

PharmaEngine

智 擎 生 技 製 藥

Yuanta investor conference 4162.TWO

2022/03/10

Hong-Ren Wang, Ph.D.

President and CEO

Disclaimer

This presentation contains certain forward-looking statements.

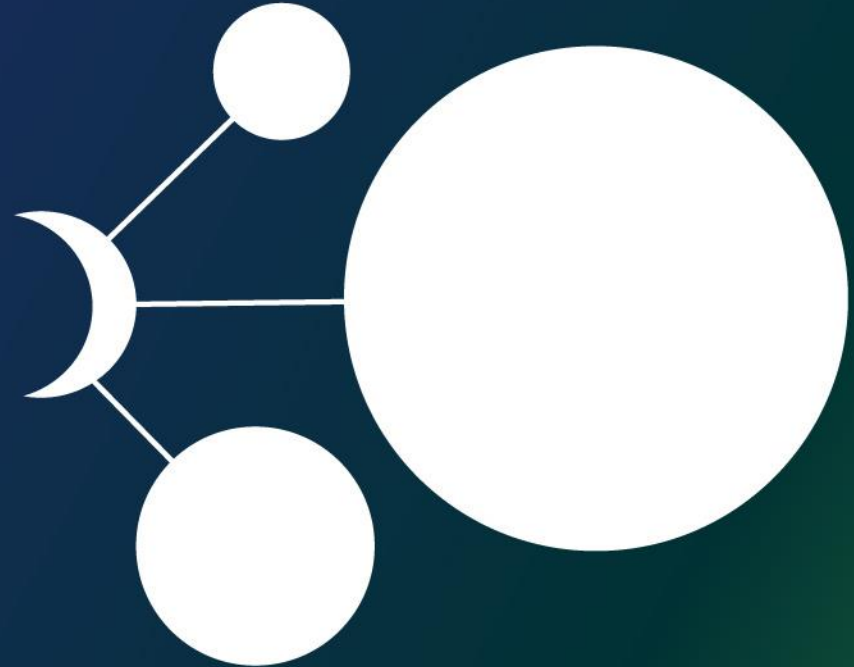
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6. Increased government pricing pressures
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Agenda

1. FY21 Operational Highlights
2. FY21 Operational Overview
3. Research and development
 - ▣ ONIVYDE®
 - ▣ PEP07 (SOL-578)
4. Vision for 2022
5. Q&A



Management Team with International Experience



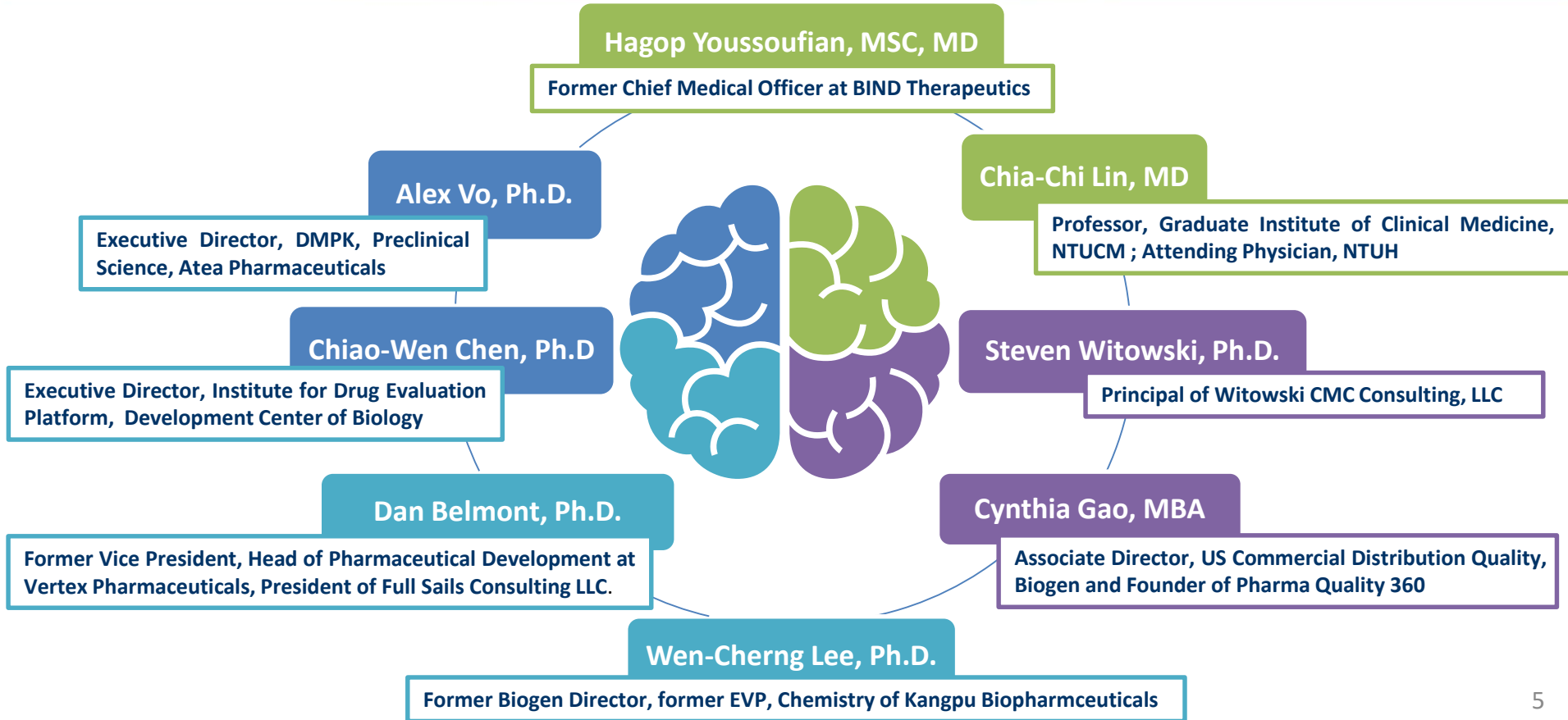
President & CEO

Dr. Hong-Ren Wang

15+ years of pharmaceutical industry experience. In addition to new drug development, worked on novel drug delivery/device combination through drug evaluation, PK/device combination modeling, and novel formulation design.

- Ph.D. in Materials Science and Engineering from Massachusetts Institute of Technology, Cambridge, Massachusetts, USA.
- Worked with Transform Pharmaceuticals, Vertex Pharmaceuticals, Microchips Biotech and Proteostasis Therapeutics with increasing responsibilities.
- Broad industry experience of selection and development of new chemical entities (NCEs) from preclinical to NDA/MAA applications including three FDA/EMA approved commercial products. (Incivek, Kalydeco, and Orkambi)

International Drug Development Consultants



Commercial



1. ONIVYDE® 2L PDAC treatment got reimbursements in Korea.
2. ONIVYDE® EU/Asia Royalties with strong growth momentum.
 - Sales in Japan staggering growth
3. ONIVYDE® 2L SCLC/1L PDAC phase III trial enrollment completed.

Pipeline



1. PEP07 preclinical progress as expectation
2. Early stage projects entering evaluation

Operation



1. +20% non-GAAP revenue as RD expenses
2. FY21 Cash and cash equivalents:
 - NTD\$3.8 bn
3. Long-lasting dividend payout :
 - NTD\$ 2.7/share (+8% YoY) 2021

FY21 Operational Overview

ONIVYDE® EU/Asia Royalties with strong growth momentum



Sales and Royalties Drives Long-term Growth

NTD \$(000)

Items \ Year	2017	2018	2019	2020	2021	20/21 YoY (%)
Taiwan Sales	40,651	87,384	180,389	214,828	235,469	9.6%
Royalties from Europe and Asia	63,526	109,825	133,651	271,584	419,366	54.4%
Milestone	749,500	96,221	0	569,600	0	-
Total	853,677	293,430	314,040	1,056,012	654,835	(40.8%)

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

FY21E Financial Results

NTD\$ (000)	2021	2020	Amount Change	% Change
Operating revenue	654,835	1,056,012	(431,273)	(38)
Operating costs	37,073	37,234	(161)	(0.4)
Gross profit	617,762	1,018,778	(401,016)	(39)
Sales expenses	36,731	37,115	(384)	(1)
G&A expenses ¹	81,885	76,230	5,440	7
R&D expenses	136,887	95,728	41,159	43
Total operating expenses	255,073	209,073	46,000	22
Operating income	362,689	809,705	(447,016)	(55)
Total non-operating income and expenses ²	182,706	(57,230)	239,936	N.A.
Income before income tax	545,395	752,475	(207,079)	(28)
Income tax expense	119,364	148,194	(28,830)	(19)
Profit for the period	426,031	604,281	(178,250)	(29)
Common stock	1,465,968	1,465,968	-	-
EPS(NT\$)	2.95	4.15	(1.2)	(29)

1. Impairment loss (impairment gain and reversal of impairment loss) determined in accordance with IFRS 9: NTD\$ 215K
2. non-operating income increased by PEP503 settlement: US\$ 6.5M (NTD\$ 182M)

Research and development

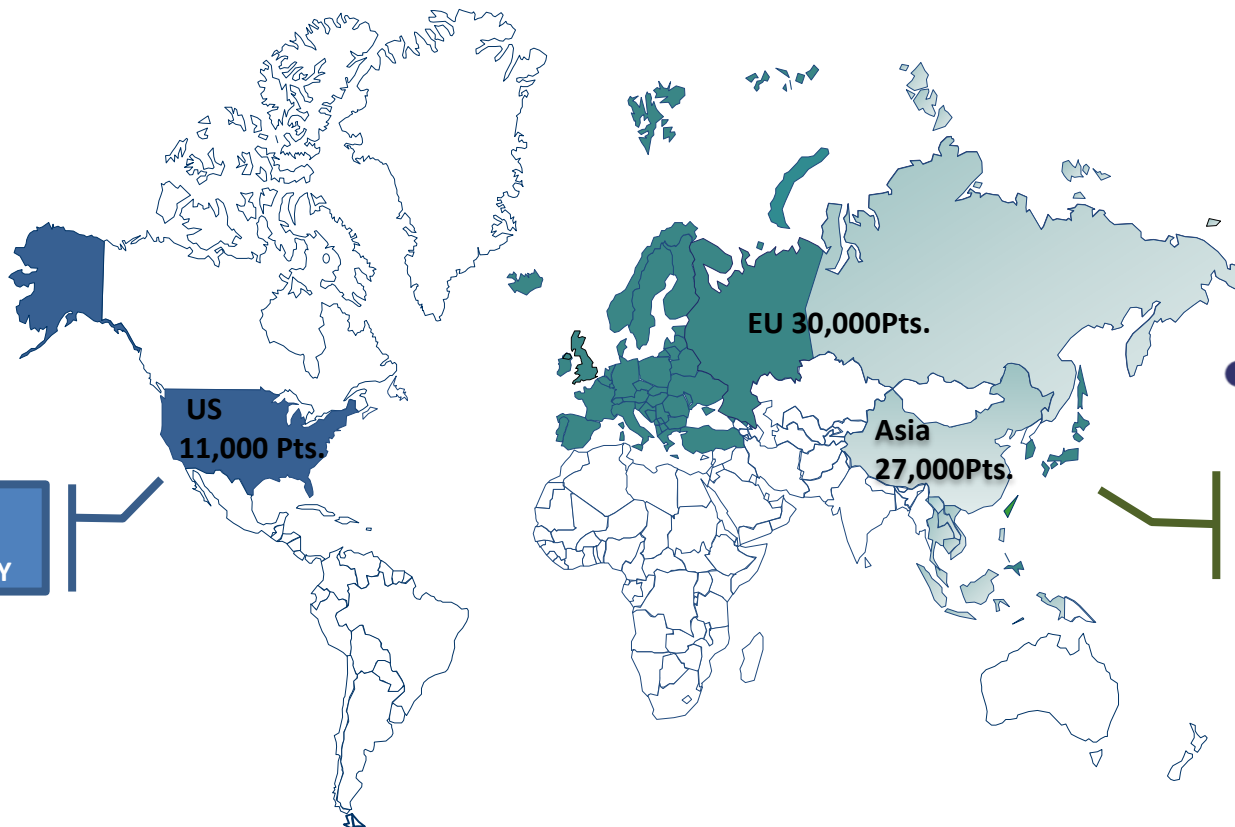
ONIVYDE® with favorable Life Cycle Management

PEP07 (SOL-578) preclinical progress as expected

Multiple projects entering evaluation process



ONIVYDE® Has Strong Growth Momentum in Global at 2L PDAC



FY21 US Sales

US\$ 145M, +7% YoY

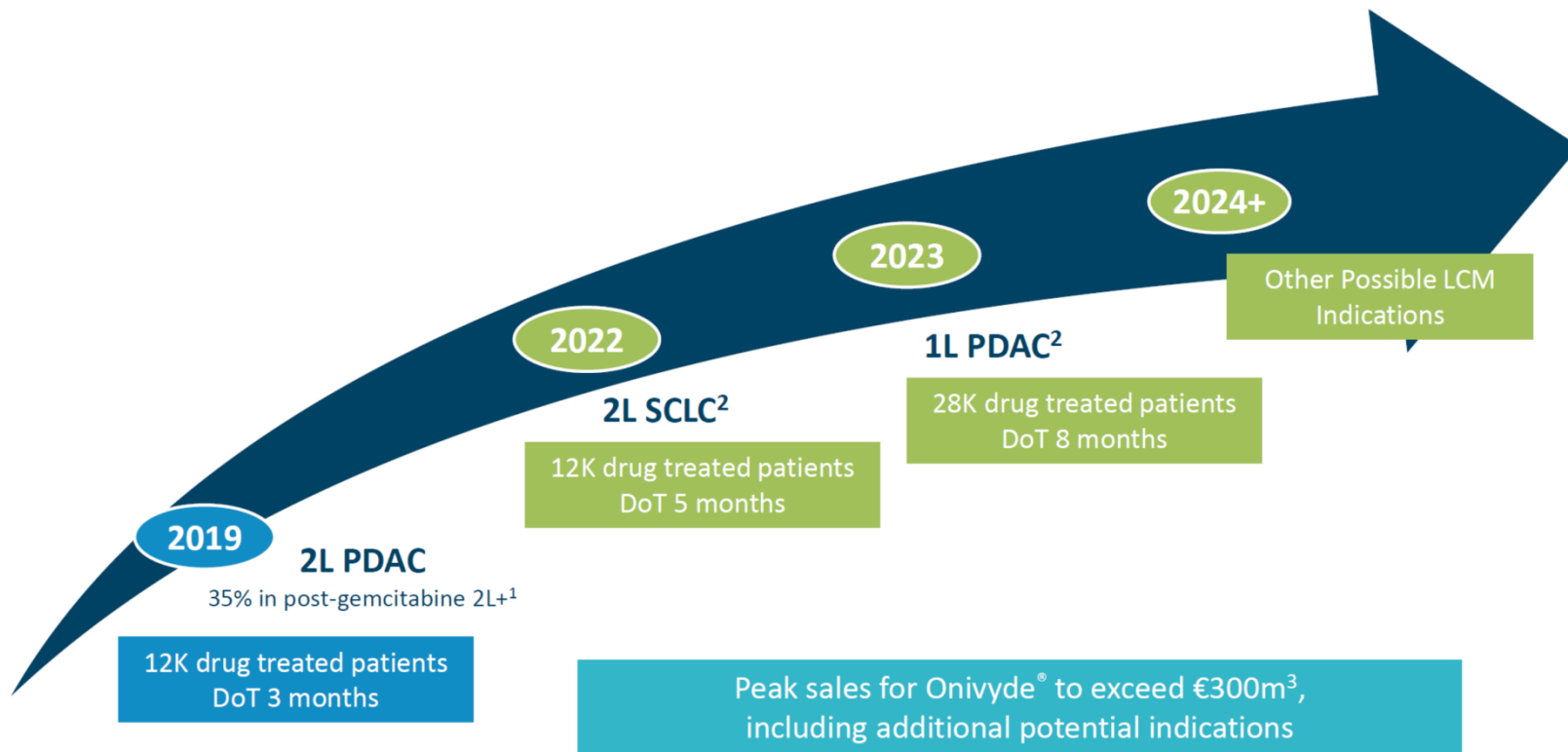
FY21 Sales & Royalties

US\$ 22.3M, +34.6% YoY

Approved

Yet approved

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



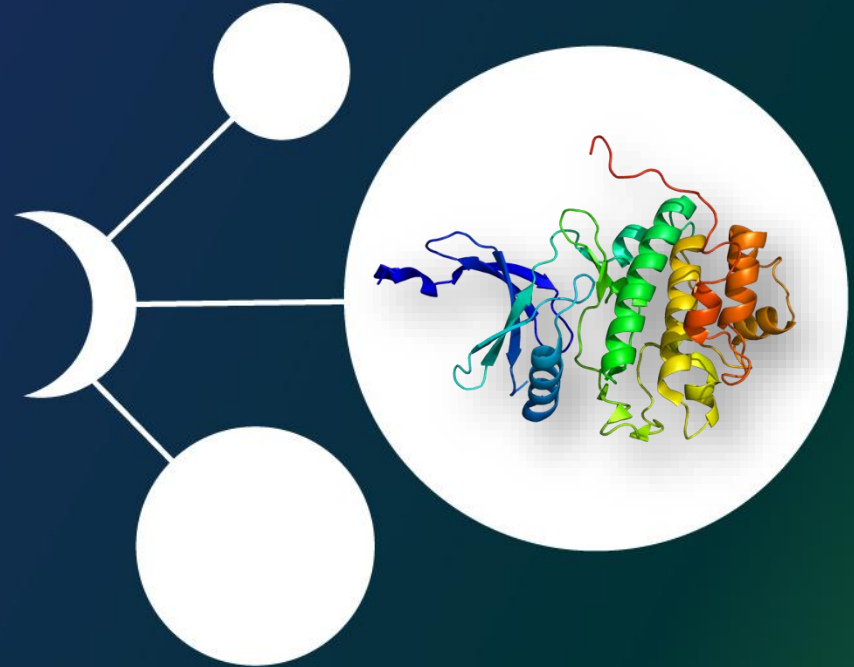
Improved toxicity profile versus SoC chemotherapies with severe side effects



Strong leverage of current organization by our global partners

PEP07 (SOL-578)

Preclinical progress as expectation





 Founded	2005
 Location	Cambridge, UK
 Type	Privately Held
 Focus	Oncology, Drug Discovery, Medicinal Chemistry & Collaboration
 Partnerships	  



Robert Boyle
CEO & Board of Directors



Stuart Travers
COO & Board of Directors

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

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

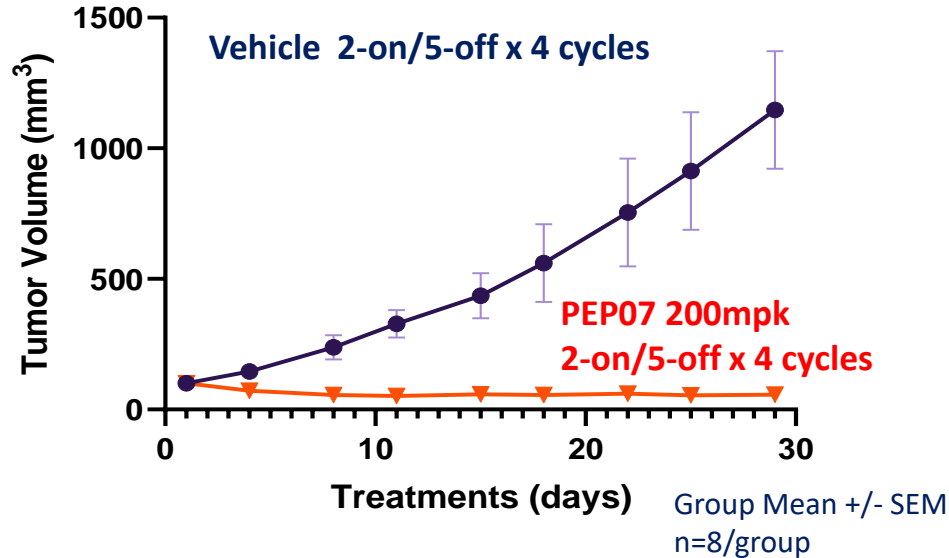
	Drug	Potency	Selectivity	Specificity	Oral Bioavailability
Eli Lilly	LY2606368	●	●	●	●
Genetech	GDC-0575	●	●	●	●
Sierra Oncology	SRA-737	●	●	●	●
Esperas Pharma	LY2880070	●	●	●	●
PEI/Sentinel	PEP07/SOL-578	●	●	●	●

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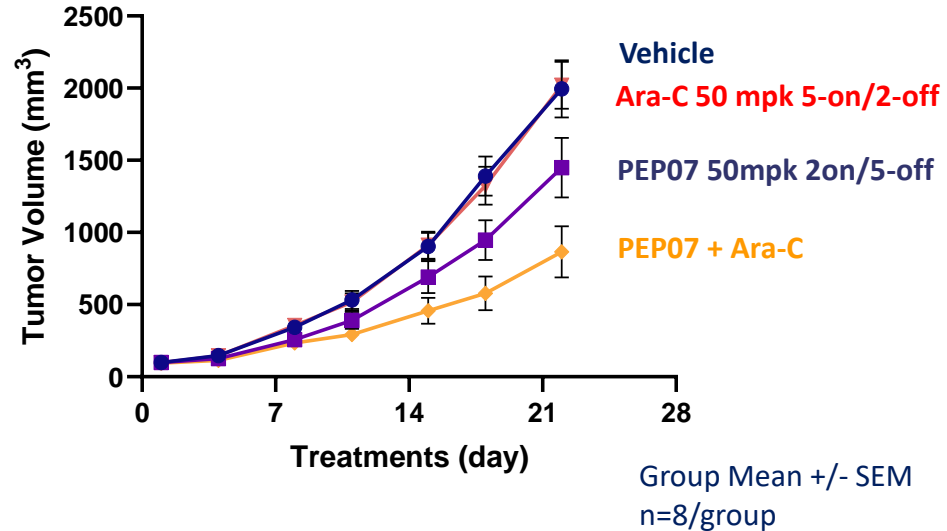
PEP07 (SOL-578) : Significant Efficacy in Hematologic Malignancies as Monotherapy and Combination therapy

Acute Myeloid Leukemic (AML)

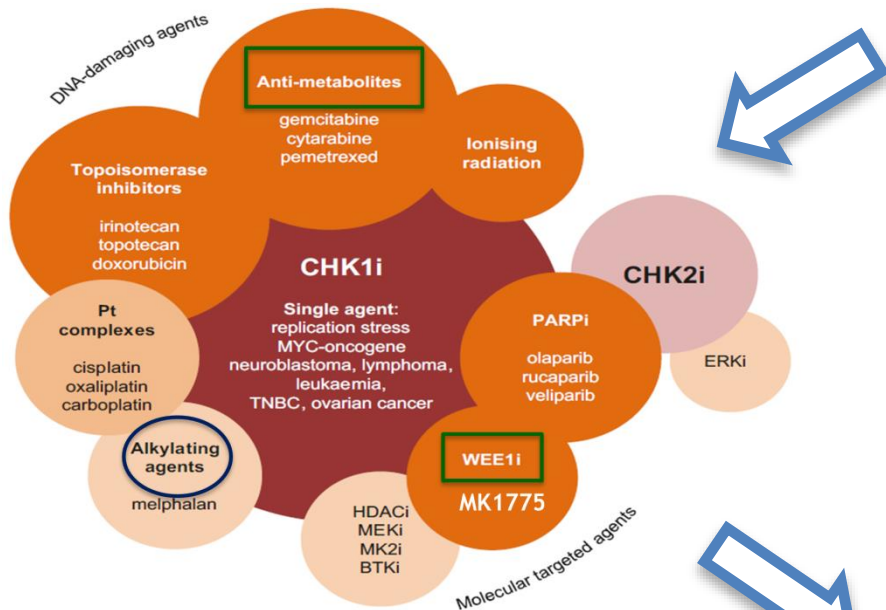
Ara-C Sensitive



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) Early Clinical Development Plan

P1a monotherapy, dose escalation/expansion in AML, MCL, and advanced or metastatic solid tumor

P1b Combo, dose escalation/expansion in AML

P1b Combo, dose escalation/expansion in MCL

P1b Combo, dose escalation/expansion in selected solid tumors

Preclinical biomarker study is ongoing for further design of clinical trials

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	█																											
CMC Development	█												█															
Toxicology Development							█																					
IND Preparation/ Submission																												

February 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

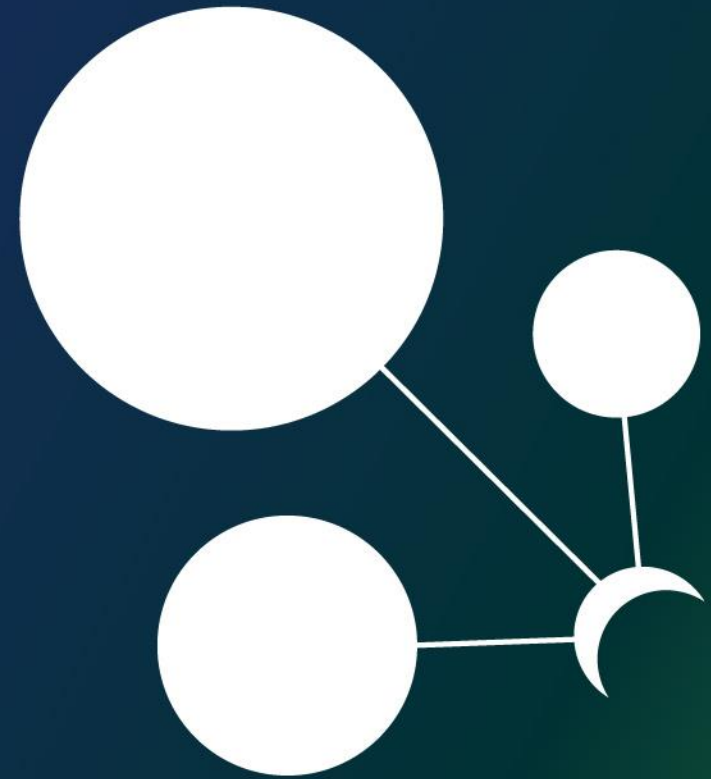
Toxicology

- GLP study initiated

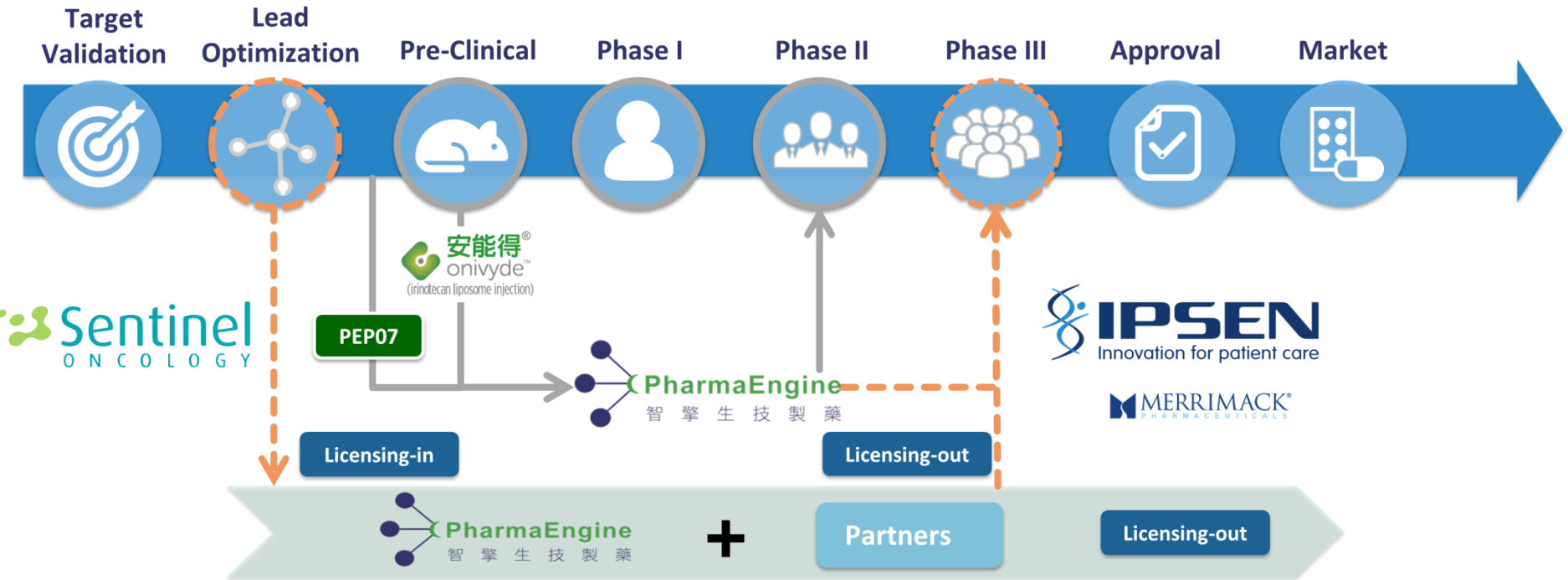
IND Prep. & Sub.

- Target submission on 2022Q3



Vision for 2022



Virtual Pharmaceutical Company Business Model



Pipeline Portfolio

	Indications	Lead	Preclinical	Phase I	Phase II	Phase III	Approval	Rights	Partner	
Products	2L PDAC(US, EU, JP, TW)						APPROVED	★Milestone (EU/Asia) ★Royalty (EU/Asia) ★Taiwan Sales		
	2L PDAC (CN)						1H22			
	1L PDAC						Data readout (2023)			
	2L SCLC						Data readout (2022)			
Pathway 1	CHK1i (PEP07)	TBD	IND Filing 2H22						★Global	
	PEPxx	TBD	Co. Dev							
	TBD	TBD								
Pathway 2	Other Precision Oncology	PEPxx	TBD							
		PEPxx	TBD							
		TBD	TBD							

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 (2022/2023)

Advancement and growth of early-stage pipeline

1. PEP07 IND/CTA submission and approval
2. 2nd DDR project
3. Other precision oncology projects



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