Polaris Group

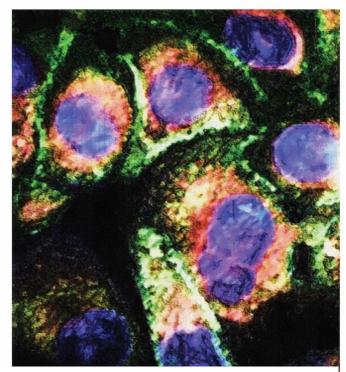
臨床報告

AACR 今年12月封面

努力目標: 代謝療法成為癌症治療最重要手段, ADI-PEG20成為代謝療法主角

Molecular Cancer Therapeutics

About the Cover



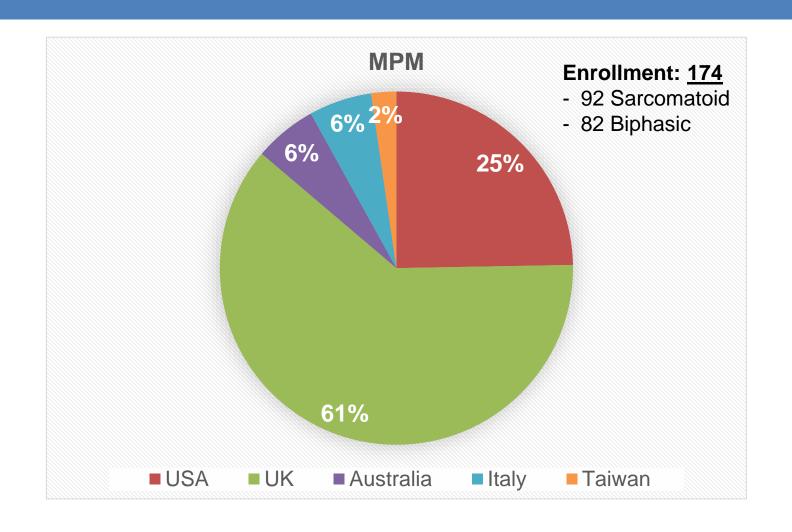
ABOUT THE COVER

Pancreatic cancer is notoriously difficult to treat. One potential opportunity for targeting pancreatic cancer is through its modified amino acid metabolism. Specifically depriving arginine-dependent tumor cells of arginine can lead to cell death. To achieve this, a polyethylene glycol (PEG)-conjugated arginine deiminase construct (ADI-PEG20) was previously designed and tested as a monotherapy in clinical studies with limited success. In the cover image, adapted from Figure 3 of the associate manuscript, Singh and colleagues demonstrate ADI-PEG20 radiosensitized pancreatic cancer cells by inducing ER stress (red fluorescence, BIP). Therefore, ADI-PEG20 could be combined with radiation therapy in patients whose tumors are arginine-dependent. Read the full study on page 2381.

ATOMIC Clinical Trial Summary (肺間皮癌臨床)

- Phase 2/3 Trial in advanced MPM
- Target Total Enrollment: 176 for Phase 2; 386 for whole Phase 2/3
- Randomized: 174* Enrolled (as of 29 November 2019)

ATOMIC Enrollment by Country

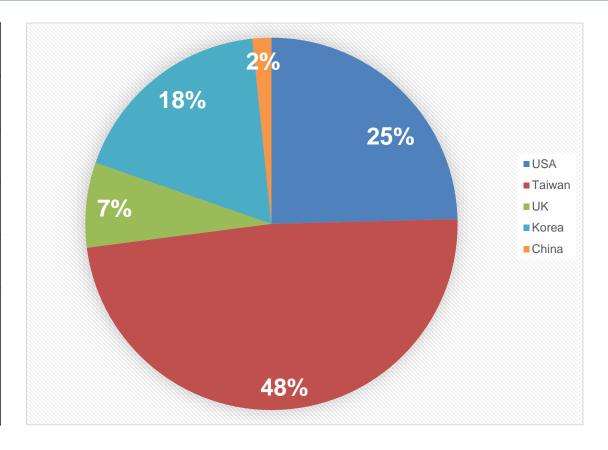


FOLFOX Clinical Trial Summary (Phase 2) (肝癌聯合用藥臨床報告)

- Phase I/II trial in Advanced Gastrointestinal Malignancies focusing on Hepatocellular Carcinoma (HCC).
- Target Enrollment Planned for Phase 2 HCC: 225

Enrollment Summary

US	28
Taiwan	62
UK	7
Korea	25
China	2
Total Subject enrolled	124*



*As of 03 Dec 2019

Soft Tissue Sarcoma Clinical Trial Summary

- Phase II Trial in grade 2 or 3 soft tissue sarcoma
- Target Enrollment Planned for Phase 2:75
- Enrollment 58 (as of December 7, 2019)

Global enrollment Clinical Trial Comparison

	# of Enrollment		
	Global		
Study	2018 1-12	2019 1-2	2019 3-11
ATOMIC	69	14	79
FOLFOX	24	2	72
Sarcoma	16	4	37
AML	7	0	0
Pembro	20	0	0
Total	136	20	188

Monthly Average Enrollment Year 2018 to 2019 February: 11.14

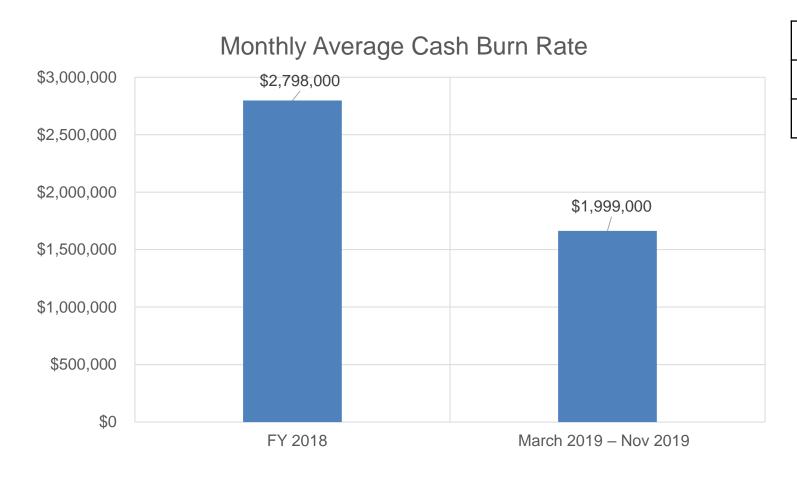
Monthly Average Enrollment Year 2019 March to November: 20.9



營運現況

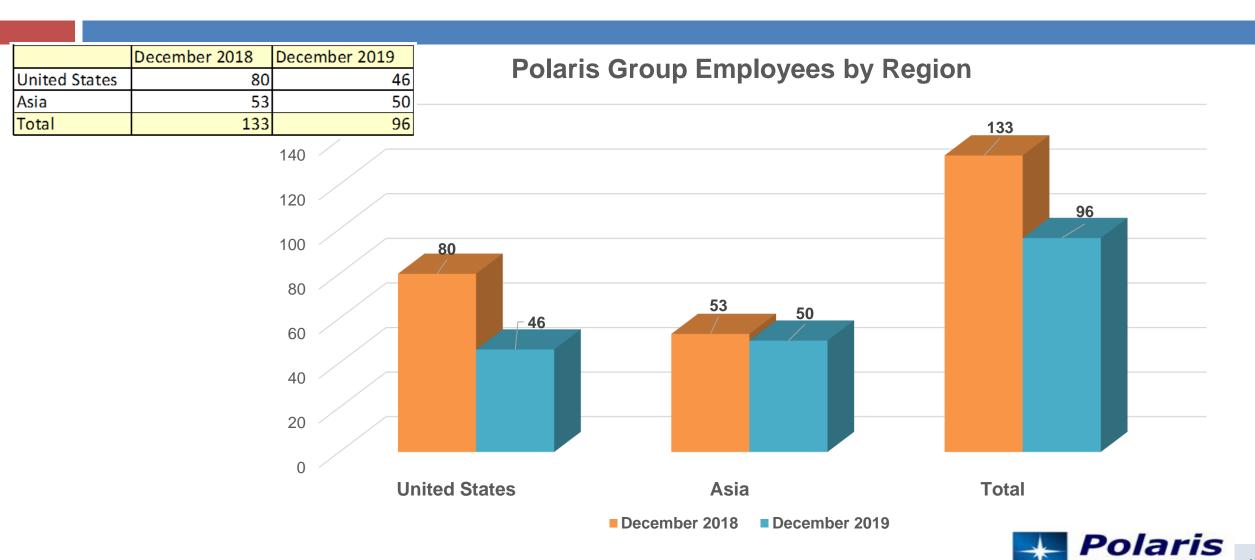


Cash Burn Rate Comparison



Description	Amount
FY 2018	USD \$2,798,000
March 2019 - Nov 2019	USD \$1,999,000

Comparison Headcounts by Region



CDMO Business Update

- Signed first contract in November 2019.
 - → Polaris first ever operating revenue contract
- Target a market of more than 200 potential CDMO clients

Operation Summary March To November 2019

- Lowered monthly cash burn rate by 30%
- 200% average monthly clinical trial patient enrollments
- Reduced finance and administration expenses by 50%
- First ever PI meeting held in Taipei
- First ever CDMO contract
 - → all using existing resources
- Re-engineered IT infrastructure
- Launched Online PI Meeting Platform
- Consolidated Office Facilities including Taiwan & US

資金及展望



資金與展望

為什麼這麼大的私募?

今年的財務困境

• 二月底公司帳戶餘額 404萬 美元

累積應付帳款 -200萬

· 每月開支(2018年平均值) -280萬

•

•

◆ 三月 完成私募 (@21.83 NTD) 500萬 美元

◆ 六月 完成現金增資 (@ 12 NTD) 2320萬

8/25 必須還國開行 - 250萬 美元 (成都8000萬人民幣借款)

• 11/1 必須還新光銀行 -1000萬

• 12/25 必須還公司債(含利息) -1500萬



執行撙節計劃,積極募資

募資的艱難挑戰

- 小額或5億台幣以下的資金於事無補
- 再度現金增資的可行性很低
- 私募條件嚴苛,困難度很高 ★

募資10億還是30億?哪一個較容易?



三年目標

- 財務方面: 估計明年初帳上餘額約25億台幣不再對外募資的情況下:
- 支撐公司的所有開支
- 支持招收800.位臨床試驗的病人
- 取得重大成果

發展策略

- 減輕負擔,活化資產
 - -- 北加州工廠

現況:每年開支700萬美元

產能利用率極低

新策略:生物藥代工(CDMO)

採美國與中國聯合的研發製造模式

目標 :兩年內自給自足

成都工廠

- 狀況:已經花費~5,000.萬美元
 - -- 已經閒置多年(>3年)
 - -每年開支 250萬美元



成都工廠

• 策略:

- -- 以成都公司為主體在大陸募資
- -- 將中國權利轉至成都公司
- -- 規劃以申請中國藥証為目標的臨床試驗
- -- 啟動1,000.升的生產線建置

目標:

- -- 一年內完成在大陸募資,之後不再需要母公司挹注資金
- -- 3年內完成1,000.升生產線可量產
- -- 3年內在大陸取得重大成果

發展策略

• 轉化財務負擔的工廠成為可能的獲利來源,並建立量產能量

• 將80%以上資金用於臨床試驗

• 就市場及各種癌症與全球重要藥廠尋求合作

發展策略--臨床試驗

- 估計未來三年招募至少800位病人參與臨床試驗
 - 肺間皮癌 (MPM)
 - 肝癌 (HCC)
 - -- 軟組織肉瘤
 - 腦膠狀母細胞瘤(GBM) ~ 160 (phase 1B & 2)
 - 其他

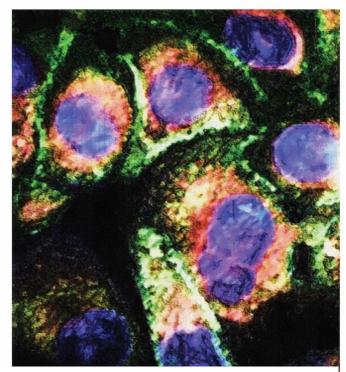
- + 210 (phase 3)
- + 130 (phase 2/3)
- ~ 300 (phase 3)

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躍馬救黎民

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怎 堪毒疣 霸 横

Q&A

