



# 投資人說明會4162.TWO

2021年08月10日

## 免責聲明

- 本簡報中所提及之預測性資訊包括營運展望、財務狀況以及業務預測等內容，乃是建立在本公司從內部與外部來源所取得的資訊基礎。
- 本公司未來實際所可能發生的營運結果、財務狀況以及業務成果，可能與這些明示或暗示的預測性資訊有所差異。其原因可能來自於各種因素，包括市場風險、市場需求，以及本公司持續推出新藥產品專案等因素。
- 本簡報中對未來的展望，反應本公司截至目前為止對於未來的看法。對於這些看法，未來若有任何變更或調整時，本公司將盡力隨時再度提醒或更新。

# 目 錄

1 2021年上半年企業亮點

2 2021年上半年營運概況

3 研發專案進度

安能得<sup>®</sup>(ONIVYDE<sup>®</sup>)銷售狀況及市場潛能

PEP07(SOL-578)研發現況

4 2021年下半年營運展望

5 Q&A

# 1 2021年上半年企業亮點

## 生技人才陸續加入 智擎研發團隊



總經理  
王宏仁 博士

美國麻省理工學院  
Materials Science and Engineering

★投身製藥領域超過15年

- ◆ 專精藉由藥物評估、藥物動力學及醫療器材模型建構、特殊製劑設計來研發新型藥物傳輸/醫療器材的組合。
- ◆ 美國生技公司從事藥物開發，從臨床前到NDA/MAA申請的新藥開發。  
Transform Pharmaceuticals公司  
Vertex Pharmaceuticals公司  
Microchips Biotech公司  
Proteostasis Therapeutics公司
- ◆ 曾參與等 Incivek、Kalydeco 和Orkambi等三個FDA / EMA批准上市產品的新藥開發。

## 國際專家顧問團隊

- ◆ Hagop Youssoufian, MSC, MD, former Chief Medical Officer at BIND Therapeutics
- ◆ Dan Belmont, Ph.D. in Chemistry, former Vice President, Head of Pharmaceutical Development at Vertex Pharmaceuticals, President of Full Sails Consulting LLC.
- ◆ Steven Witowski, Ph.D. in Analytical Chemistry, Principal of Witowski CMC Consulting, LLC
- ◆ Alex Vo, Ph.D. in Biochemistry, Executive Director, DMPK, Preclinical Science, Atea Pharmaceuticals

## 穩定的現金流入

- ◆ ONIVYDE於歐亞地區之2020年度淨銷售額達到第一期銷售里程碑，智擎公司收取美金2千萬元的銷售里程碑授權金(認列於2020年度)。
- ◆ 現金及約當現金暨按攤銷後成本衡量之金融資產-流動(三個月以上之定存)成長幅度為21%  
2021Q2新台幣41億元  
2020Q4新台幣34億元

## PEP07進度合乎預期

- ◆ 截至目前為止，本公司的PEP07相關前臨床試驗進度符合預期。

## 2 2021年上半年營運概況

# 2021年上半年營業概況

單位:新台幣仟元

	2021Q2	2020Q2	Amount Change	% Change
營業收入	273,908	173,879	100,029	58
營業成本	19,238	18,207	1,031	6
營業毛利	254,670	155,672	98,998	64
推銷費用	15,501	12,029	3,472	29
管理費用	39,944	29,238	10,706	37
研究發展費用	70,519	47,148	23,371	50
營業費用	125,964	88,415	37,549	42
營業利益	128,706	67,257	61,449	91
營業外收入(支出)	174,554	5,784	168,770	2,918
稅前淨利	303,260	73,041	230,219	315
所得稅費用	61,913	9,835	52,078	530
本期淨利	241,347	63,206	178,141	282
基本每股盈餘(元)	1.66	0.43	1.23	286

註:營業外收入增加主要係收取PEP503的補償金,美金6.5M(NTD182百萬)



# 安能得營收成長趨勢

單位: 新台幣仟元

項目	年份	2017年度	2018年度	2019年度	2020年度	2021年上半年 (較2020年同期成長率)
台灣銷貨收入		40,651	87,384	180,389	214,828	112,521(8%)
歐亞銷售權利金收入		63,526	109,825	133,651	271,584	161,387(131%)
里程碑授權金收入		749,500	96,221	0	569,600	0
合計		<u>853,677</u>	<u>293,430</u>	<u>314,040</u>	<u>1,056,012</u>	<u>273,908(58%)</u>

3

## 研發專案進度

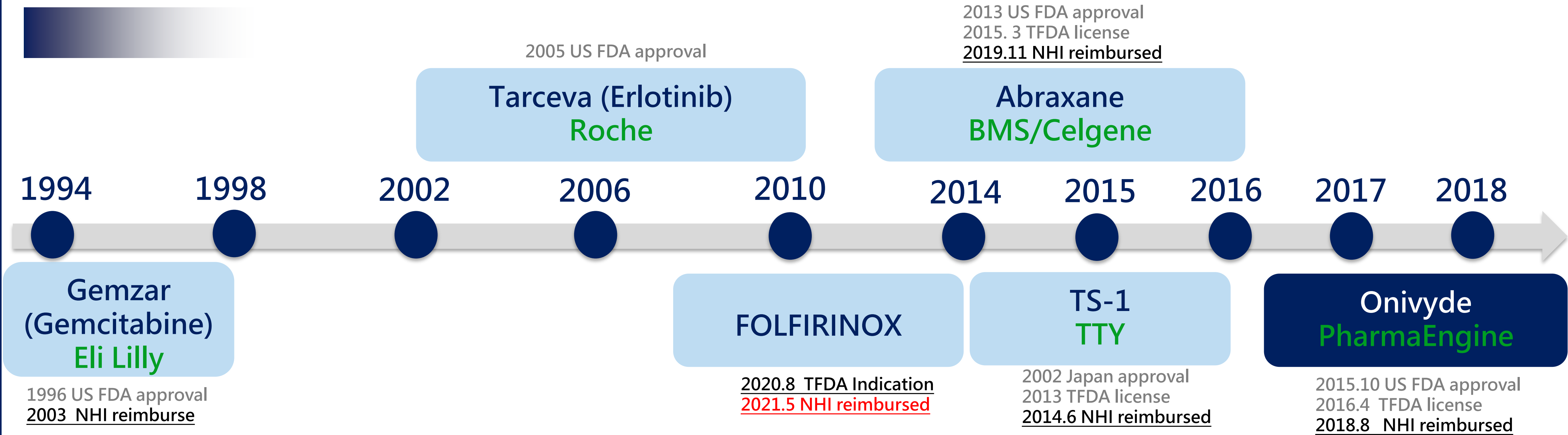
# 研發專案進度

產品	適應症	前臨床	臨床一期	臨床二期	臨床三期	核准	商業權利	
安能得® (PEP02)	胰腺癌 (二線)						已核准	里程碑授權金(歐洲/亞洲) 權利金(歐洲/亞洲) 台灣銷售
	胰腺癌 (一線)					Fast Track		
	小細胞肺癌 (二線)					Fast Track		
	研究者發起臨床試驗案							
產品	適應症	前臨床	臨床一/二期	臨床二/三期	核准	商業權利		
Hensify® (PEP503)	軟組織肉瘤 (放射線治療)						CE MARK	雙方合意終止該專案在 亞太地區的授權合作契約
	頭頸癌 (放射線治療)					Fast Track		
	頭頸癌 (放射線治療+化療)							
	直腸癌 (放射線治療+化療)							
產品	適應症	前臨床	臨床一期	臨床二期	臨床三期	核准	商業權利	
PEP07(SOL-578)	血液及固體腫瘤						全球	

**安能得® (ONIVYDE®)**

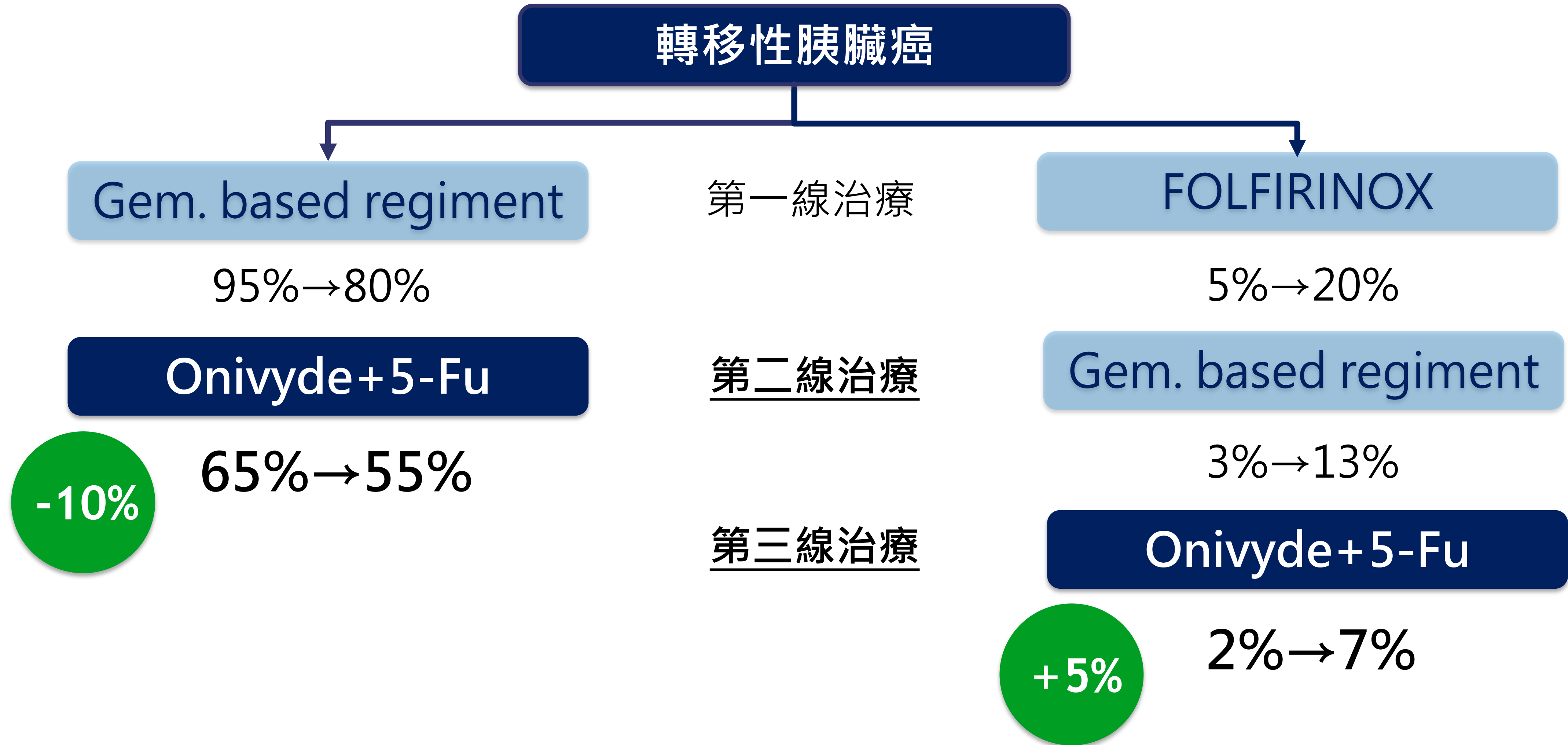
**銷售狀況及市場潛能**

# 胰臟癌在台灣的治疗進展



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

# 轉移性胰臟癌治療台灣市場分析

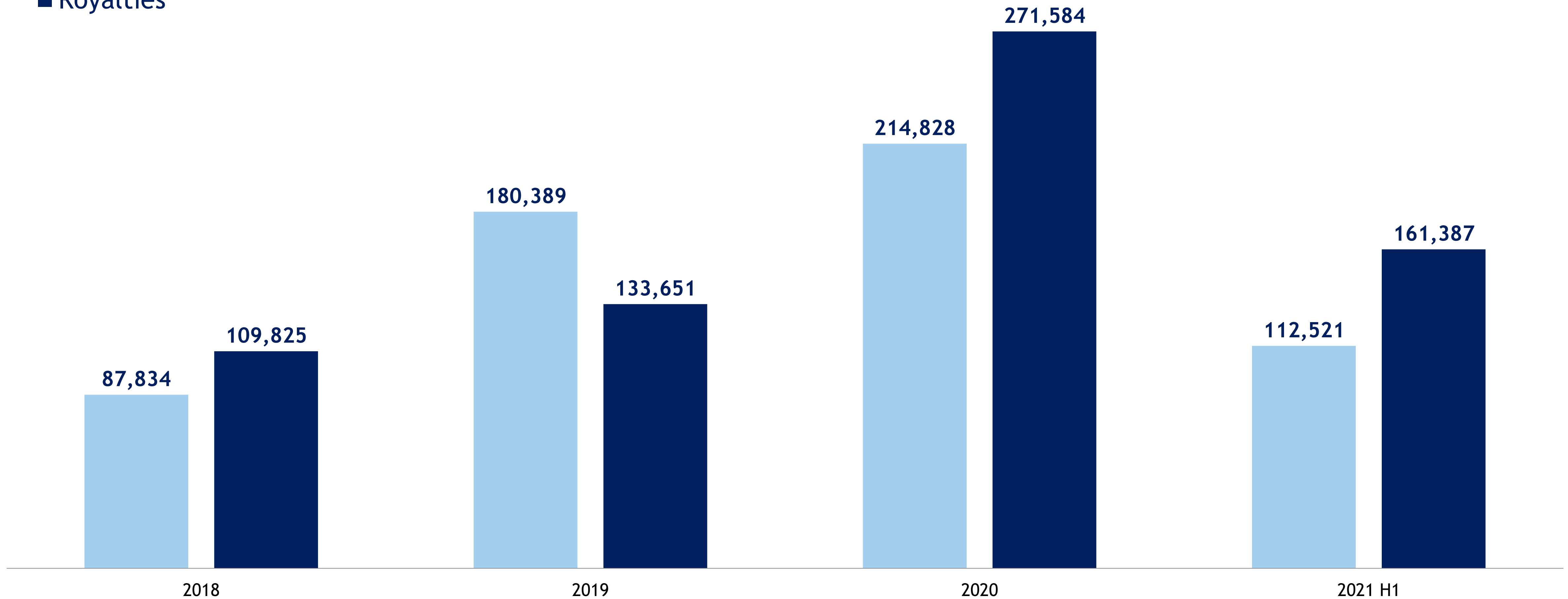


# 安能得營業收入及權利金收入

安能得已在全球40多個國家上市

Thousand NTD

■ Taiwan Sales  
■ Royalties



# PEP07 (SOL-578)研發現況





# Sentinel

ONCOLOGY

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

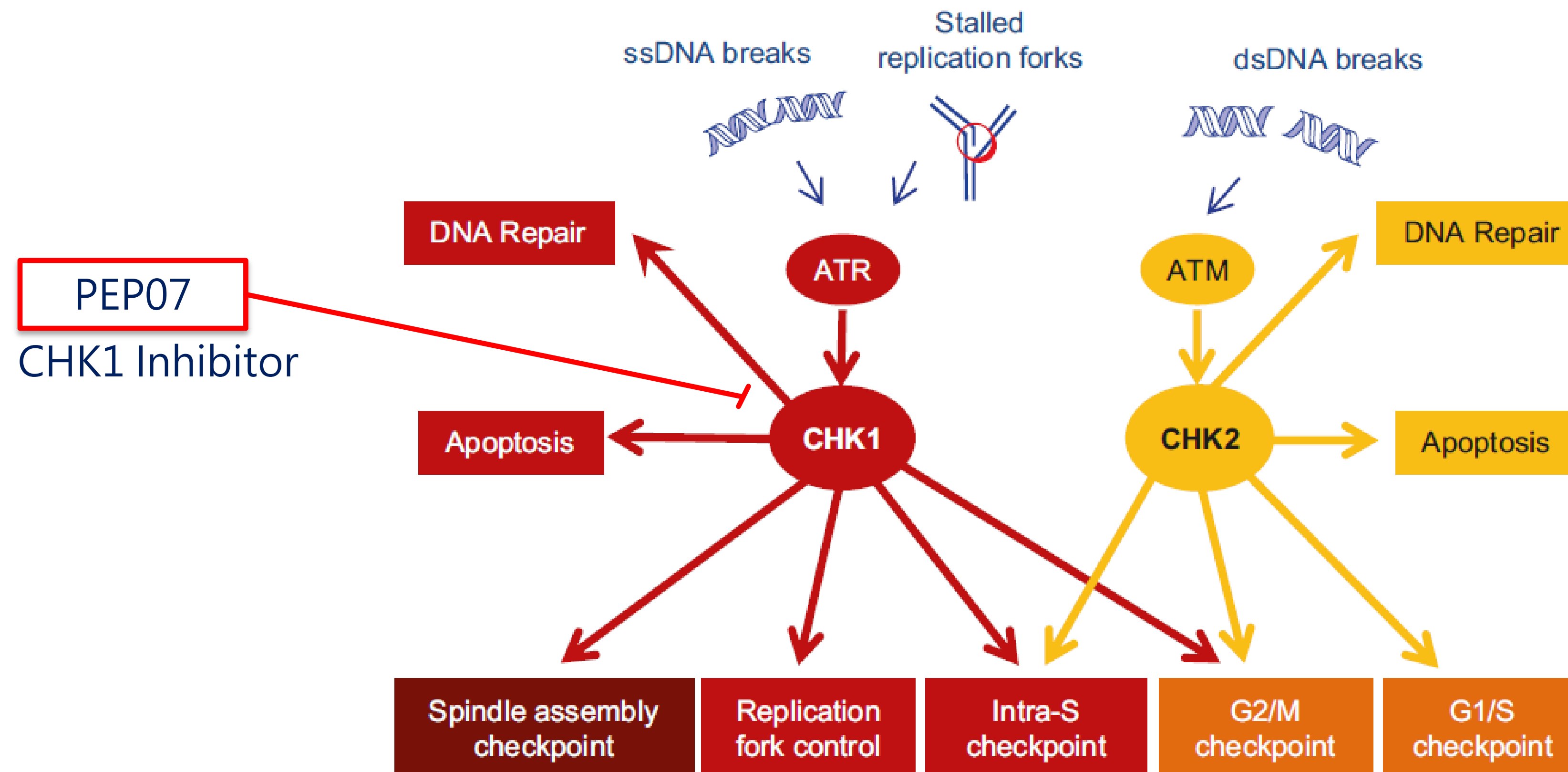


**Robert Boyle**  
CEO & Board of Directors



**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*

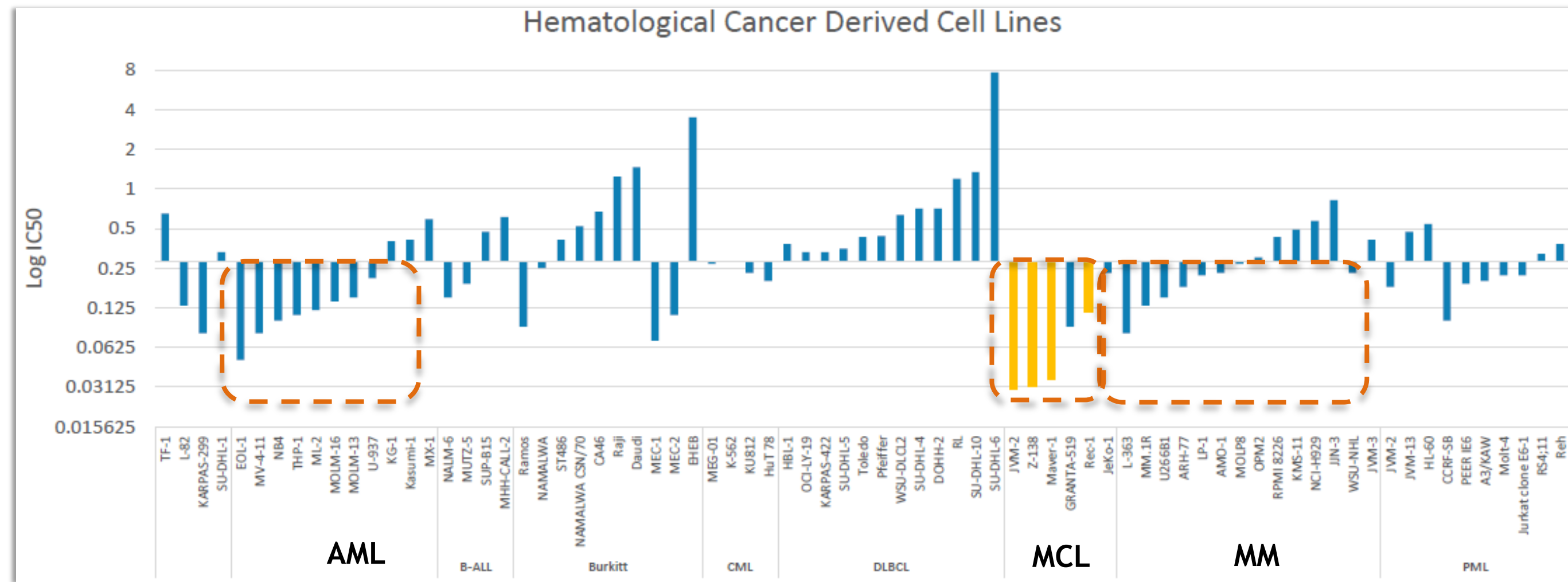
# PEP07(SOL-578) - Best-in-Class Chk1 Inhibitor

- 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	●	●	●	●
<b>PEI/Sentinel PEP07/SOL-578</b>	●	●	●	●

● Excellent
● Good
● Fair
● Poor
● Unknown

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

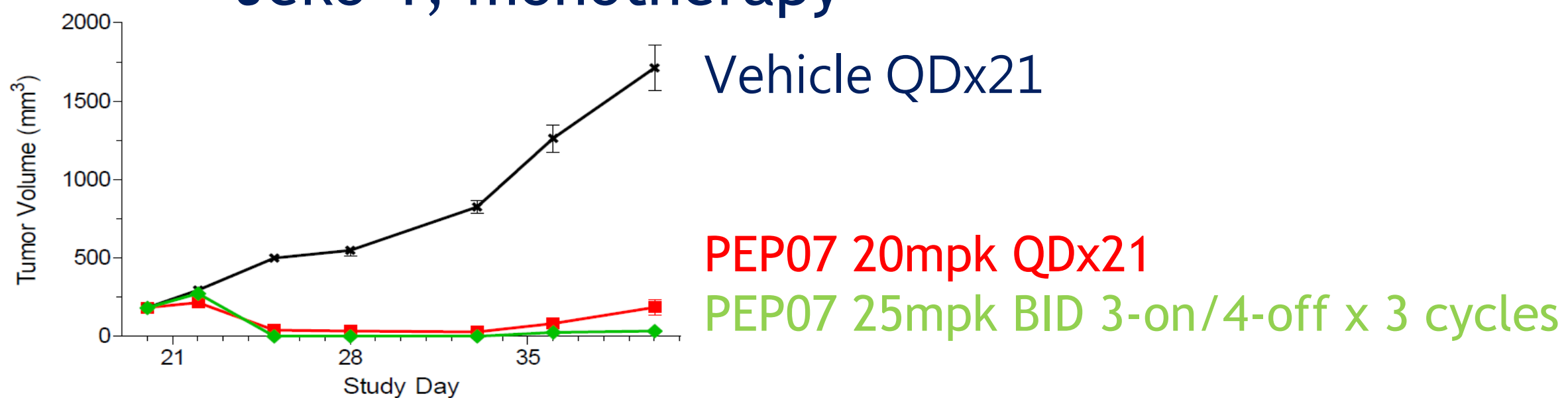


## Enzyme selectivity of PEP07

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

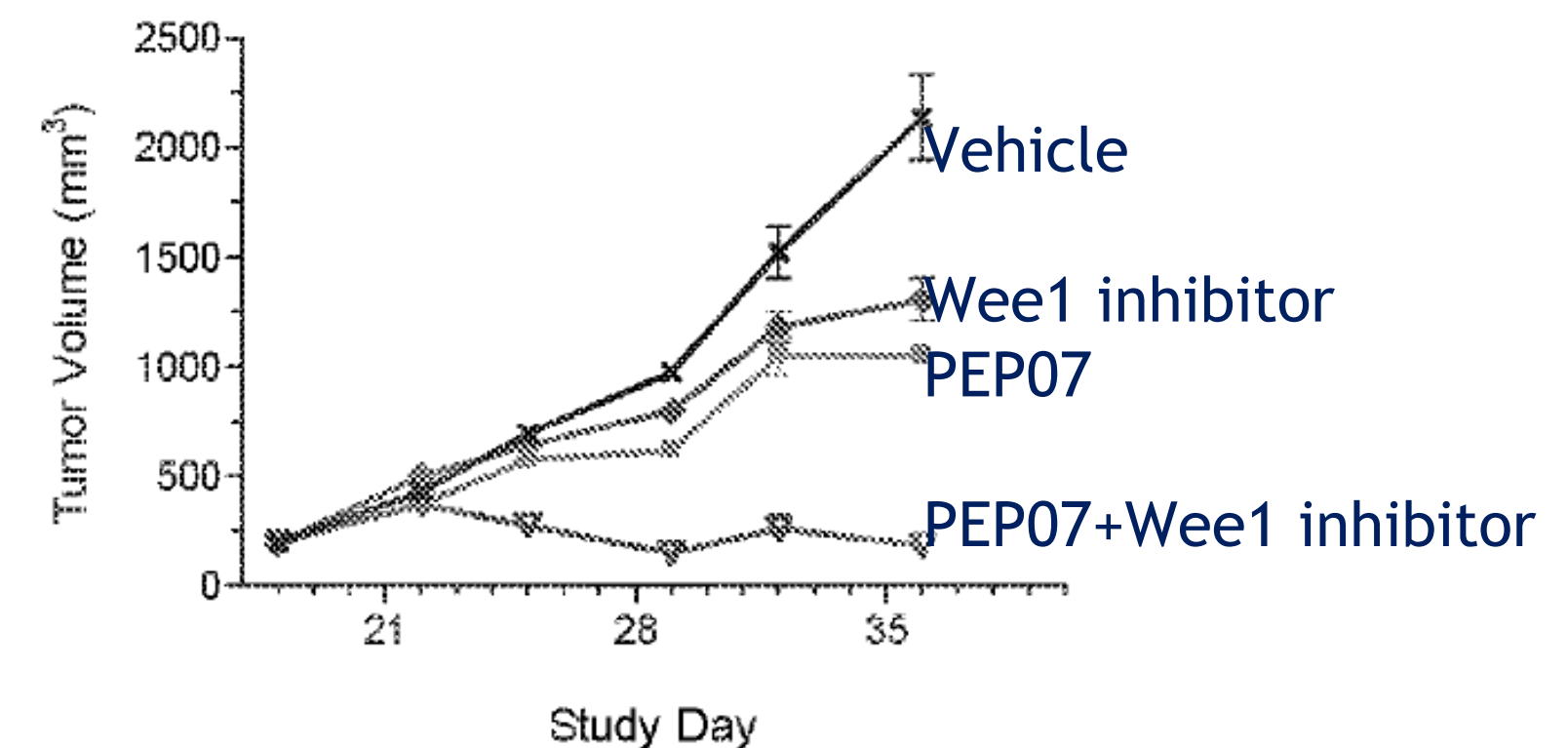
## Mantle Cell Lymphoma (MCL) :

### Jeko-1, monotherapy



Group Mean +/- SEM  
n=10/group

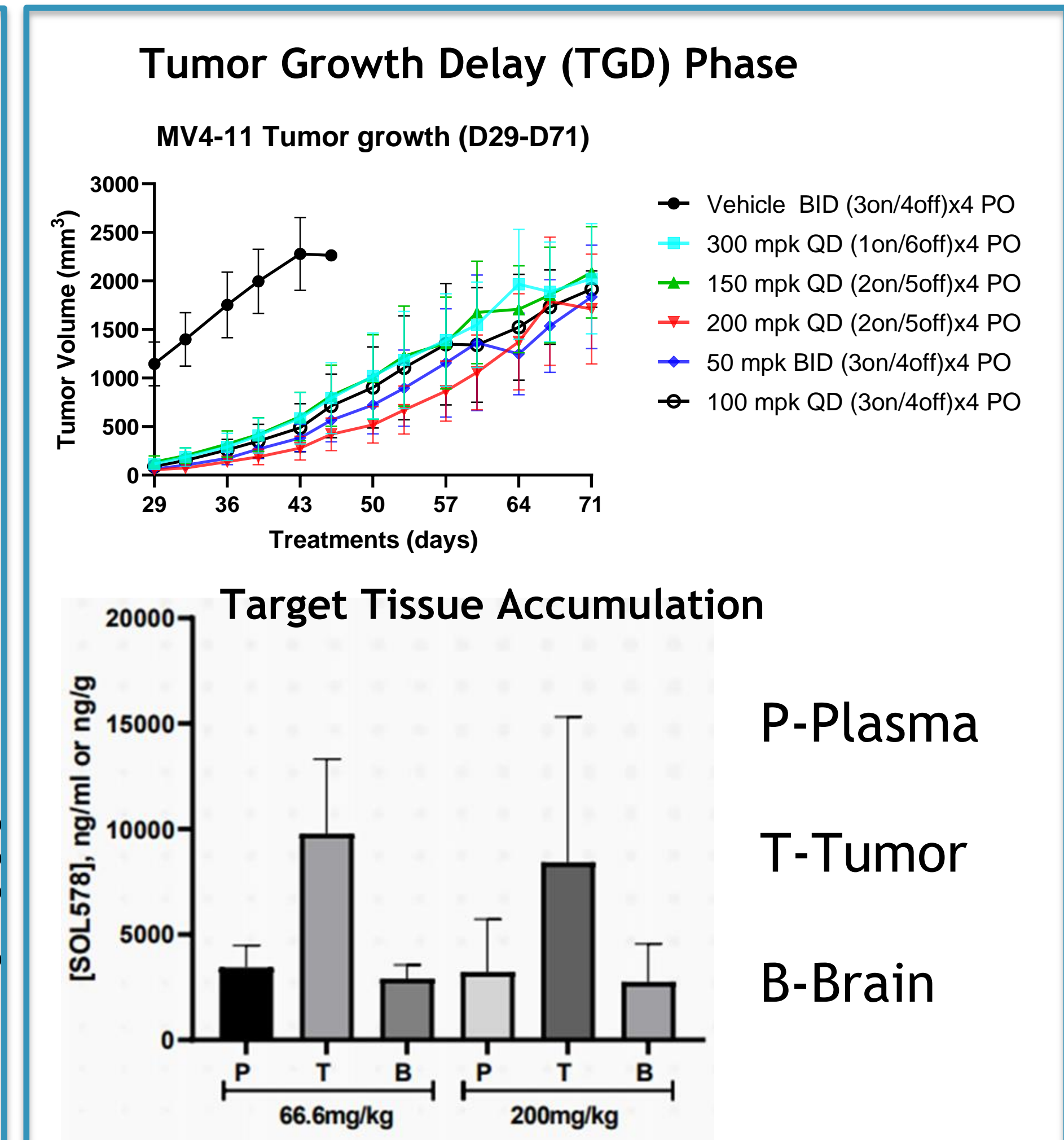
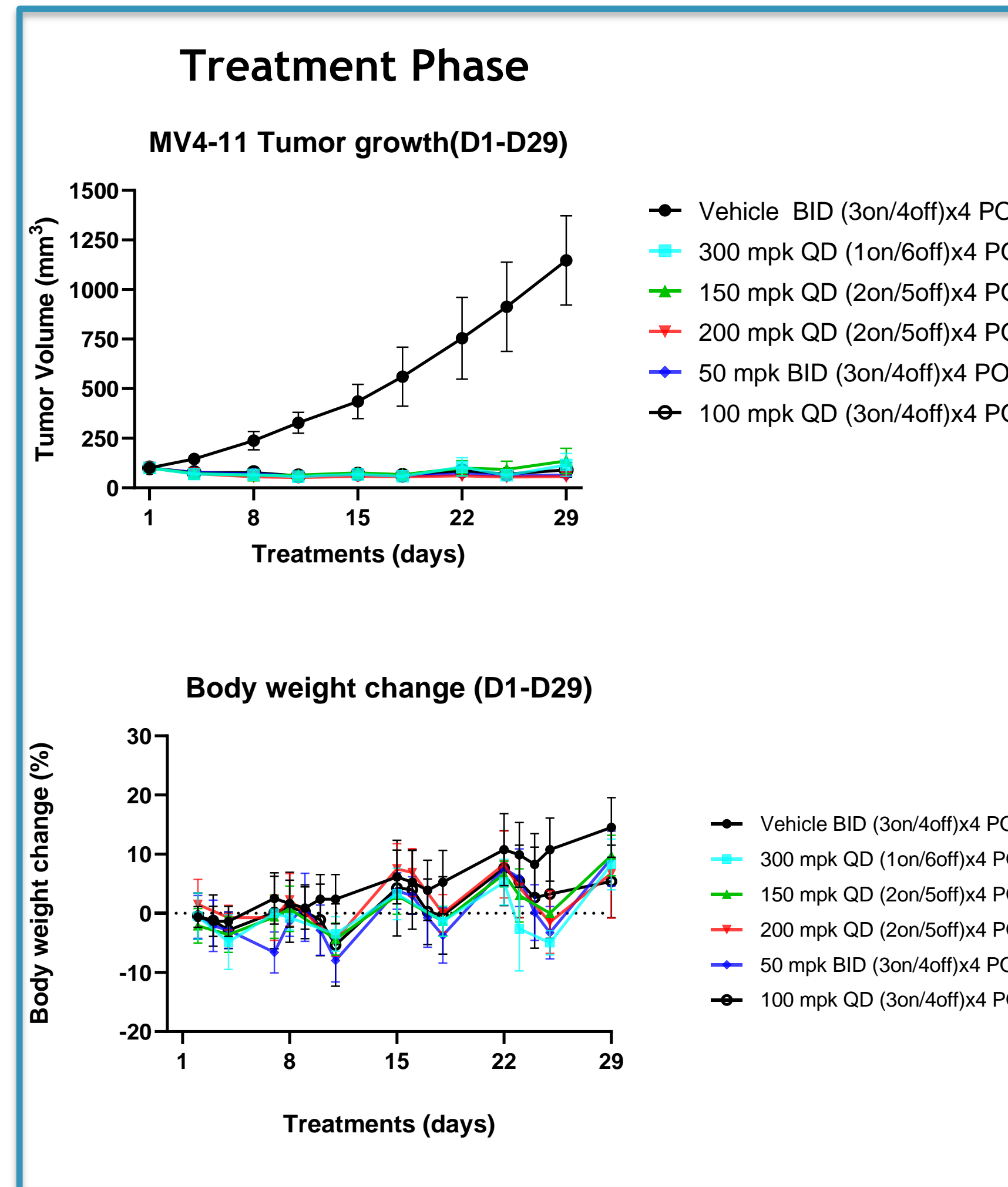
## Jeko-1, combination therapy



Drugs were treated QD 3-on/4-off x3 cycles

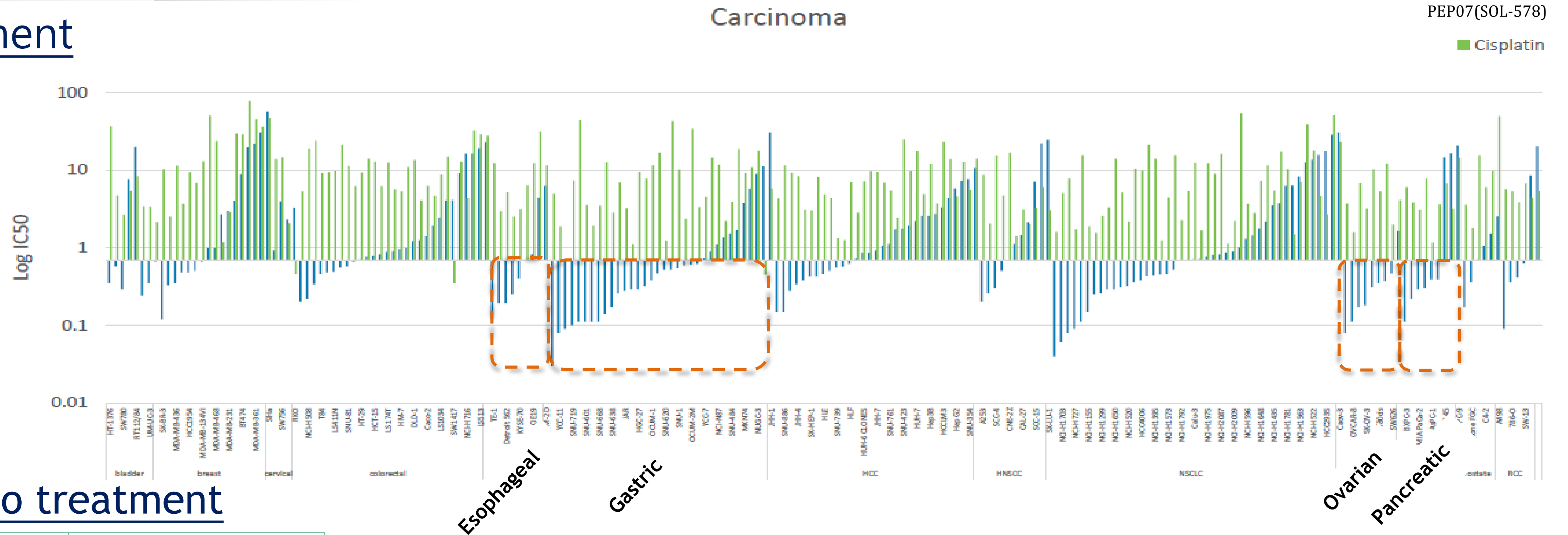
# PEP07 (SOL-578) Produces the Significant Single Agent Antitumor Activity and Tumor/Brain Penetration

- PEP07 showed complete inhibition of tumor growth during dosing (>90% TGI), with grow back following treatment end
- Interrogating the intermittent dosing schedule show no difference between schedules with the same weekly dose
- Body weights drop on dosing but quickly recover
- **2-on/5-off** schedule showed best TGD and selected for combination studies
- Target tissue accumulation:  
**Brain**/Plasma ratio: 0.89-0.92  
**Tumor**/Plasma ratio: 2.81-2.59



# PEP07 (SOL-578) Mono and Combo Activities

## Mono 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

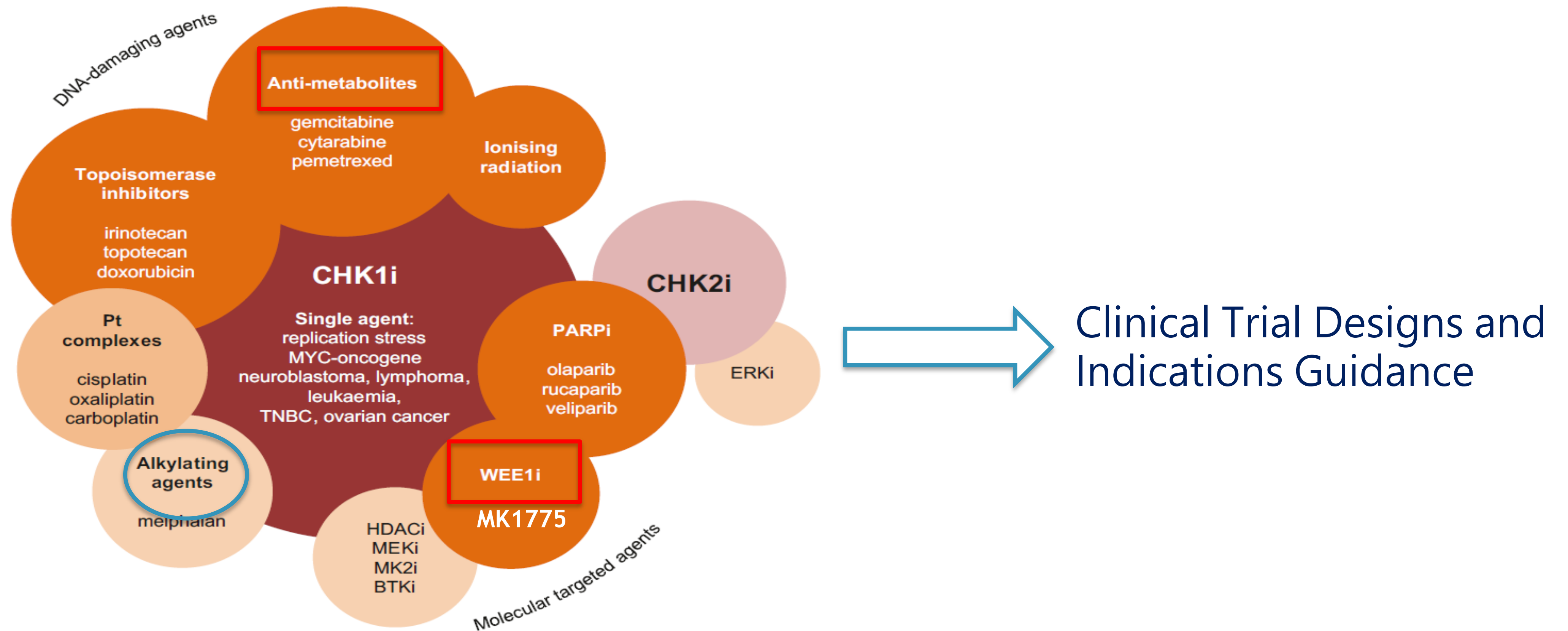
**CI=0.9-1.1 (additivity):**

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, other NHLs, 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 other NHLs ★
- 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
Preclinical Development	[Active]																	
CMC Development	[Active]																	
Toxicology Development							[Active]	[Active]	[Active]	[Active]	[Active]	[Active]	[Active]	[Active]	[Active]	[Active]	[Active]	[Active]
IND Preparation/ Submission													[Active]	[Active]	[Active]	[Active]	[Active]	[Active]

August of 2021

### Preclinical

On schedule, *in vivo* combination efficacy study is currently ongoing

### CMC

On schedule, non-GMP scale escalating production is currently ongoing

### Toxicology

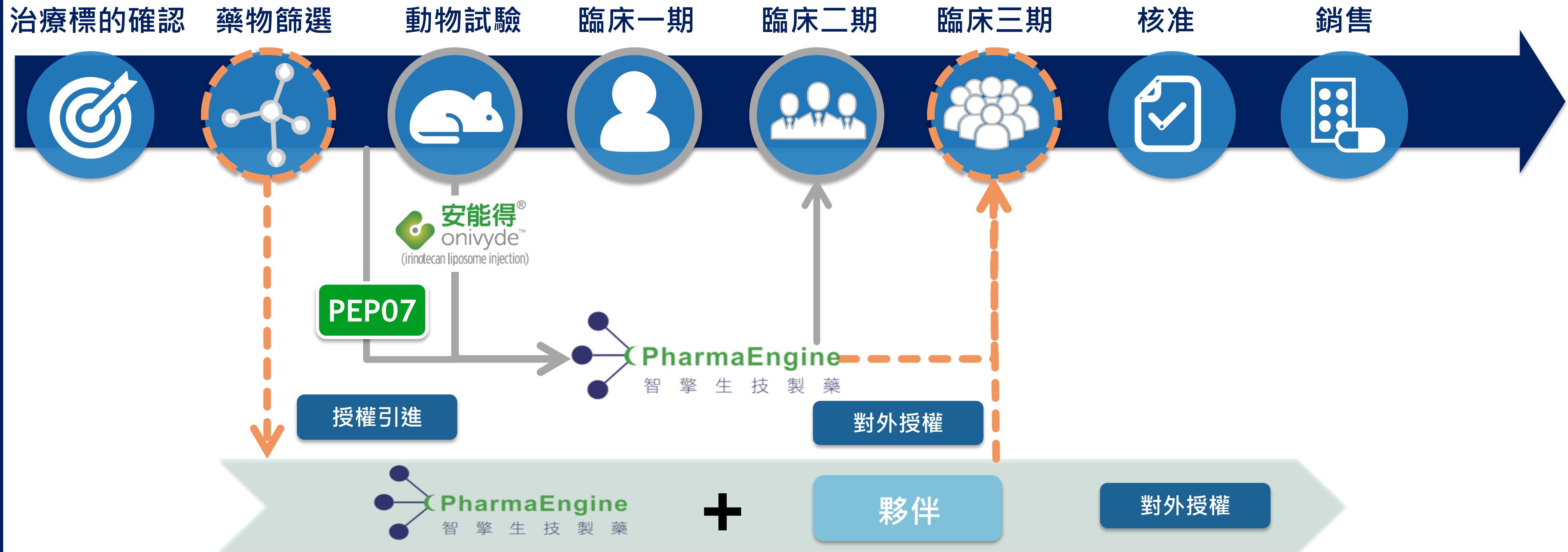
On schedule, completed the CRO evaluation and the plan is initiated in this July IND Prep. & Sub.

### IND Prep. & Sub.

Target completion 2022Q2

# 4 2021年下半年營運展望

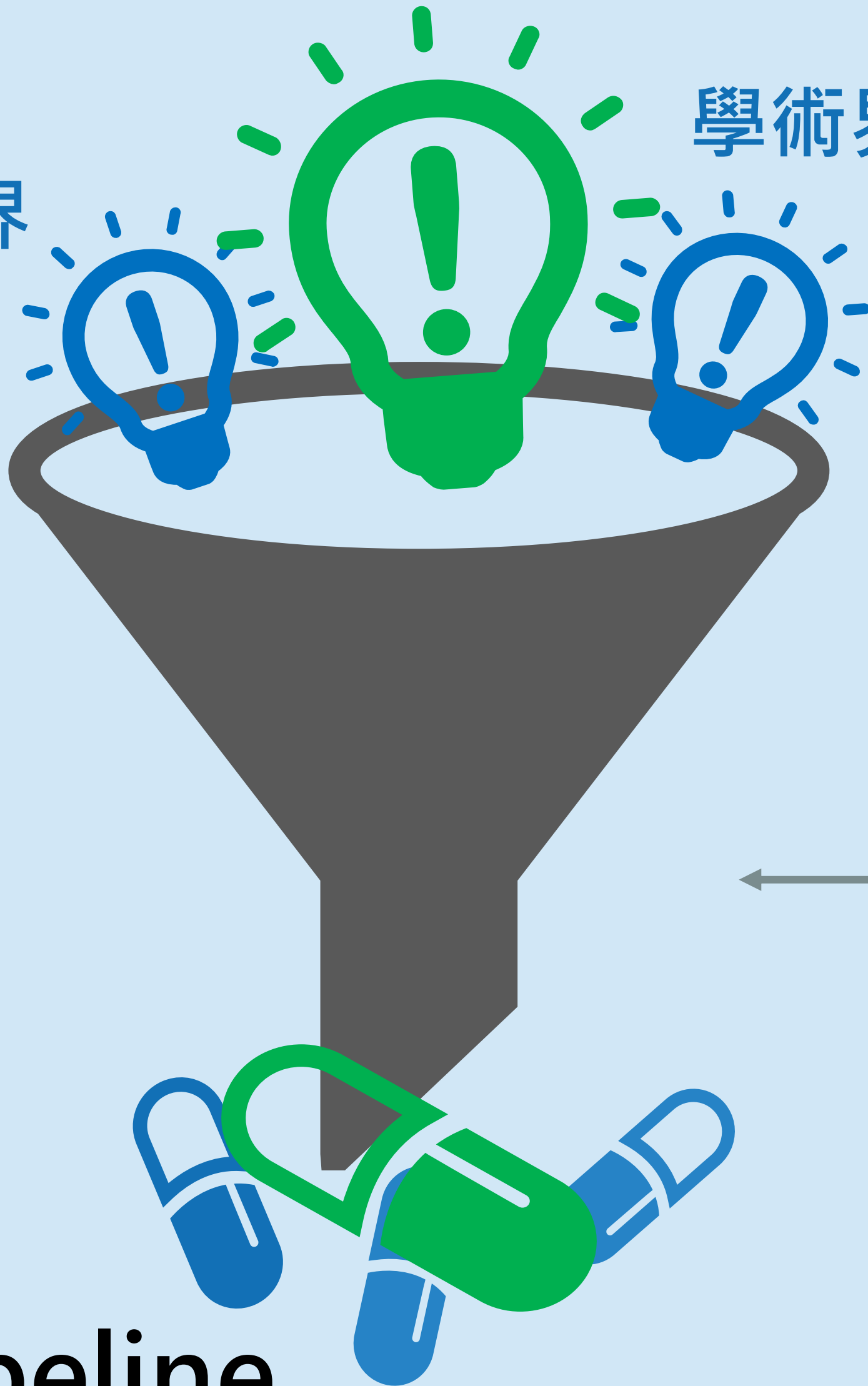
# Virtual Pharmaceutical Company Business Model



# 內部創新

產業界

學術界/研究單位



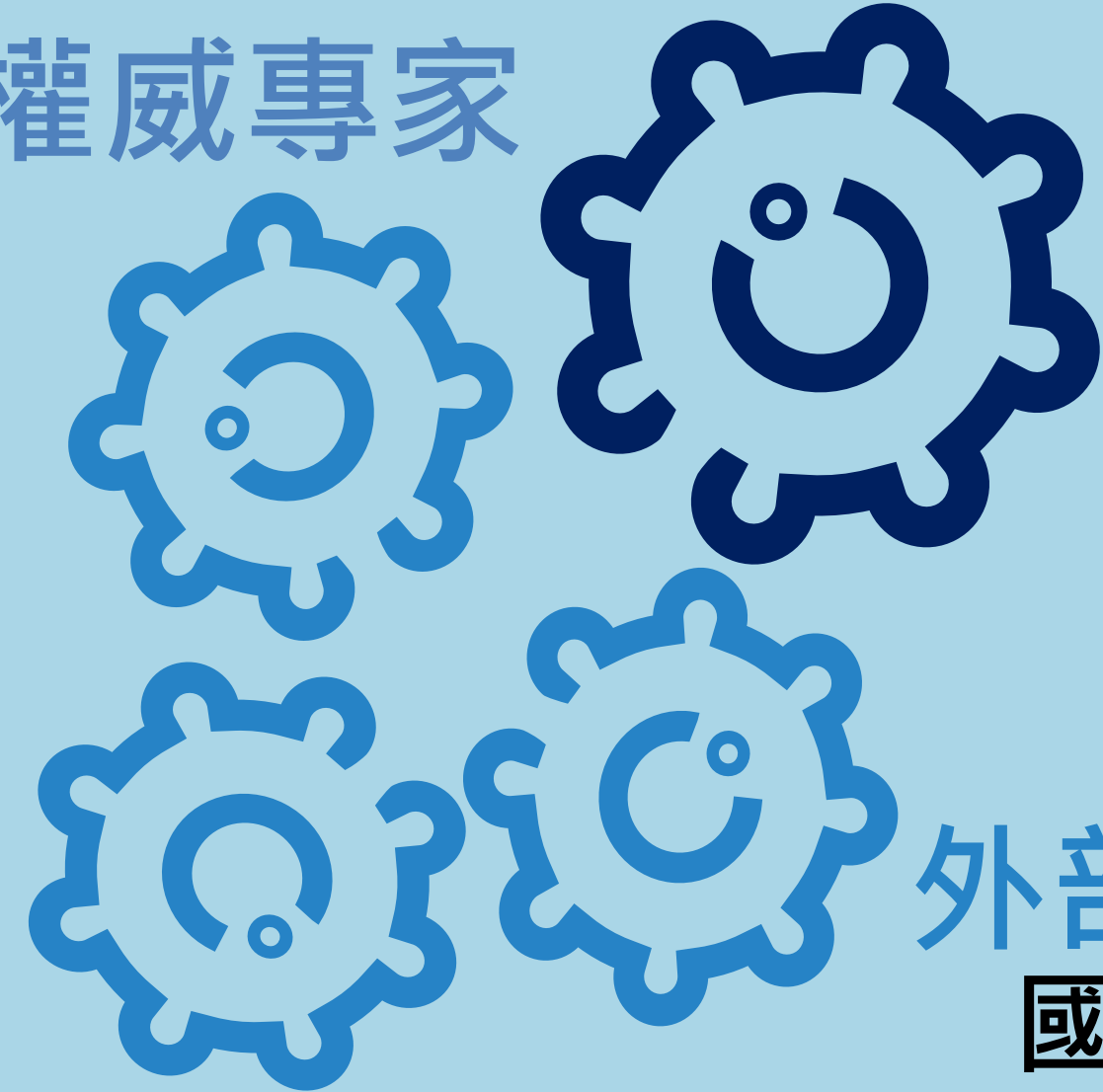
評估 授權引進

產品開發

## 內部人才

強化擴充

權威專家



外部顧問  
國際化

受託研究機構/  
受託開發與代工機構

審慎評估並建立  
長期合作關係

### PEI Pipeline

### Resource Pool

開始進行新專案  
term-sheet的協商

完成PEP07於  
2021年的開發計畫

持續進行PEP503  
資料轉移及  
試驗藥物銷毀

2021年下半年營運展望

持續引進國內外  
生技人才

ONIVYDE自2021/8/1起  
納入韓國之健保給付

# 5 Q&A