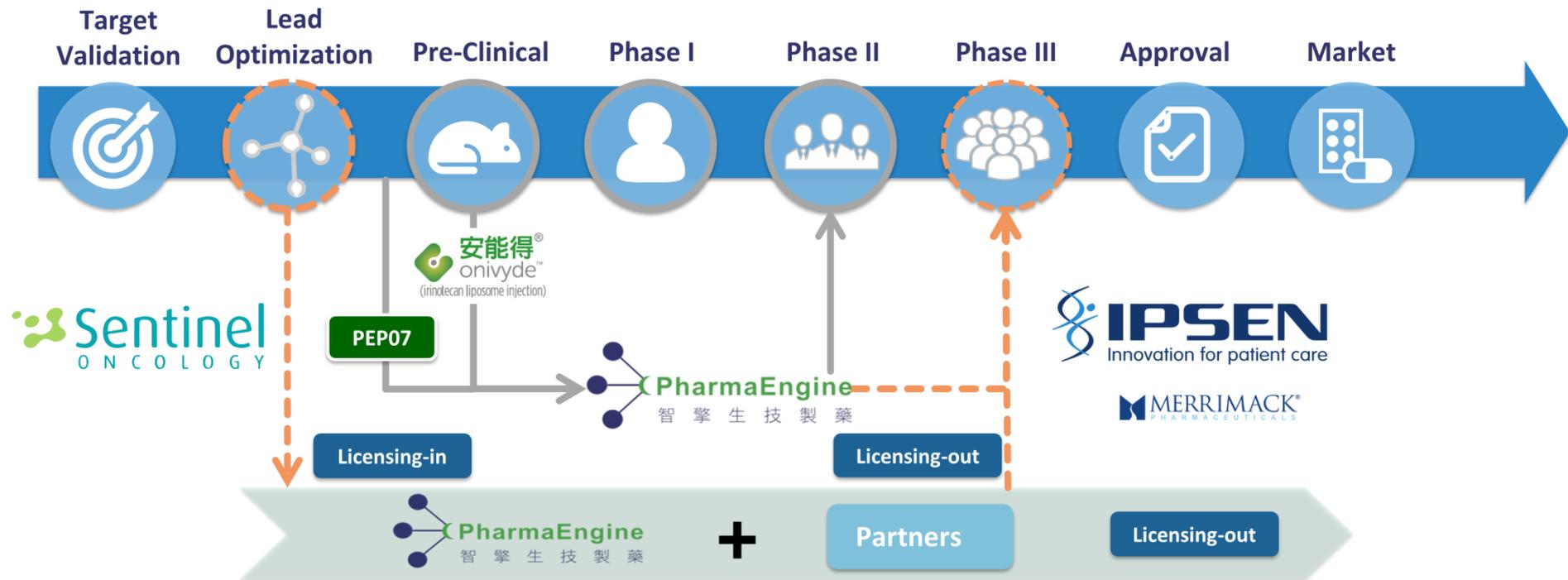
IND Prep. & Sub.

Target submission on 2022Q3

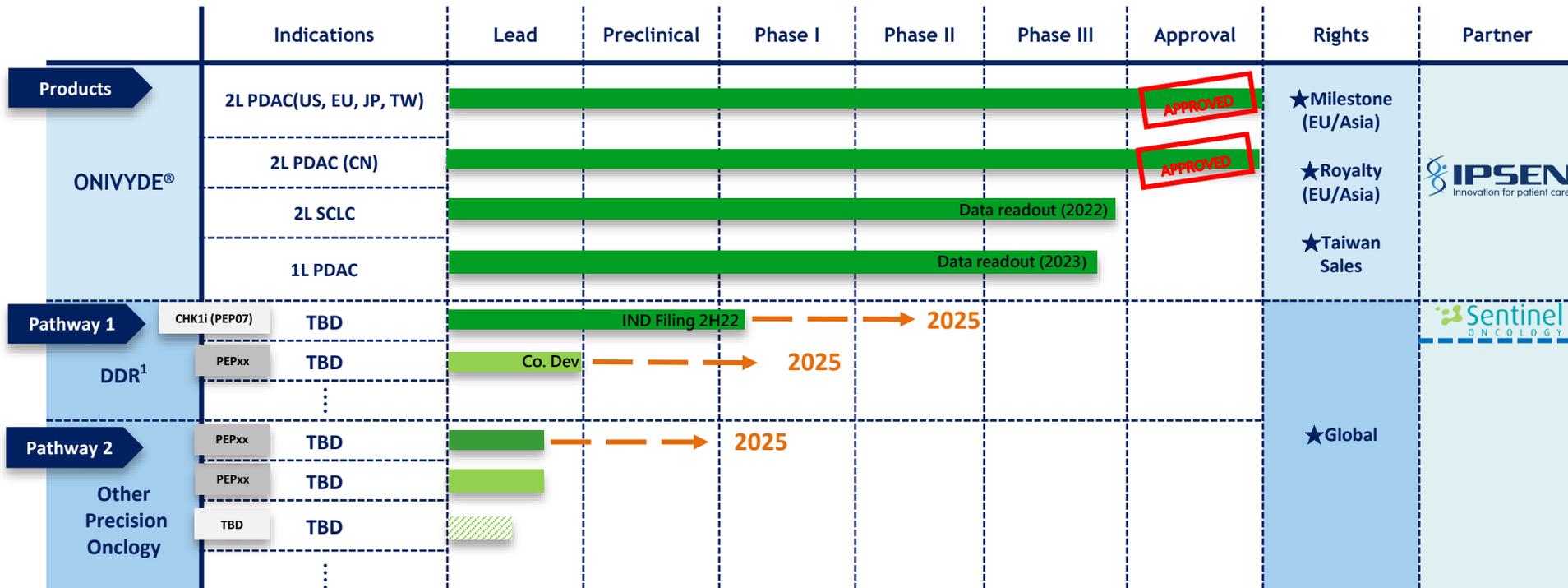
Vision for 2022



Virtual Pharmaceutical Company Business Model



Pipeline Portfolio



1. DDR: DNA Damage Response (BRCA1/2, CHK1/2, WEE1, etc...)

2022: Year of Revitalization and Marching Forward

Growth through ONIVYDE® life cycle management

1. 2L PDAC get approval and reimbursement in additional countries
2. 2L SCLC Phase III data readout
3. 1L PDAC Phase III data readout (2023)

Advancement and growth of early-stage pipeline

1. PEP07 IND/CTA submission and approval
2. 2nd DDR project license in
3. Initiate other precision oncology projects development



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