

PharmaEngine

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2022 QIC

Healthcare Forum

Hong-Ren Wang, Ph.D.

President and CEO

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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:

1. Pricing and product initiatives of competitors
2. Legislative and regulatory developments and economic conditions
3. Delay or inability in obtaining regulatory approvals or bringing products to market
4. Fluctuations in currency exchange rates and general financial market conditions
5. Uncertainties in the discovery, development, or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side effects of pipeline or marketed products
6. Increased government pricing pressures
7. Interruptions in production
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Mission

Unlock value for promising therapeutic candidates & Extend patients' lives

Vision

Top tier innovative oncology drug development company in Asia



2022 Marks PharmaEngine's 20th Year Committing to Oncology New Drug Development



2003-2010

2003- 2010

- Founded the Company
- Licensed-in PEP02 for Asia territory in 2003
- Expanded PEP02 license to the EU territory in 2005
- Completed PEP02 Phase 2 study for 2nd-line PDAC in the US and TW in 2010

2011-2015

- Licensed-out PEP02 (ONIVYDE®) in 2011
- IPO at Taipei Exchange in 2012
- Turned profitable since 2014
- ONIVYDE® as First US FDA approved cancer drug from Taiwan in 2015
- ONIVYDE® listed as SoC for 2L PDAC in ESMO clinical guideline since 2015

2016-2021

- ONIVYDE® listed as SoC for 2L PDAC in NCCN clinical guideline since 2016
- Built a marketing & sales team in Taiwan in 2016
- First sales milestone achievement in 2020
- Exclusive collaboration with Sentinel Oncology for PEP07 in 2020



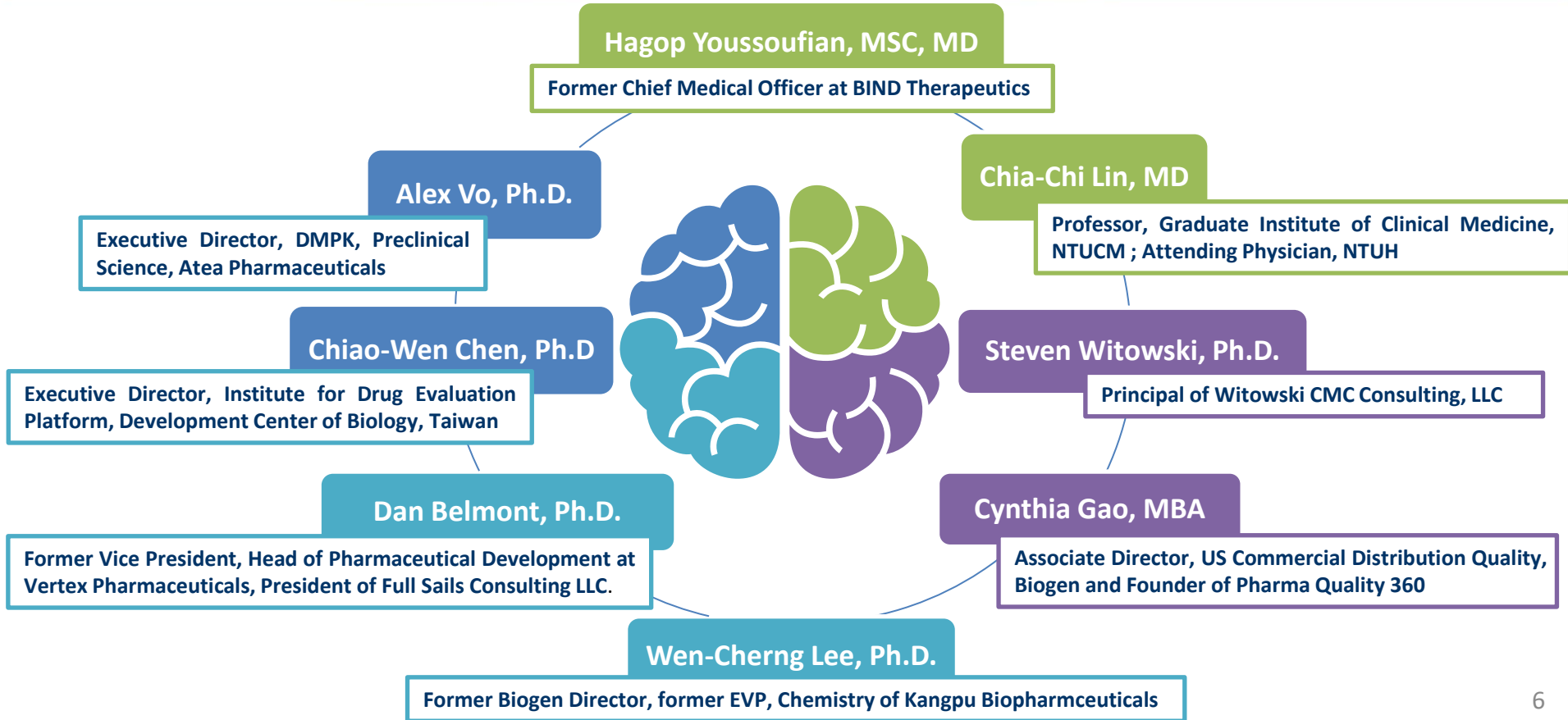
President & CEO

Dr. Hong-Ren Wang

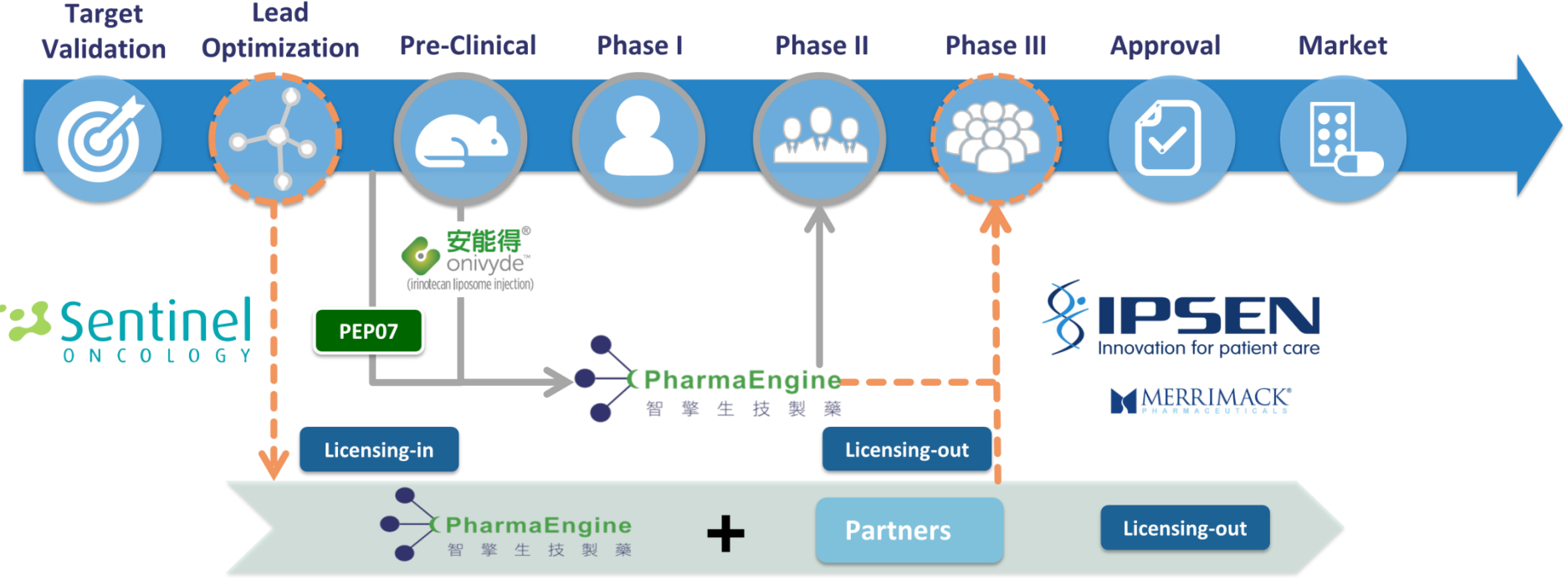
15+ years of pharmaceutical industry experience. In addition to new drug development, worked on novel drug delivery/device combination through drug evaluation, PK/device combination modeling, and novel formulation design.

- 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)

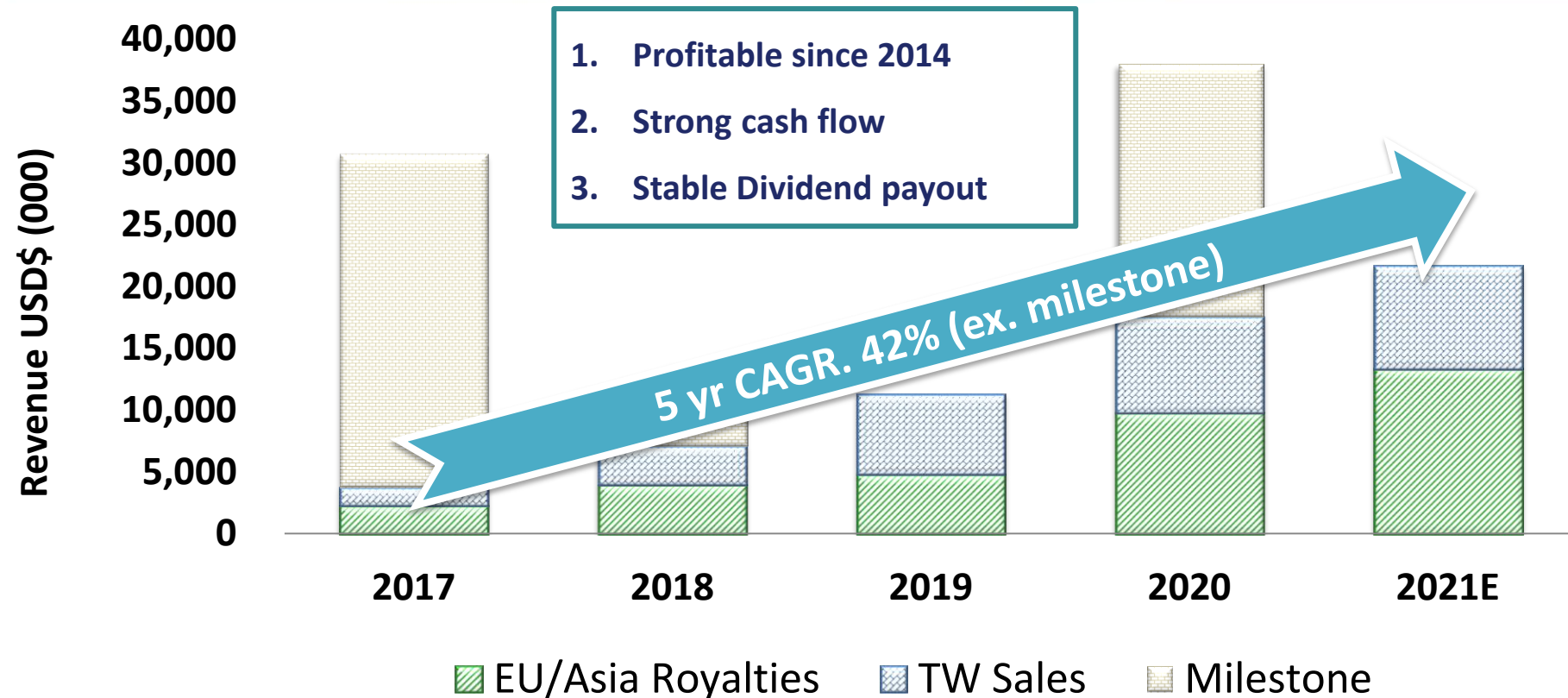
International Drug Development Consultants



Virtual Pharmaceutical Company Business Model



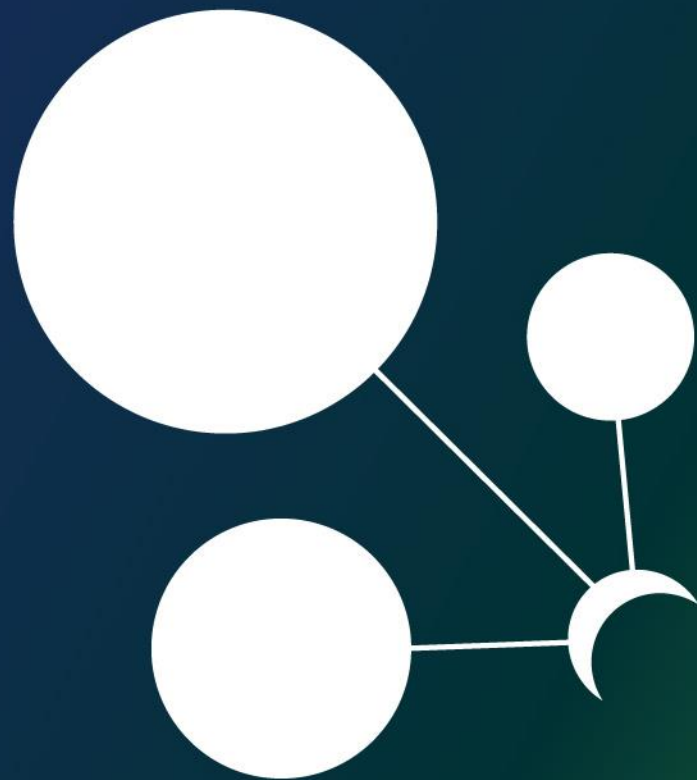
Profitable R&D Biotech



Taiwan Sales belongs to PharmaEngine, Inc.

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

Vision 2025



Vision 2025 to Deliver Sustainable Growth and Enhanced Value

Commercial



ONIVYDE® life cycle management (LCM) through new indications and market expansion with our partners

Pipeline



Pipeline delivering

- 1 Mid stage projects for out-license
- 2 Early stage projects at Phase I/II
- 3 Lead optimization/preclinical projects

Operation



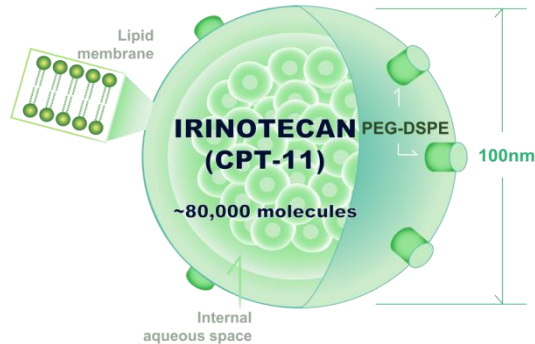
- +20% non-GAAP revenue as RD expenses
- Long-lasting dividend payout
- In/Out-license or M&A

Commercial

ONIVYDE® Life Cycle Management

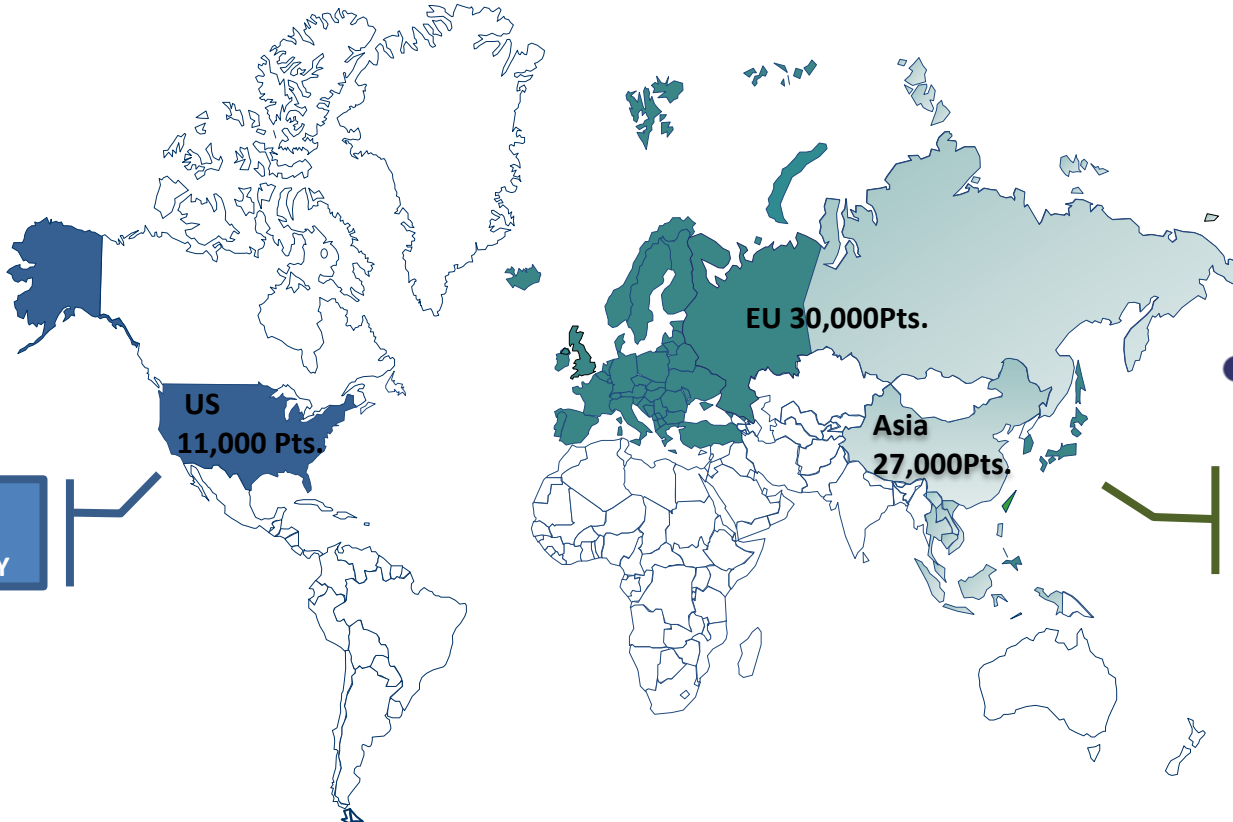


- **First** FDA-approved drug in post-gemcitabine pancreatic cancer
- **Category 1** evidence in NCCN and ESMO clinical practice guideline



- ONIVYDE® is a liposome formulation of irinotecan
- Sustained release profile
- Preferential tumor accumulation
- Site-specific activation

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



FY21 US Sales

US\$ 145M, +7% YoY

**US
11,000 Pts.**

EU 30,000 Pts.

**Asia
27,000 Pts.**

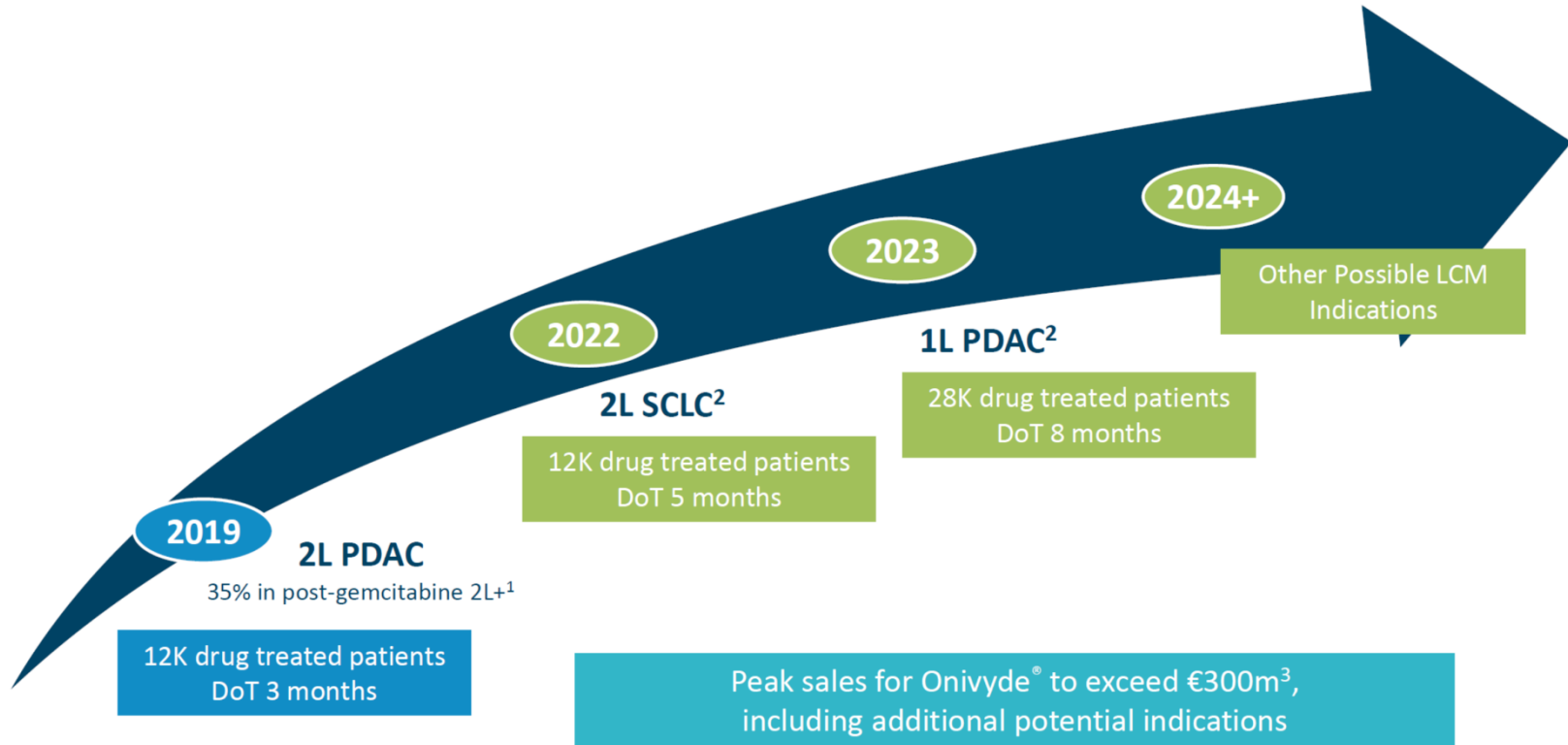
3Q21 Sales & Royalties

US\$ 16.2M, +67% 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

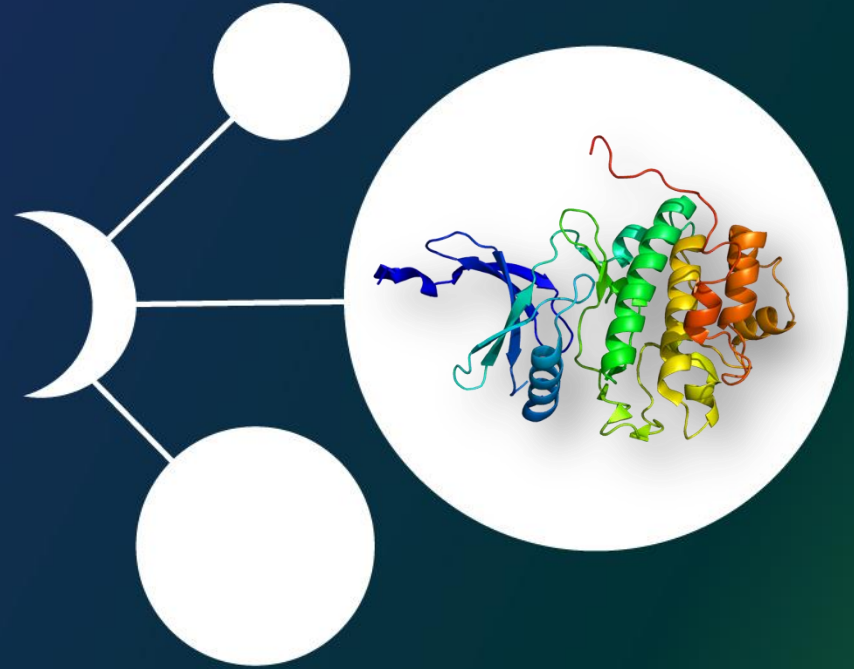


Improved toxicity profile versus SoC chemotherapies with severe side effects





Strong leverage of current organization by our global partners

R&D Portfolio



Pipeline Portfolio

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

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



 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.

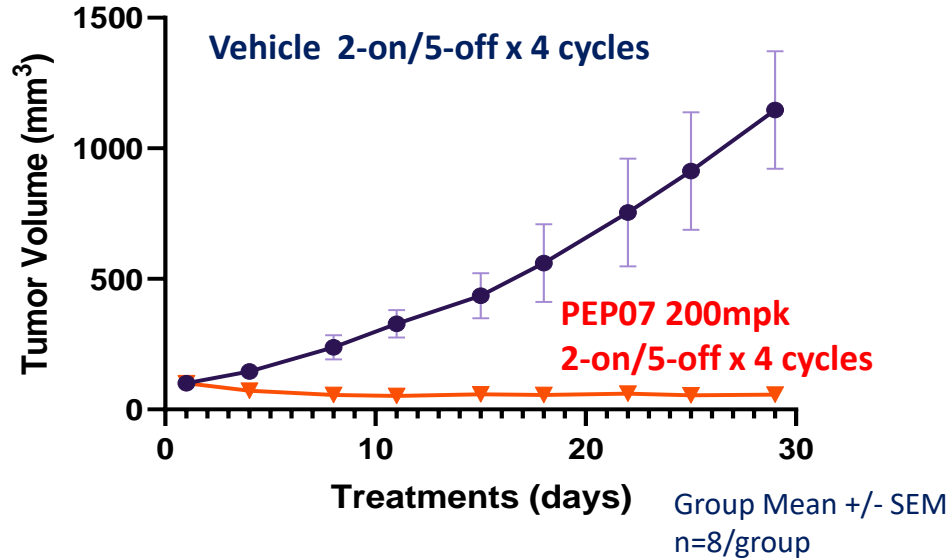
	Drug	Potency	Selectivity	Specificity	Oral Bioavailability
Eli Lilly	LY2606368	●	●	●	●
Genetech	GDC-0575	●	●	●	●
Sierra Oncology	SRA-737	●	●	●	●
Esperas Pharma	LY2880070	●	●	●	●
PEI/Sentinel	PEP07/SOL-578	●	●	●	●

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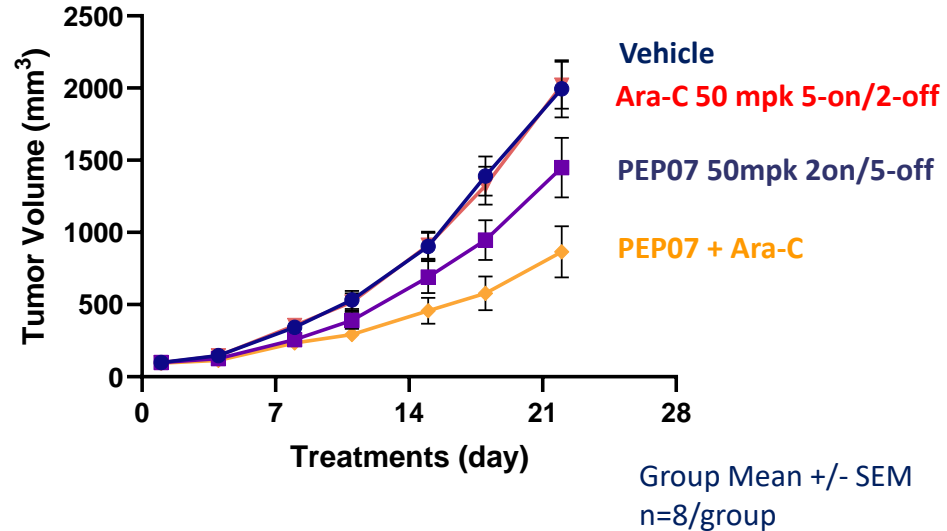
PEP07 (SOL-578) : Significant Efficacy in Hematologic Malignancies as Monotherapy and Combination therapy

Acute Myeloid Leukemic (AML)

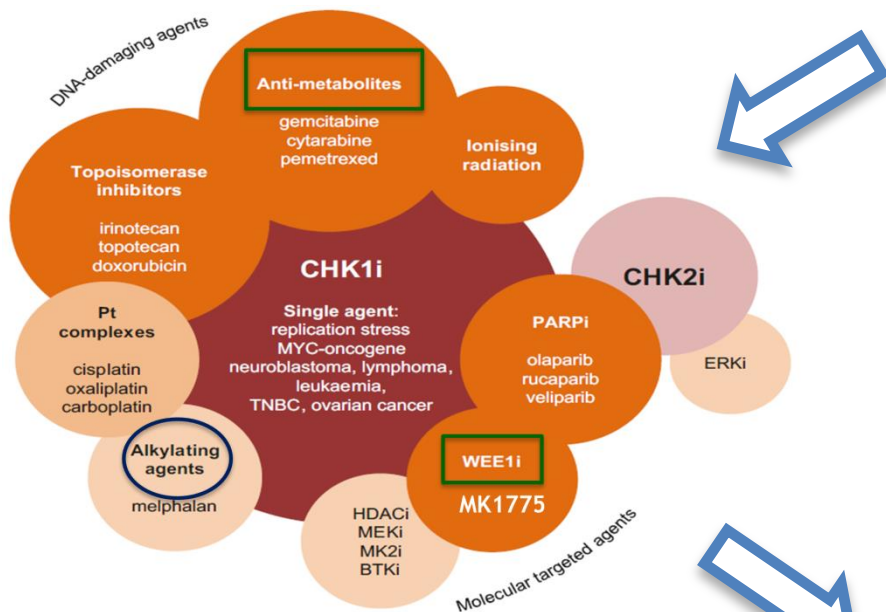
Ara-C Sensitive



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

2022: Year of Revitalization and Marching Forward

Growth through ONIVYDE® life cycle management

1. 2L PDAC get China (NMPA) approval
2. Reimbursement in additional EU countries for 2L PDAC indication
3. 2L SCLC Phase III data readout
4. 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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