

Taiwan Stock Market Discovery Forum



4162.TWO

April 9th, 2021

Safe Harbor Statement

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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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
8. Loss of or inability to obtain adequate protection for intellectual property rights
9. Litigation
10. Loss of key executives or other employees
11. Adverse publicity and news coverage

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Any statements regarding earnings growth is not a profit forecast and should not be interpreted to mean that PharmaEngine's earnings or earnings per share for this year or any subsequent period will necessarily match or exceed published earnings or earnings per share forecasts of PharmaEngine, Inc.

Agenda



- Introduction of PharmaEngine New President/CEO
- 2020 Financial Results
- Pipeline Updates
 - Sales Performance and Territories Status of Onivyde®
 - PEP07 Development Strategy
- Q&A

Introduction of PharmaEngine New President/CEO

Dr. Hong-Ren Wang

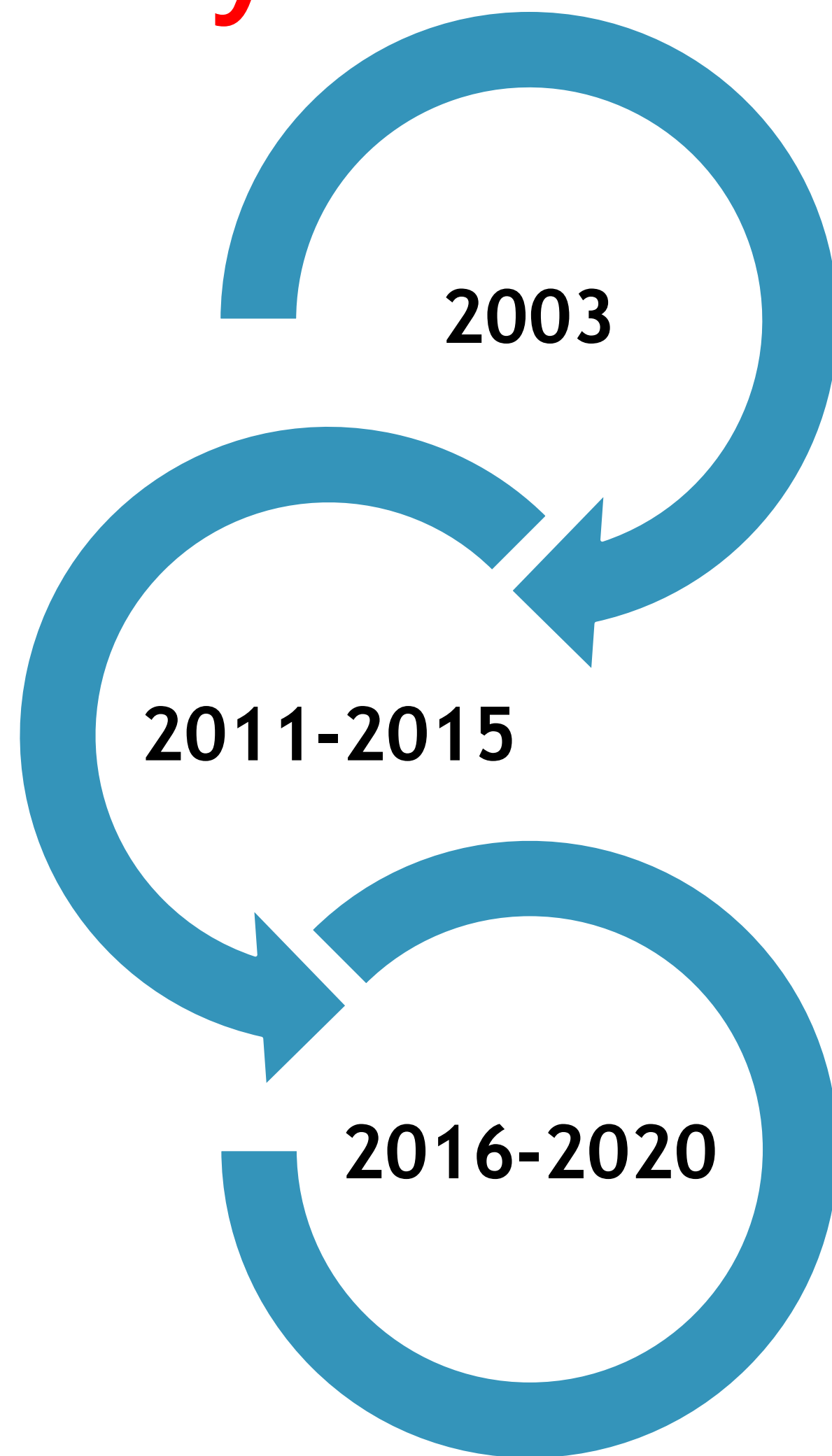
15+ years of pharmaceutical industry experience. In addition to new drug development, he worked on novel drug delivery/device combination through drug evaluation, PK/device combination modeling, and novel formulation design.



- Ph.D. in Materials Science and Engineering from Massachusetts Institute of Technology, Cambridge, Massachusetts, USA.
- Worked with Transform Pharmaceuticals (a subsidiary company of Johnson & Johnson), Vertex Pharmaceuticals, Microchips Biotech and Proteostasis Therapeutics with increasing responsibilities in drug development.
- 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)

Year 2021 marks PharmaEngine's

18th year committing to oncology new drug development



2003

- Company founded
- Licensed-in PEP02 (Onivyde)

2011-2015

- Licensed-out PEP02 (Onivyde) in 2011
- Licensed-in PEP503 in 2012
- IPO at Taipei Exchange in 2012
- Turned profitable since 2014

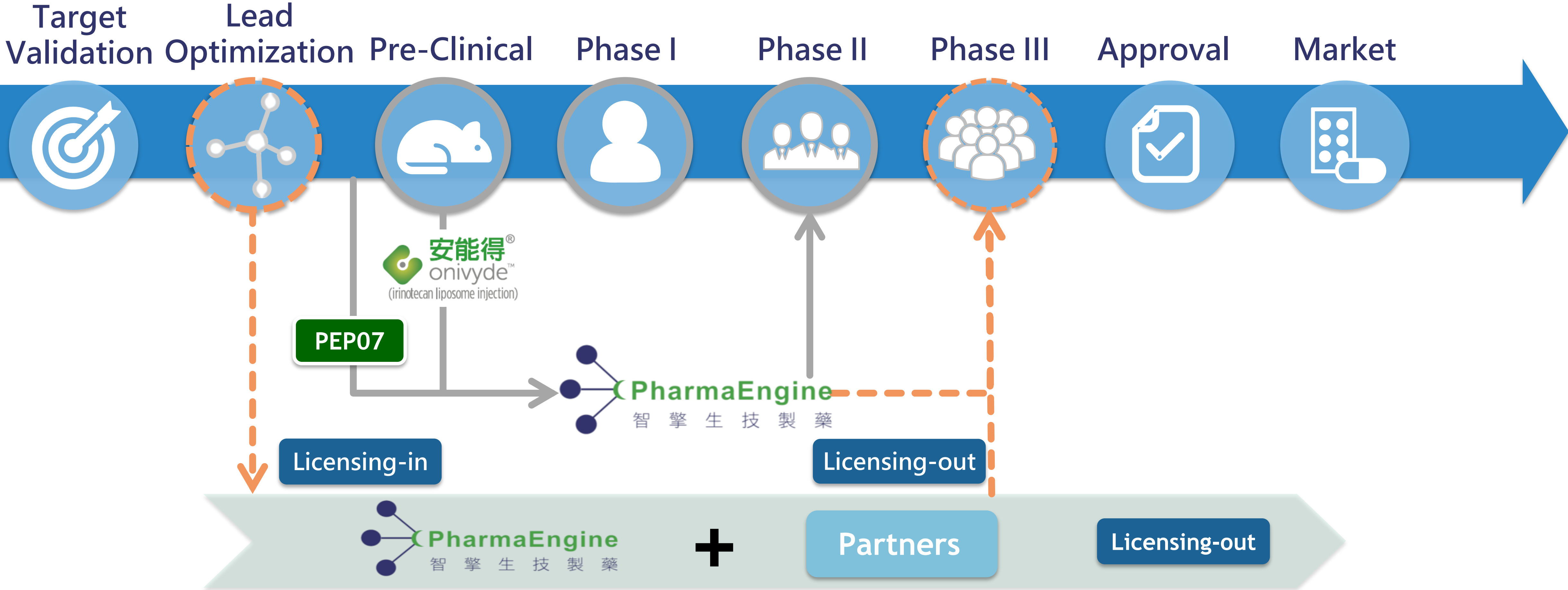
2016-2020

- Built a marketing & sales team in Taiwan in 2016
- Generated positive data of PEP503 in STS pivotal trial in 2018
- PEP503 CE Mark for STS in 2019
- Establish a strong and diversified portfolio

2021~

- Strength R&D Team
- Broaden new projects evaluation and licensing to increase pipeline
- Accelerate development timeline (PEP07...)
- Explore opportunities for collaboration with academics

Virtual Pharmaceutical Company Business Model





2020 Financial Results

2020 Financial Results

(EXPRESSED IN THOUSANDS OF NEW TAIWAN DOLLARS)

	2020	2019	Amount Change	% Change
Operating revenue	1,056,012	314,040	741,972	236
Operating costs	37,234	31,799	5,435	17
Gross profit	1,018,778	282,241	736,537	261
Sales expenses	37,115	35,108	2,007	6
G&A expenses	76,230	83,730	(7,500)	(9)
R&D expenses	95,728	130,793	(35,065)	(27)
Total operating expenses	209,073	249,631	(40,558)	(16)
Operating income	809,705	32,610	777,095	2,383
Total non-operating income and expenses	(57,230)	17,057	(74,287)	(436)
Income before income tax	752,475	49,667	702,808	1,415
Income tax expense	148,194	7,117	141,077	1,982
Profit for the period	604,281	42,550	561,731	1,320
Common stock	1,465,968	1,466,668	(700)	(0.05)
EPS(NT\$)	4.15	0.29	3.86	1,331

Sales, Royalties, and Milestones Driving Growth

Thousand NTD

Items \ Year	2017	2018	2019	2020	2019-2020 Growth rate(%)
Taiwan Sales	40,651	87,384	180,389	214,828	19
Royalties from Europe and Asia	63,526	109,825	133,651	271,584	103
Milestone	749,500	96,221	0	569,600	NA
Total	<u>853,677</u>	<u>293,430</u>	<u>314,040</u>	<u>1,056,012</u>	236

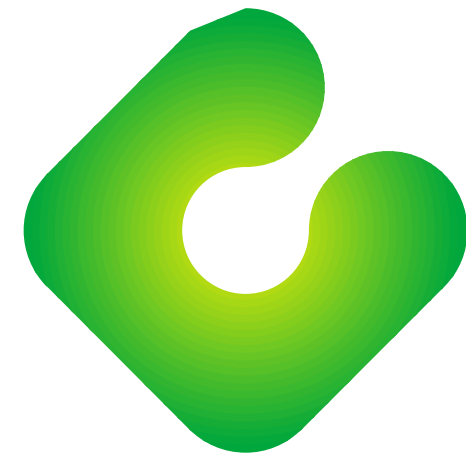


Updated Progress of R&D Projects

R&D Pipeline

Projects	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Approval	Commercial Right	
安能得® (ONIVYDE)	Pancreatic cancer (Gem based second line)	→						Milestone payment Royalty (Europe/Asia) Sales right in Taiwan
	Pancreatic cancer (Front line)	→				Fast Track		
	Small cell lung cancer (second line)	→				Fast Track		
	Investigator initiated trial	→						
Projects	Indication	Preclinical	Phase 1 / 2	Phase 2 / 3	Approval	Commercial Right		
Hensify® (PEP503)	Soft Tissue Sarcoma (RTx alone)	→ CE MARK						Grant back to Nanobiotix the Exclusive Right in Asia Pacific Region
	Head and Neck Cancer (RTx alone)	→				Fast Track		
	Head and Neck Cancer (RTx+Chemo)	→						
	Rectal Cancer (RTx+Chemo)	→						
Projects	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Approval	Commercial Right	
PEP07 (SOL-578)	Hema & Solid tumors	→					Global Right	

Sales Performance and Territories Status of Onivyde®



安能得
onivyde

Irinotecan liposome injection

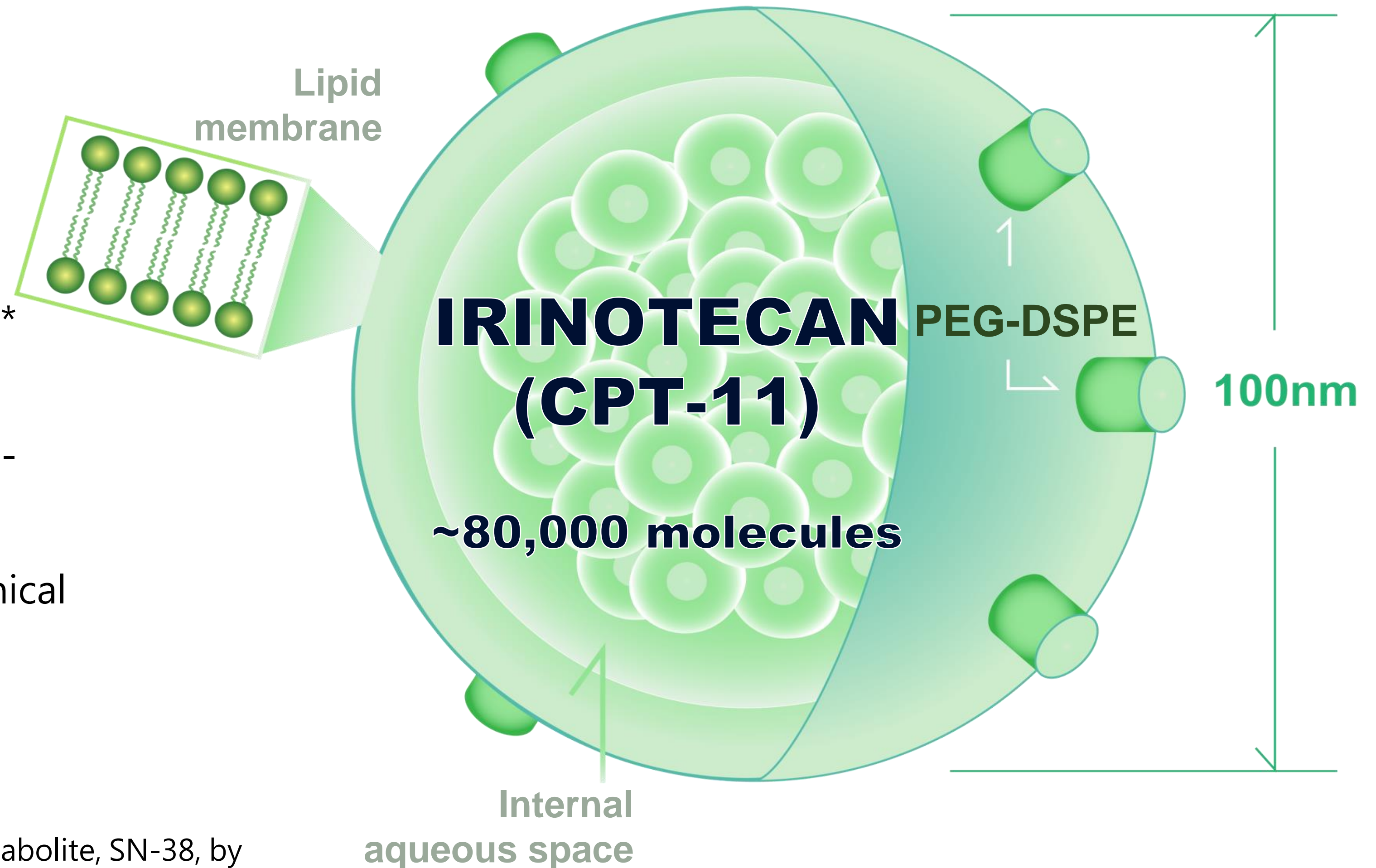
ONIVYDE is a liposome formulation of irinotecan

- Sustained release profile
- Preferential tumor accumulation (EPR effect)*
- Site-specific activation**
- First and only FDA-approved therapy in post-gemcitabine pancreatic cancer
- Category 1 evidence in NCCN and ESMO clinical practice guideline

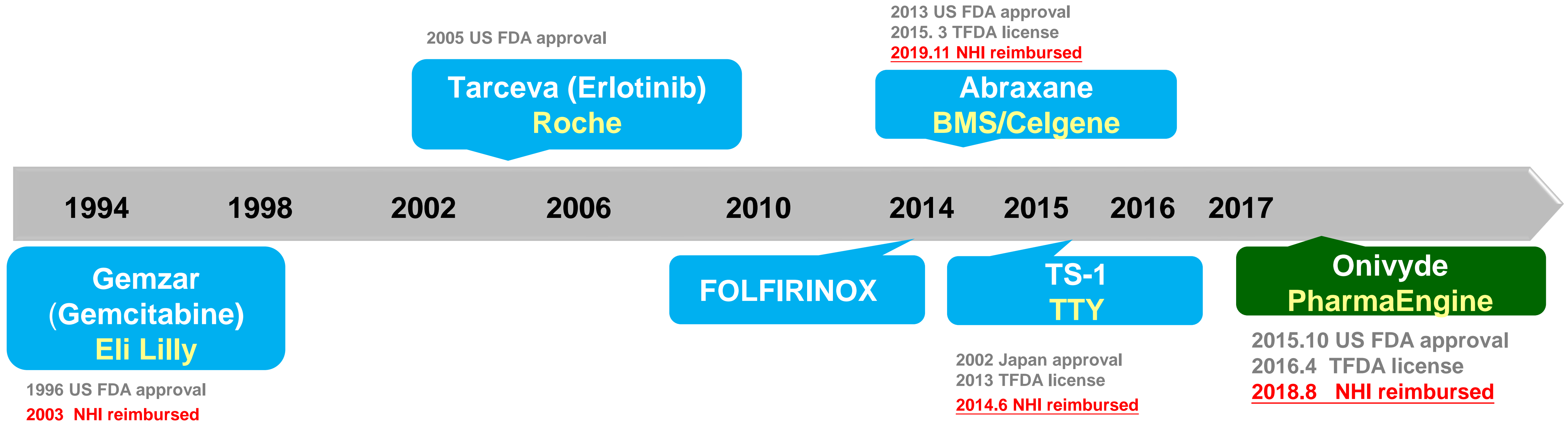
Note:

* Enhanced Permeability and Retention effect

** Irinotecan is converted into the 100 to 1000-fold active metabolite, SN-38, by enzymes around tumors.



Treatment in mPDAC in Taiwan



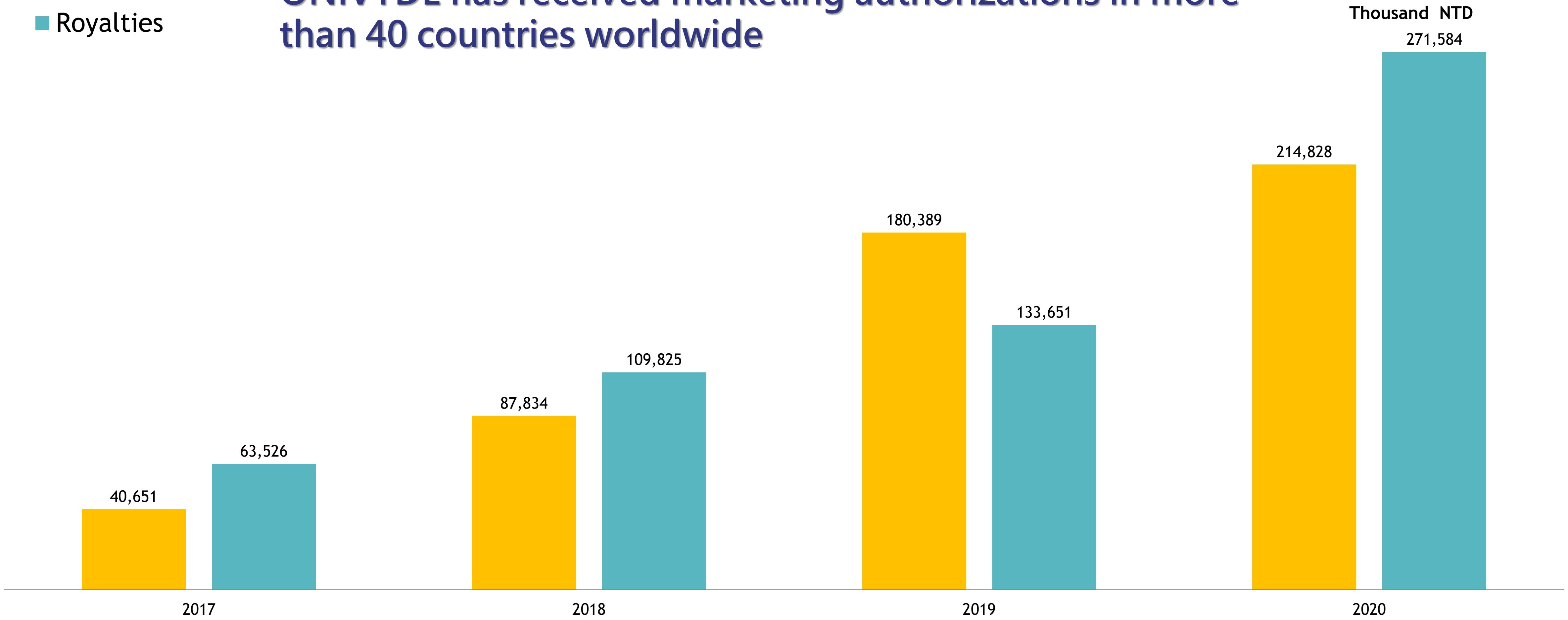
1L Most Commonly Prescribed Drugs in Taiwan		2L Most Commonly Prescribed Drugs in Taiwan	
Mono	<ul style="list-style-type: none"> Gemcitabine TS-1 	<ul style="list-style-type: none"> TS-1 Gemcitabine Others 	
2 Combo	<ul style="list-style-type: none"> gemcitabine + TS-1 gemcitabine + cisplatin gemcitabine + Abraxane gemcitabine + Tarceva Others 	<ul style="list-style-type: none"> gemcitabine + TS-1 Oxaliplatin + 5-FU/LV Onivyde + 5-FU/LV gemcitabine + Abraxane Others 	
3 Combo	<ul style="list-style-type: none"> gemcitabine + oxaliplatin + 5-FU FOLFIRINOX SLOG (gem. + oxaliplatin + Leucovorin(oral) + TS-1) 		

Revenue from Onivyde

- Taiwan Sales
- Royalties

ONIVYDE has received marketing authorizations in more than 40 countries worldwide

Thousand NTD
271,584



Sources of Revenue from Onivyde

Revenue	Terms	US\$ mn	Achieved
Upfront		10.0	✓
Development & Regulatory Milestone	Phase III 1 st patient in	5.0	✓
	Amend Agreement with MACK	7.0	✓
	NDA submission to US FDA	5.0	✓
	MAA submission to EMA	11.0	✓
	NDA submission to Korean MFDS	10.0	✓
	MAA approval	25.5	✓
	Marketing authorization by Korean MFDS	25.0	✓
	Launched and reimbursed by public insurance in three major EU countries	3.0	✓
	Others (Approval of different indications)	35.0	
Sales Milestone	Reach certain net sales in Europe and Asia	20.0	✓
		110.0	

Milestone Payments: \$121.5 mn out of \$266.5 mn achieved (\$145 mn to go)

*All development costs reimbursed by Ipsen.

Post GEM in Pancreatic Cancer Opportunity for Onivyde

ONIVYDE has received marketing authorizations in more than 40 countries worldwide
 USA (2015), Taiwan (2015), EMA (2016), Korea (2017), Australia (2016), Switzerland (2017), Japan (2020)

Post Gemcitabine Market Potential

Post GEM Opportunity for Onivyde	US	EU28	JP	TW
Pricing per vial (US\$)*	1,983	1,239	1,192	862
Treatment cost (US\$)*	52,632	32,890	31,642	22,881
Diagnosed incidence each year (pancreatic cancer pts)	46,000	76,000	22,000	2,200
Total eligible each year (pancreatic cancer pts)	16,000	25,800	6,600	800

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

Source: MACK conference call, Jan. 2016 ; Ipsen Investor Day Presentation, May 2017

R&D Pipeline

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PEP07 (SOL-578)	Hema & Solid tumors	→					Global Right	

PEP07(SOL-578) Development Strategy



Founded **2005**

Location Cambridge, UK

Type Privately Held

Focus Oncology, Drug Discovery, Medicinal Chemistry & Collaboration

Partnerships

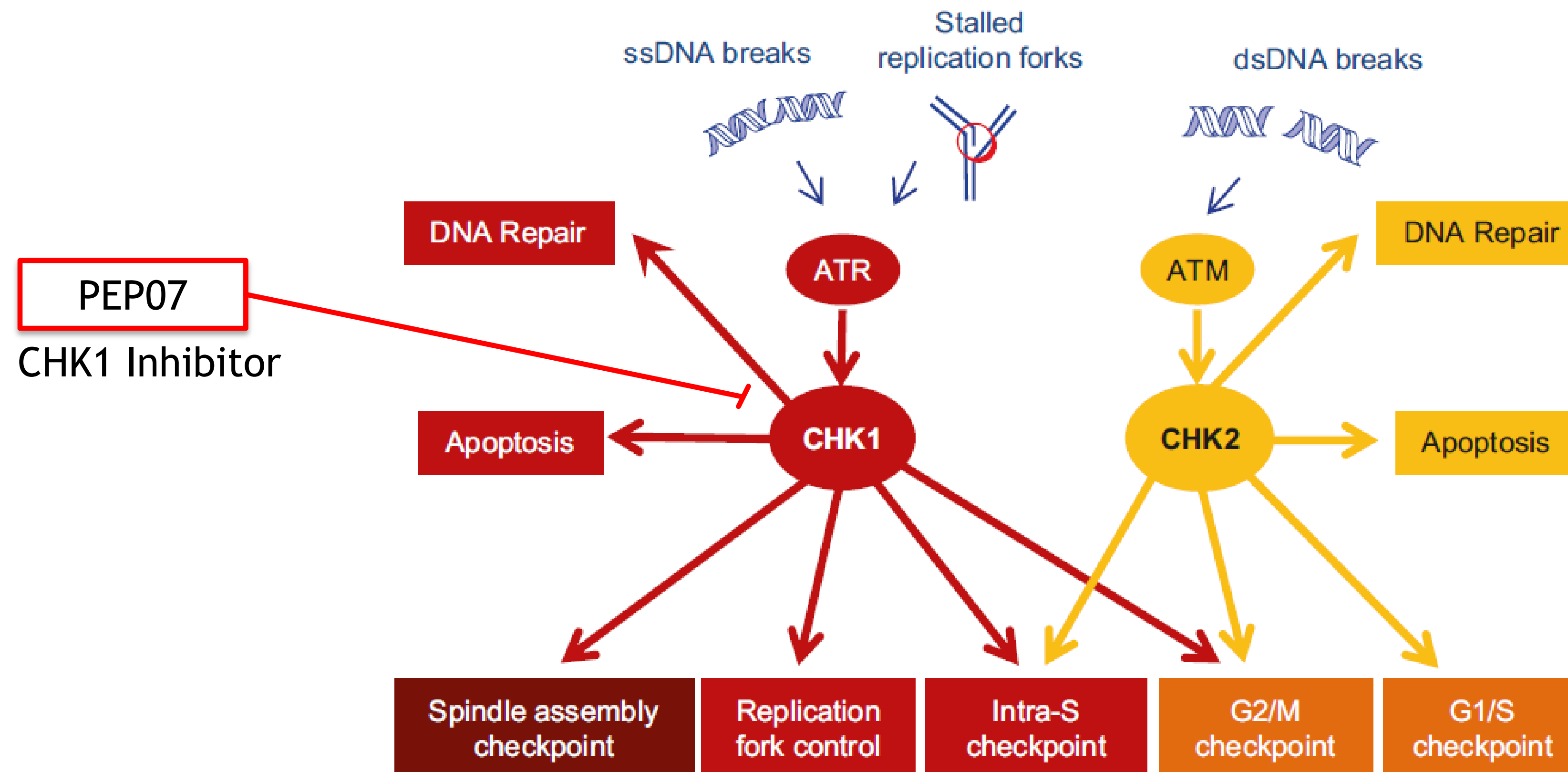


Robert Boyle
CEO & Board of Directors



Stuart Travers
COO & Board of Directors

Cell Cycle Checkpoints and DNA Damage Response (DDR)



Targeting the DNA Damage Response for Anti-Cancer Therapy, pp. 241-276, 2018

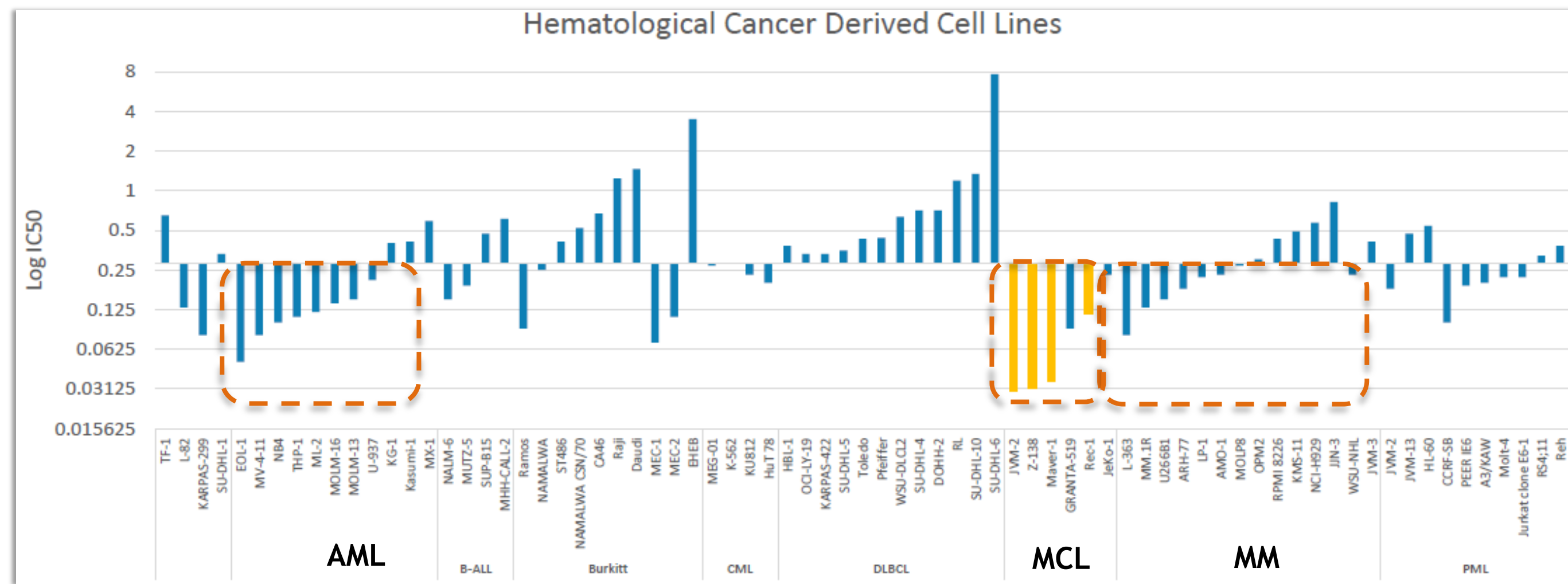
PEP07(SOL-578) - Best-in-Class Chk1 Inhibitor

- PEP07(SOL-578) is an oral inhibitor which is more potent, selective, specific than the competitors.

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

PEP07(SOL-578) Activities in Hematologic Malignancies (AML & MCL)

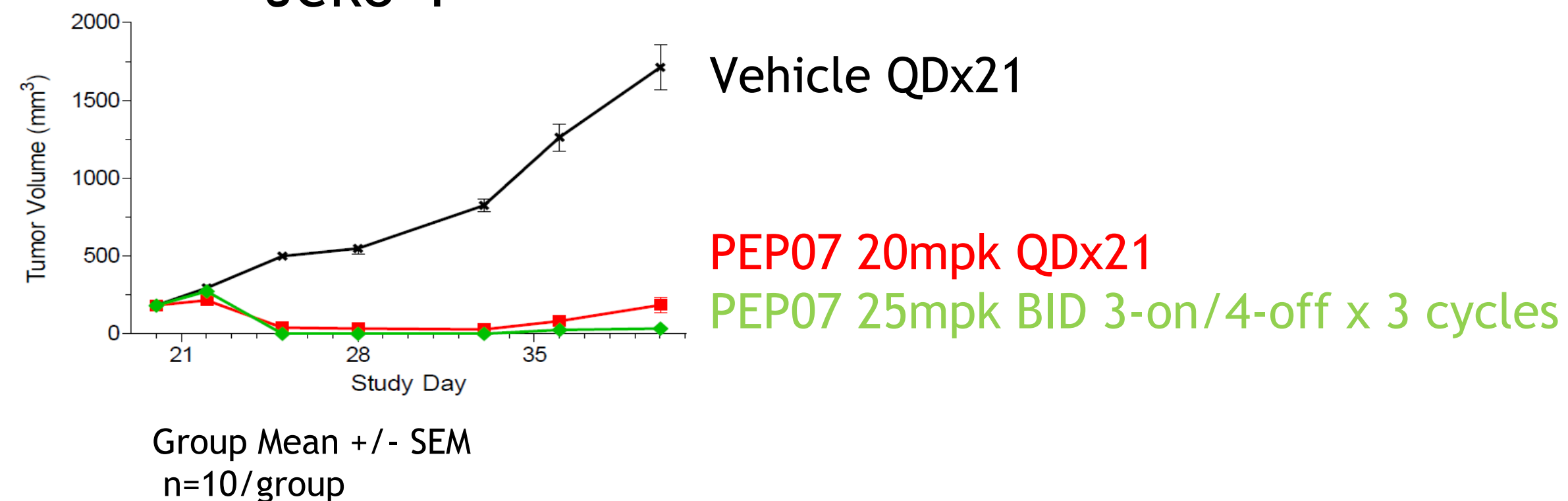


Enzyme selectivity of PEP07

Hit	Selectivity Kinase/Chk1 IC50	Cellular IC50 (nM)
Chk1	1	1 (HT-29 cells)
Rsk3	36	TBD
Flt3	32	> 5000 (MV-411 cells)
Ret	69	5000 (TT cells)
Rsk4	74	TBD
Map4k4/Hgk	209	TBD
Rsk2	72	TBD
Rsk1	134	TBD
Chk2	1405	TBD

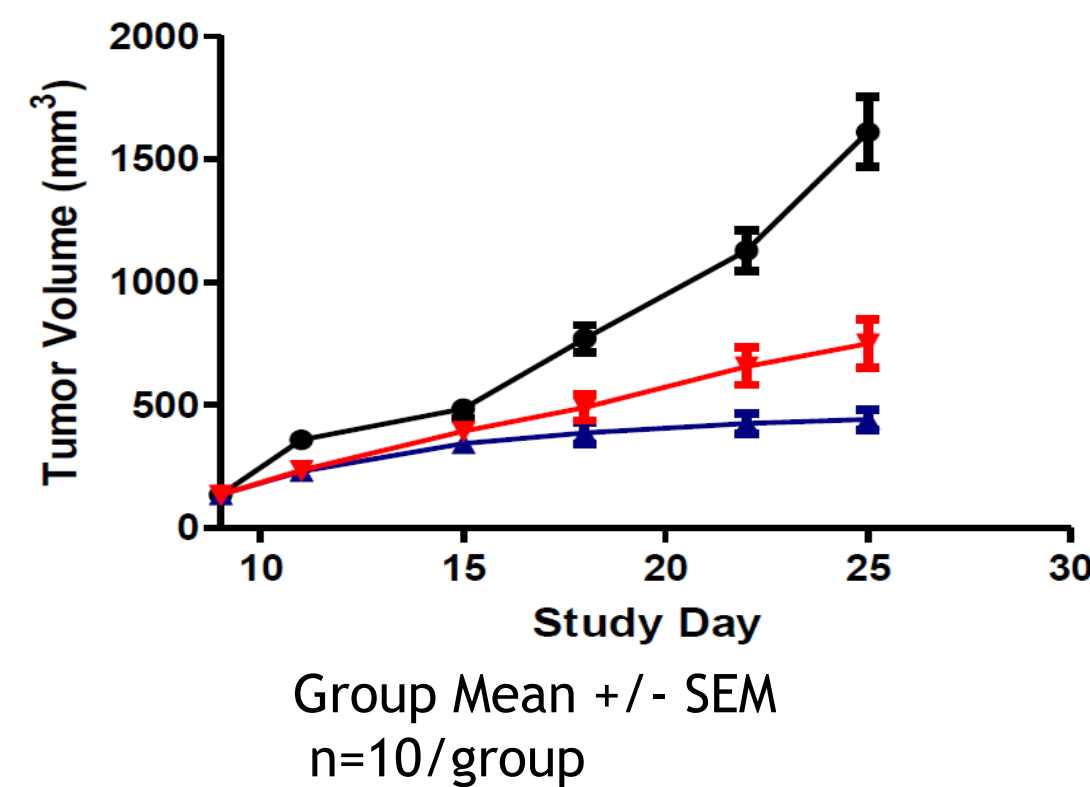
Mantle Cell Lymphoma (MCL):

Jeko-1



Acute myeloid leukemia (AML):

MV-411 Tumor Growth



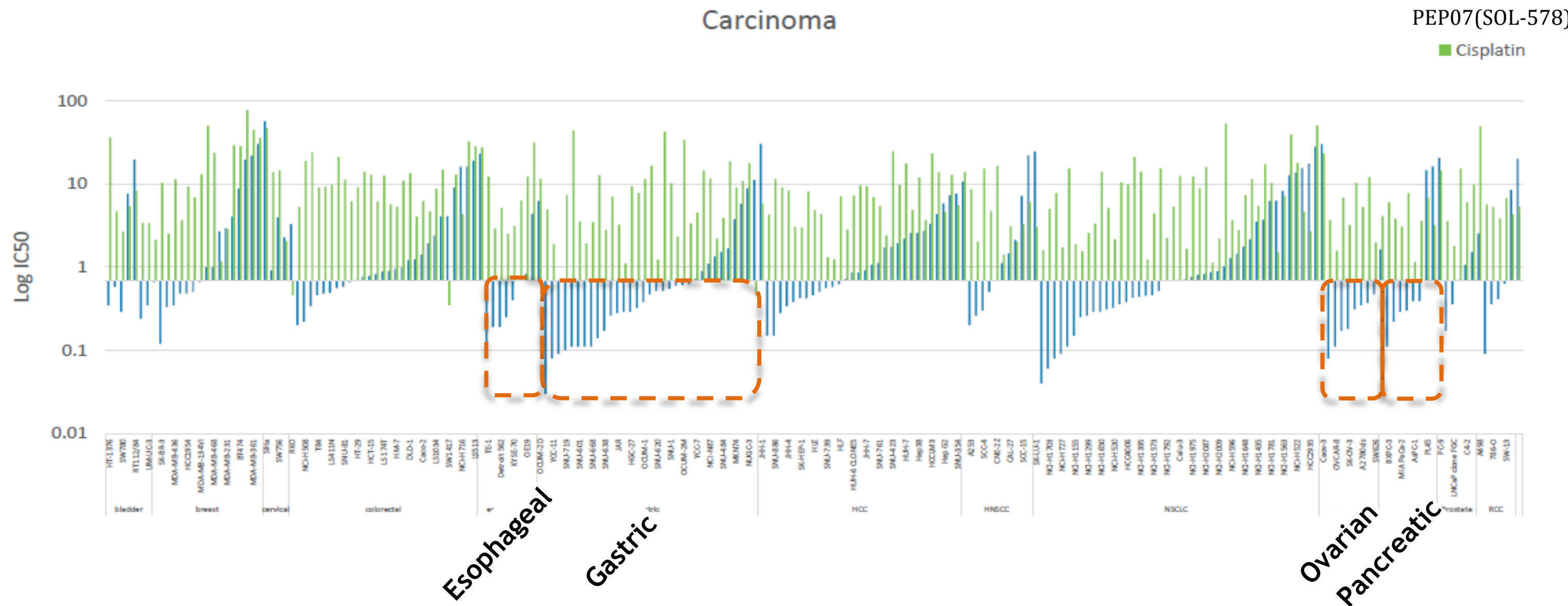
Vehicle BID 3-on/4-off x 3 cycles

PEP07 25mpk BID 3-on/4-off x 3 cycles

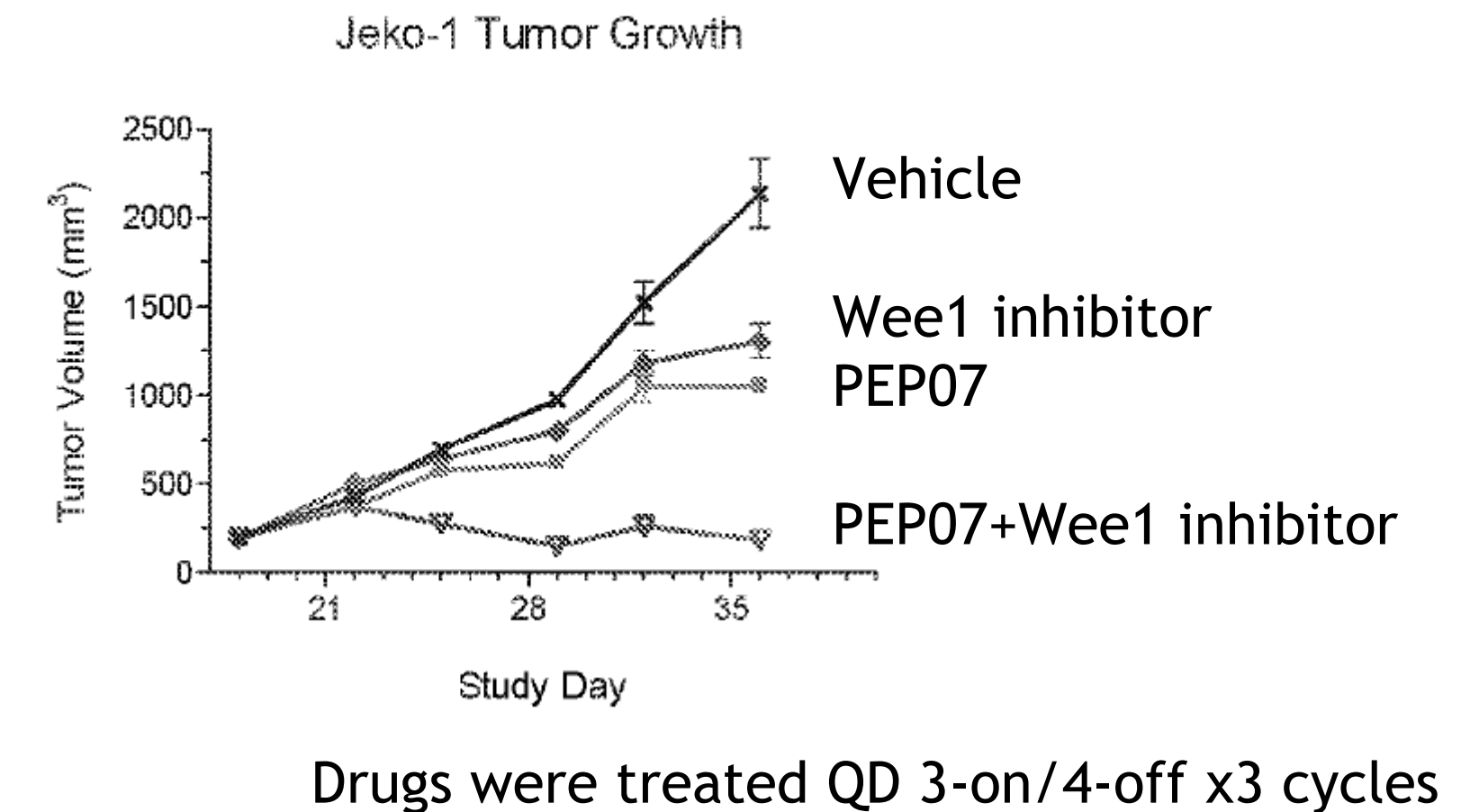
PEP07 50mpk BID 3-on/4-off x 3 cycles

PEP07(SOL-578) Mono and Combo Activities

Mono treatment



In vivo Combo treatment



In vitro Combo treatment

SOC agents	Indication	Cell line
Ara-C	AML	MV4-11 / THP-1
Cisplatin	Uterus	MFE-296
Gemcitabine	NSCLC	NCI-H1703
5-Fu	Esophagus	KYSE-270
5-Fu	Stomach	SNU-16, SNU-5
TMZ	Brain	IMR-32
Topotecan	SCLC	NCI-H1048
SN-38	SCLC	NCI-H1048
Paclitaxel	Ovary	Caov-3
Sorafenib	RCC, Liver	A498, SNU-398

CI < 0.9 (synergism):

MV4-11/Cytarabine; NCI-H1703/Gemcitabine; KYSE-270/5-Fu; THP-1/Cytarabine

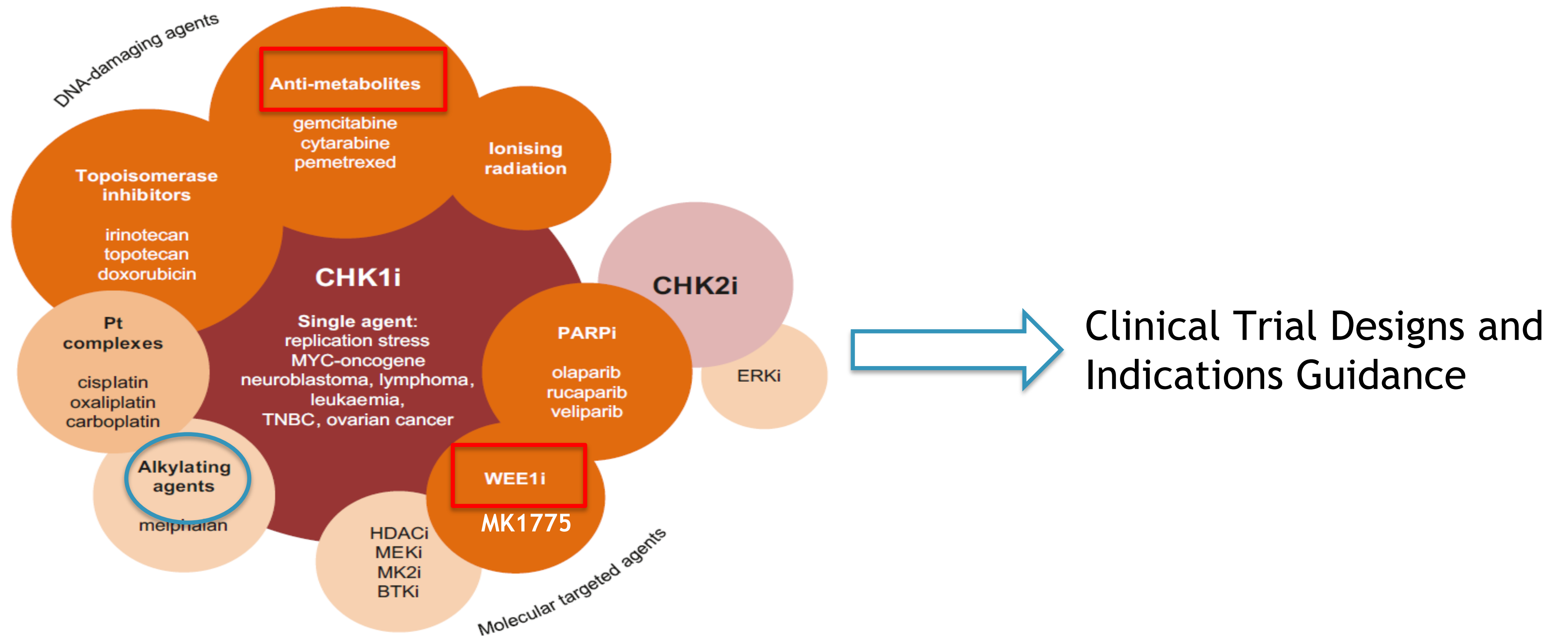
CI=0.9-1.1 (additivity):

SNU-5/5-Fu; SNU-16/5-Fu; A498/Sorafenib; IMR32/Temozolamide

CI > 1.1 (antagonism):

Caov-3/Paclitaxel; NCI-H1048/Topotecan; MFE-296/Cisplatin; SNU-398/Sorafenib; NCI-H1048/SN-38

PEP07 (SOL-578) Combination Observed Effects



: Synergistic effect verified in PEP07
 : Additive effect observed in PEP07

PEP07 (SOL-578) Early Clinical Development Plan

P1a monotherapy, dose escalation/expansion in AML, MCL, and other hema Ca, SAD/MAD

P1b Combo, dose escalation/expansion in AML *

P1b Combo, dose escalation/expansion in MCL

P1b Combo, dose escalation/expansion in other Hema Ca *

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



4/09/'21

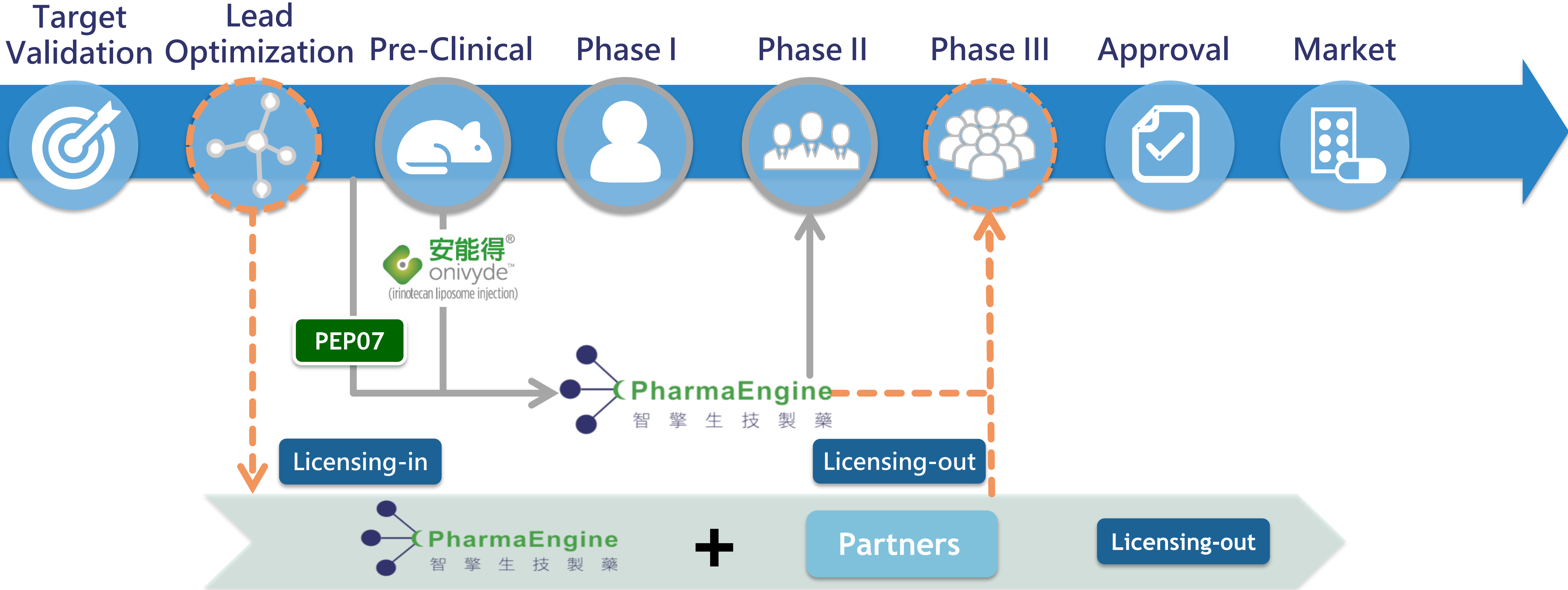
New Target Completion Date (6/30/'21)

Original Target Completion Date (11/30/'21)

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

- Preclinical : Progress ahead of original plan
- CMC : On schedule
- Toxicology : Target initiation 2021Q3
- IND Prep. & Sub. : Target completion 2022Q2

Virtual Pharmaceutical Company Business Model





Q&A