36th Annual
J.P. Morgan Healthcare Conference

MICROBIO GROUP

A Taiwanese Leading Biotech Since 1997

中天生技集團簡介

- ***1997*** 成立已有***4*** 家公開發行
- 已累計投資總值達***7*** 億美金
- ***12*** 個新藥
- ***4*** 個研發中心
- 在台灣有***2***座PIC/s GMP 等級生產廠
- 在中國有***1*** 座GMP 等級生產廠
- ***80*** 位以上科學家+ ***5*** 個合作研究機構

研發新藥產品線

Phase 1	Phase 2	Phase 3	Approved
OB318 HCC	**FB317** Anti-IgE	**FB825** Anti-CεmX	**ON101** Diabetic Foot Ulcer	**MS-20** Oncology
MB-110 HCV	**SNP630** NASH		**MB-6** Colon Cancer	**Herbiron** Anemia
FB704A Anti-IL-6	**SNP810** Analgesic and antipyretic			

2 個已上市以及8個臨床研究階段藥物

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ON101 (糖尿病足部潰瘍軟膏)

優異的臨床三期期中分析結果

傷口癒合率 > 60%

DFU尚未被滿足的醫療需求

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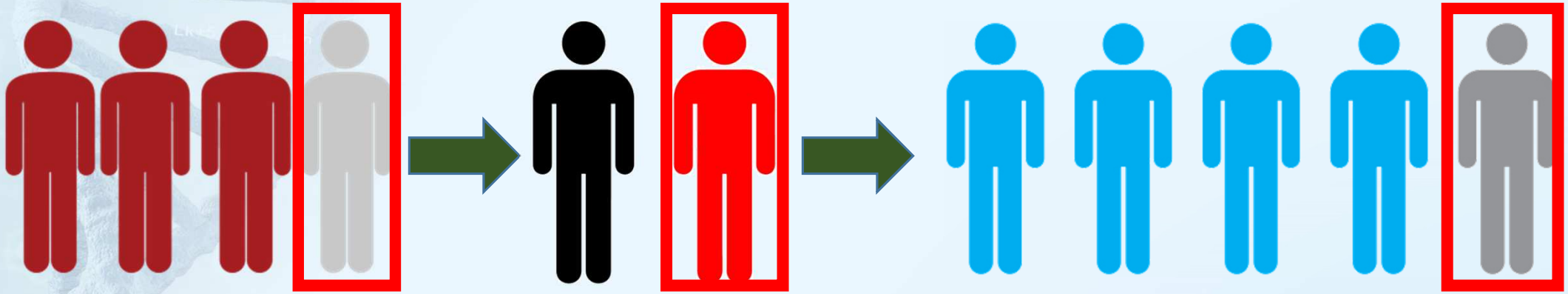
全球糖尿病患達425 million



25% 罹患DFU	>50% DFU 病患遭受感染	20% DFI 病患遭到截肢

DFU 的5年死亡率達50 %

DFU –沉重的醫療負擔

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2014 USA

- DFU imposes substantial burden on public and private payers, ranging from **$9-13 billion** in addition to diabetes treatment costs. (Diabetes Care 2014;37: 651-658)

2012 Europe

- The estimated costs associated with treatment of DFU are **EUR 10 billion** per year in Europe. (Int Wound J 2013; 10: 555-561)

2018 China

- There are estimated **7 million** DFU patients in China costing **$21 billion** in medical expenditure from hospital admission per capita is **$3000**.

ON101 臨床三期期中分析結果

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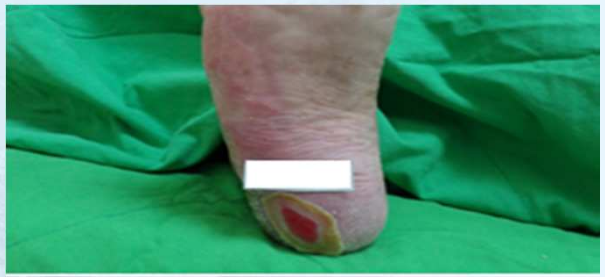
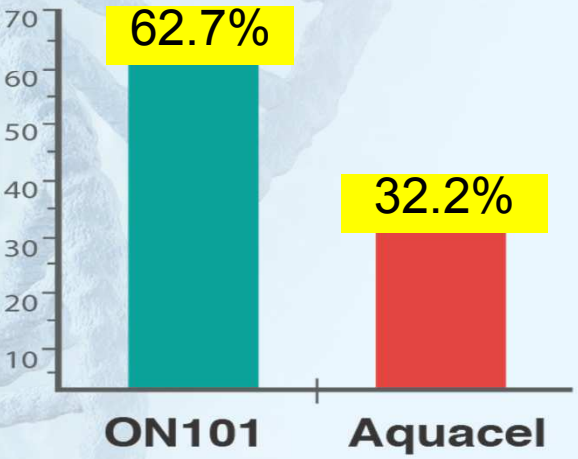
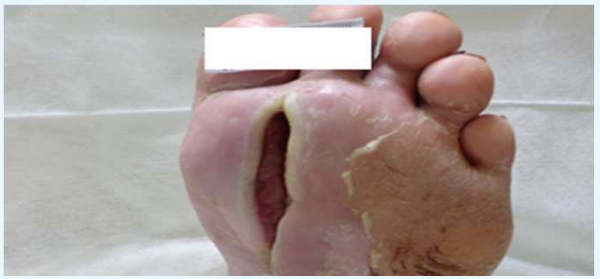
- Overall Group

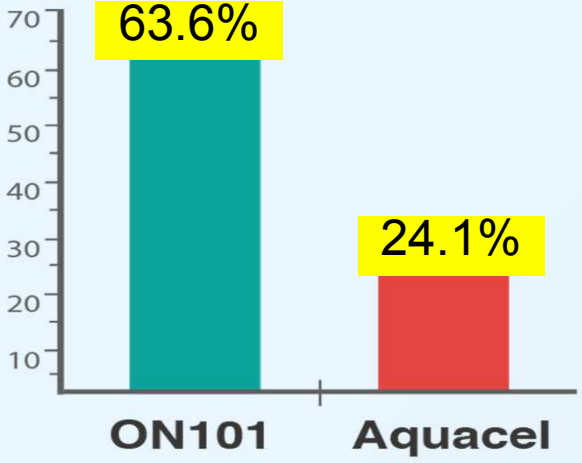




Difference = 30.5% (p<0.001)

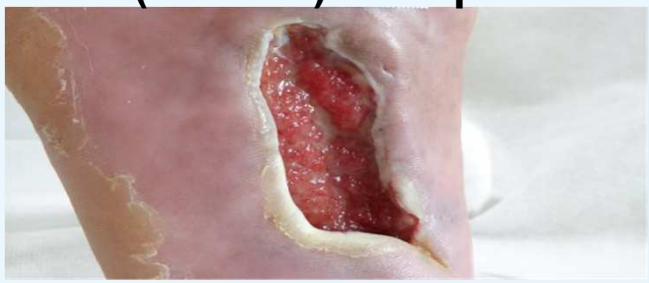
- Plantar Ulcers Group

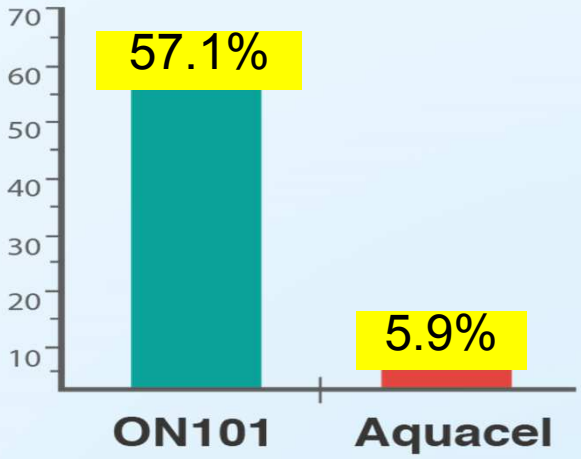




Difference = 39.5% (p=0.002)

- Large Wound Size (> 5 cm^2) Group

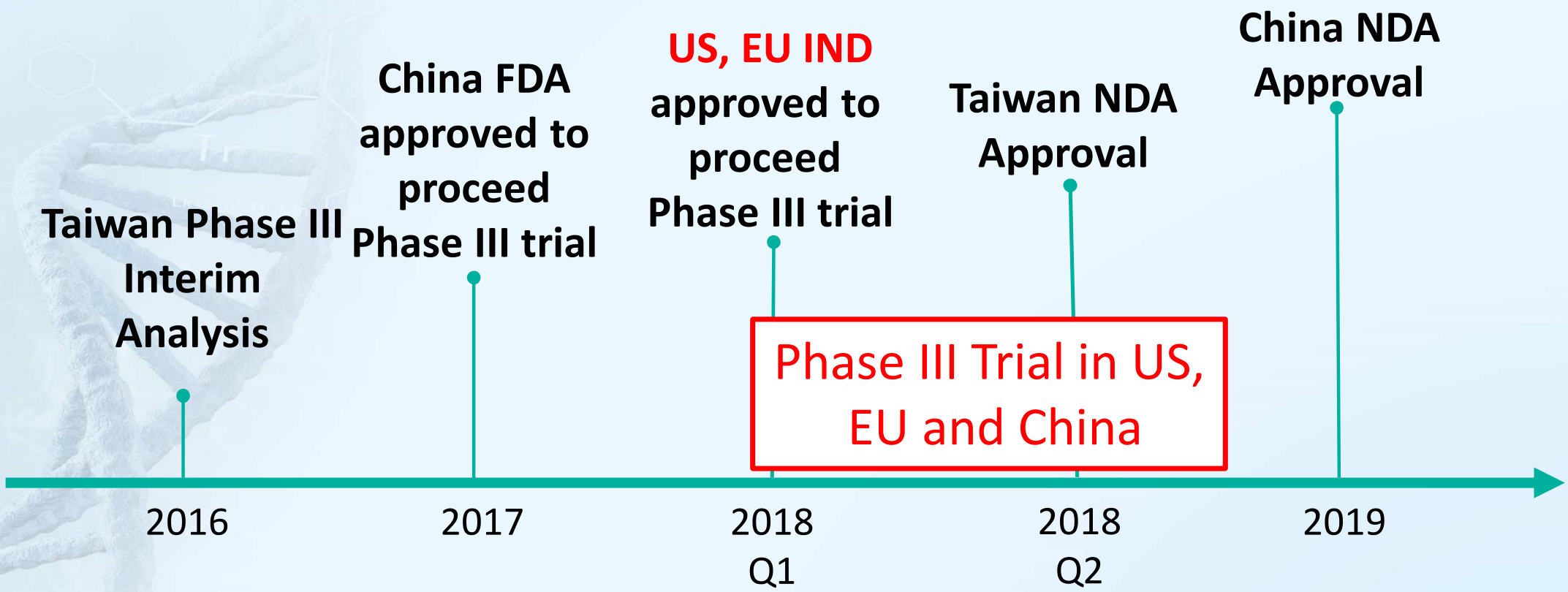




Difference = 51.2% (p=0.002)

60% 病患在16週內完全癒合

ON101 發展規劃



全球合作研發與授權

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MS20 (腸道菌共生代謝物)

發展全新適應症

人類腸道生態系統以及免疫調節增效藥物

免疫檢查點藥物病患反應率有限

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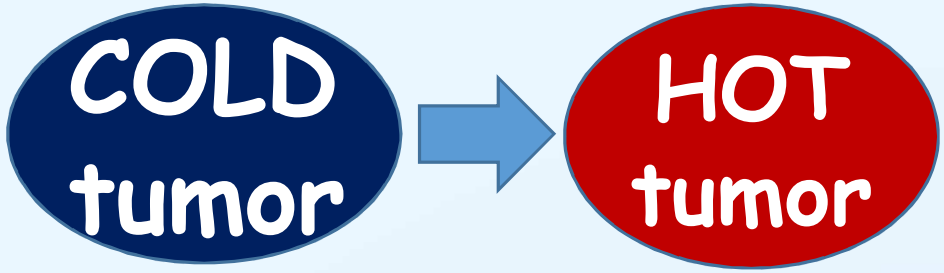
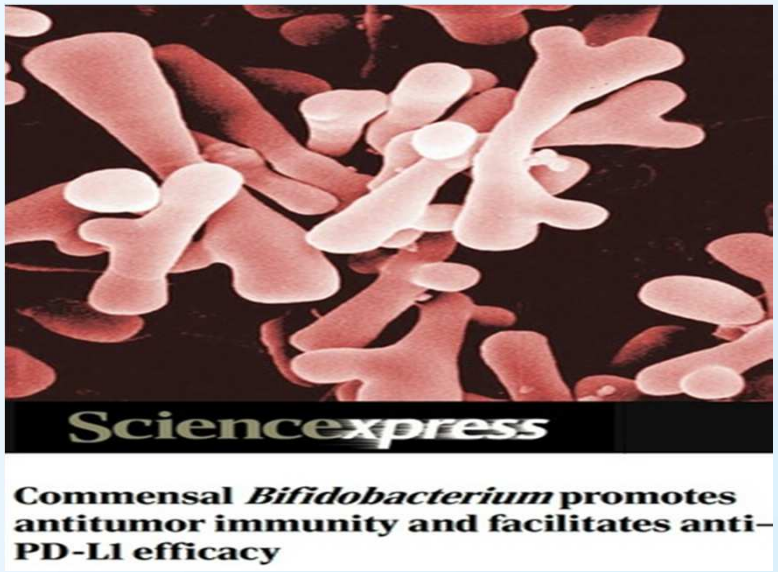
ORR			
	Opdivo	Keytruda	Yervoy
Melanoma	25-35 %	24-32 %	11 %
Lung cancer	41 %	20-26 %	-
Kidney cancer	11-25 %	-	-
Off-label use			
Prostate cancer	-	-	26 %
Triple-negative breast cancer	-	16 %	-
Ovarian cancer	-	12 %	-





Science. 2015, 350(6264):1084-1089

MS-20 人類腸道菌群生態系統

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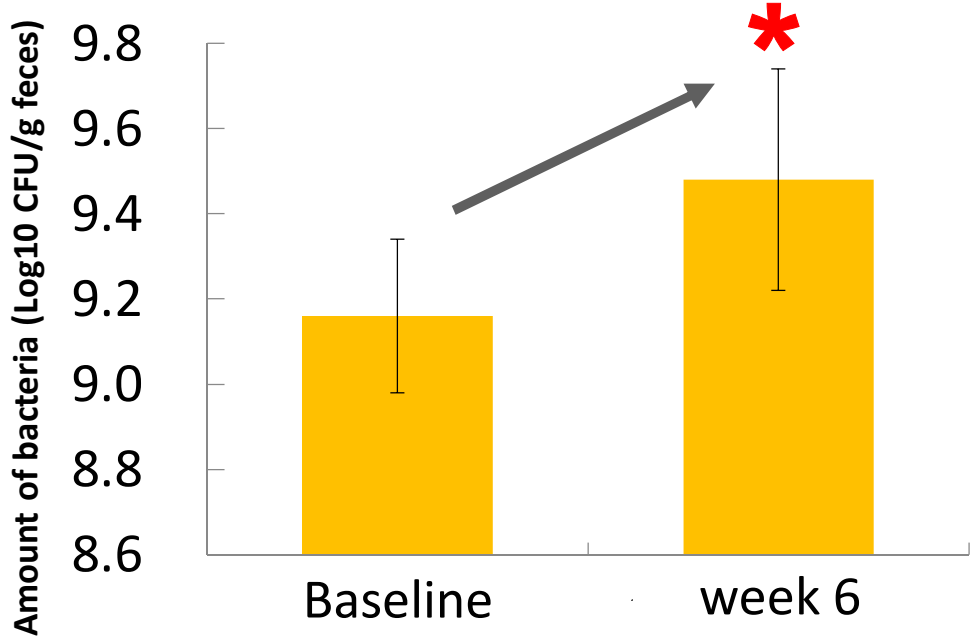
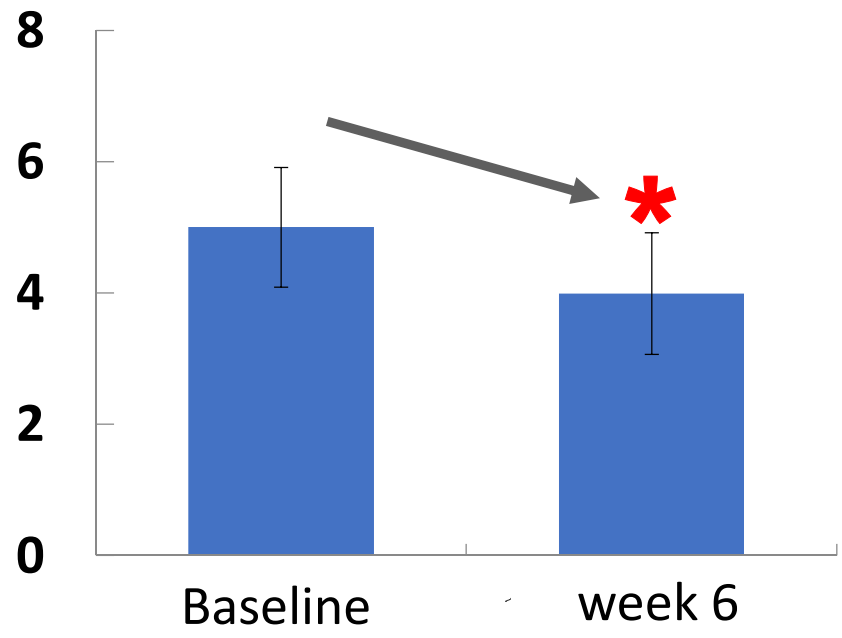
Bifidobacterium spp. (beneficial bacteria)



Clostridium perfringens (gut pathogen)



* $p<0.05$ compared with baseline

MS-20 將冷腫瘤轉變成熱腫瘤

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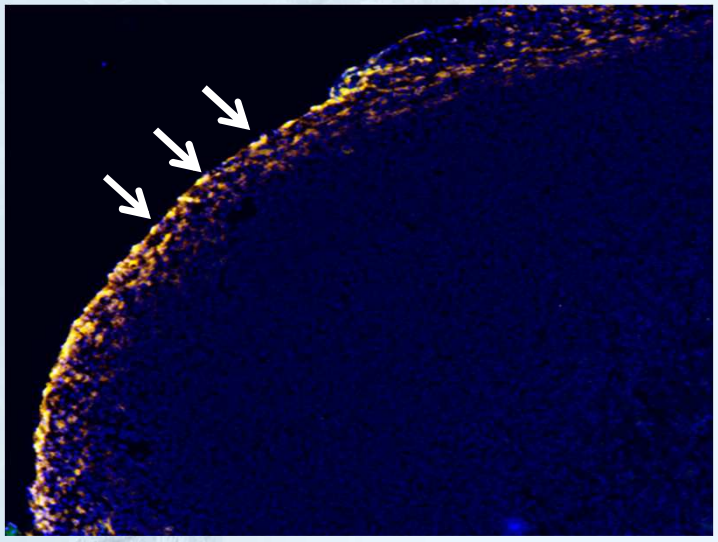
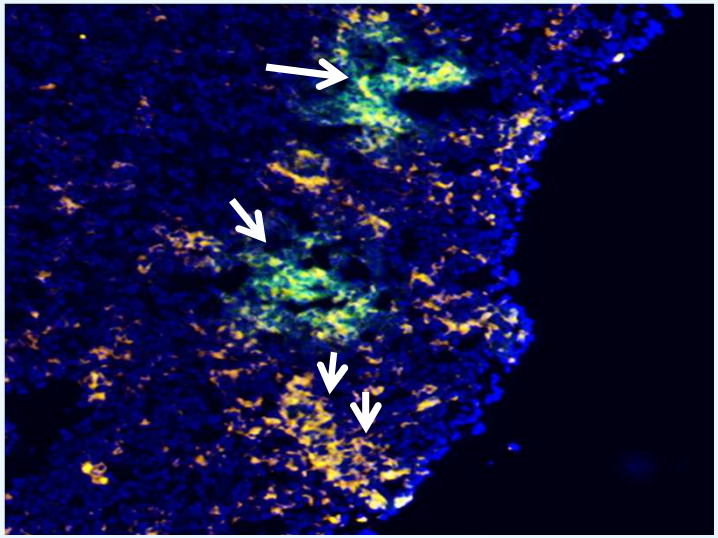
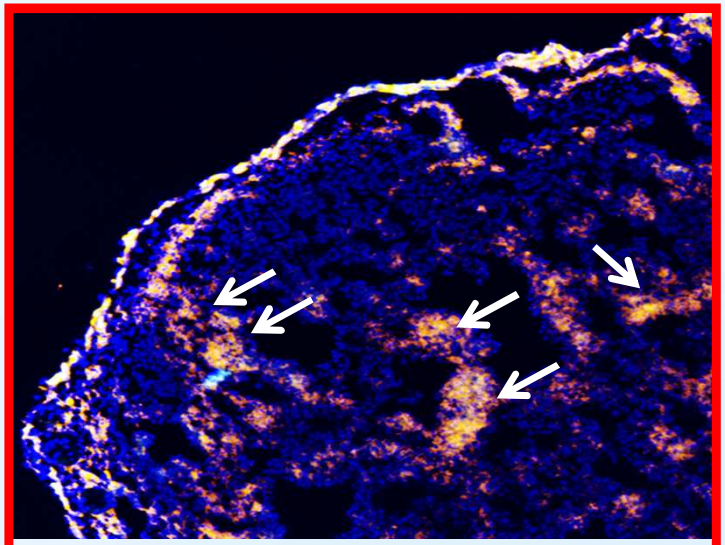
增加$CD4^+/CD8^+$ T 細胞進入腫瘤組織



Vehicle



15% MS-20



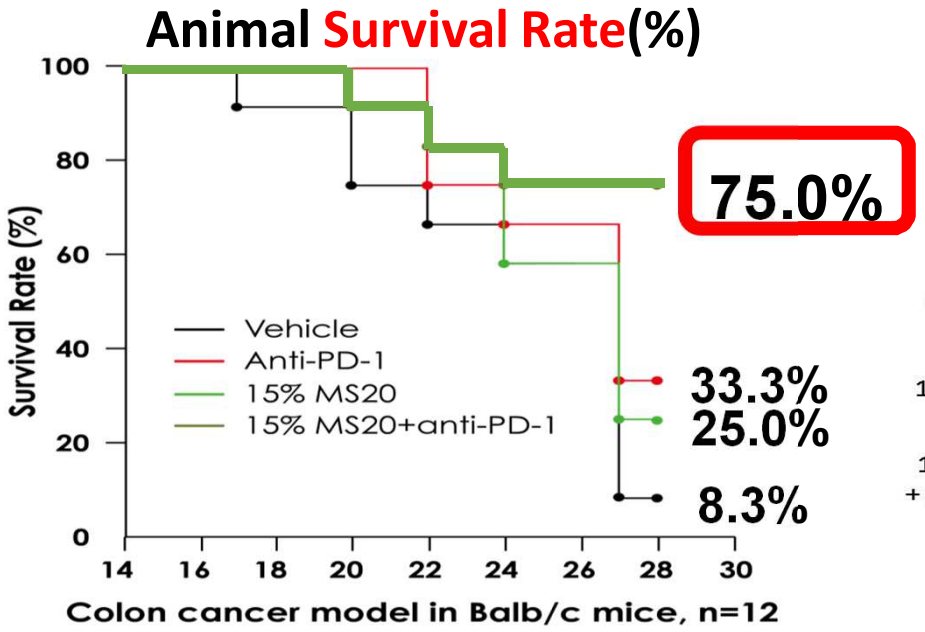
15% MS-20 + anti-PD-1

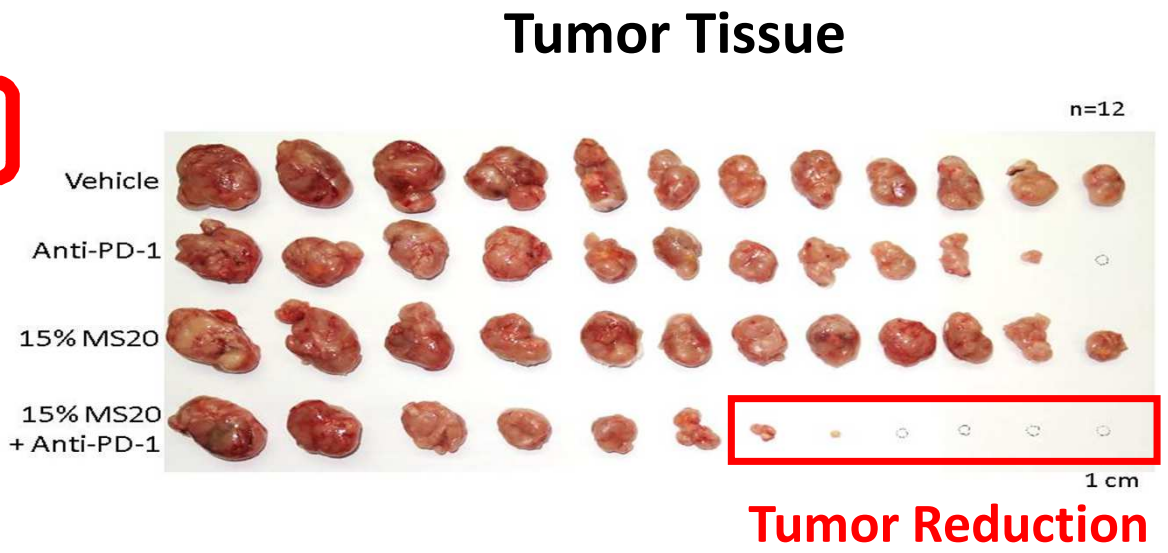
Blue: Tumor cells ; Green: Dendritic cell

Yellow: $CD4^+$ T cells ; Red: $CD8^+$ T cells

MS-20 增強抗腫瘤之免疫力

Combination Therapy of MS-20 & Anti-PD-1





增加存活率　降低腫瘤大小

MS-20 機會點

1. 調節腸胃道菌群微環境
2. 增強免疫檢查點藥物應答率

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FB825 (Anti-CεmX單抗新藥)

首次用於病患之數據

中重度異位性皮膚炎

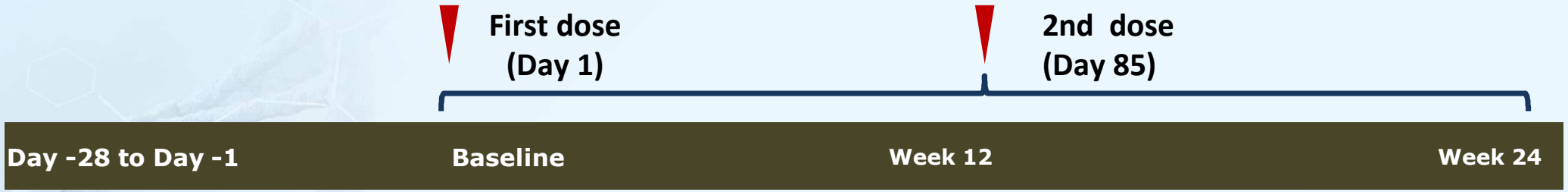
FB825 臨床試驗中心與試驗主持人

- 台灣頂尖醫學中心

  台灣大學附設醫院

- 試驗主持人 朱家瑜醫師 經歷
  - 台灣大學附設醫院國際醫療服務中心執行長
  - 台灣皮膚科醫學會常務理事
  - 中華皮膚科醫學雜誌主編
  - 第六屆 Euro-Asian Association of Dermatovenerologists Congress主席
  - 曾經參與執行多個異位性皮膚炎相關之全球性臨床試驗

FB825 臨床試驗設計



Screening (4 weeks) Emulsion standardization (1 week)	5mg/kg IV Q12W 2 doses (n=12)

- Eczema Area and Severity Index (EASI) score ≧14
- Investigator's Global Assessment (IGA) score ≧ 3
- ≧10 % body surface area (BSA) of Atopic Dermatitis involvement

每12週注射一針
用於中重度異位性皮膚炎病患

FB825 與Dupilumab之比較

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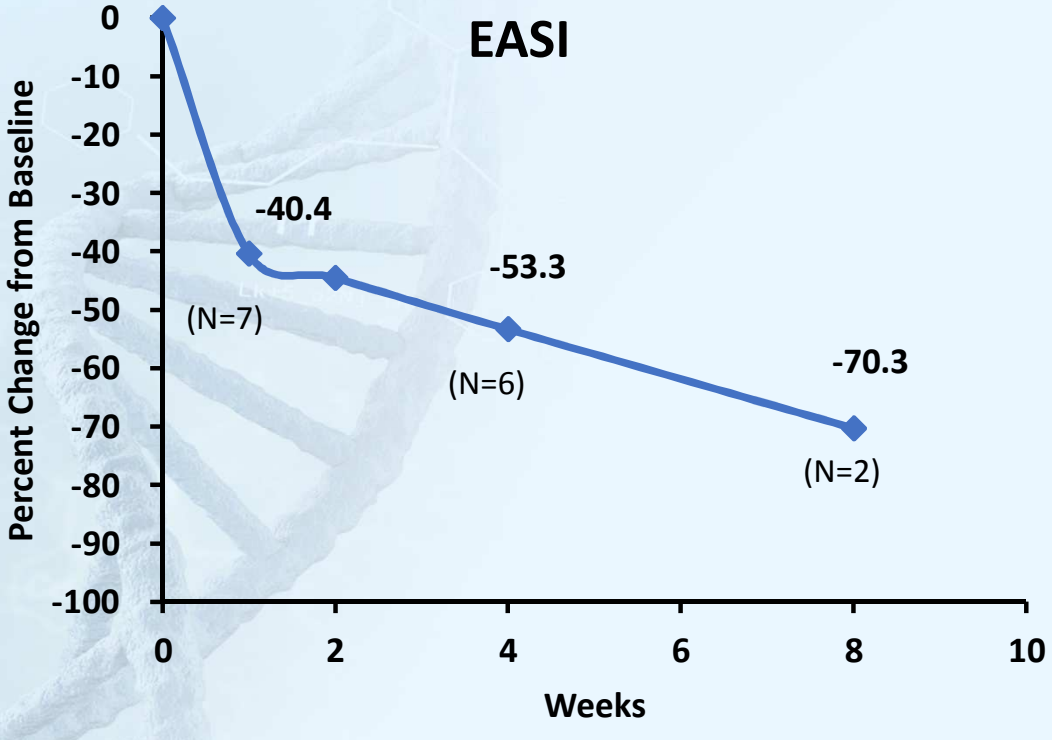
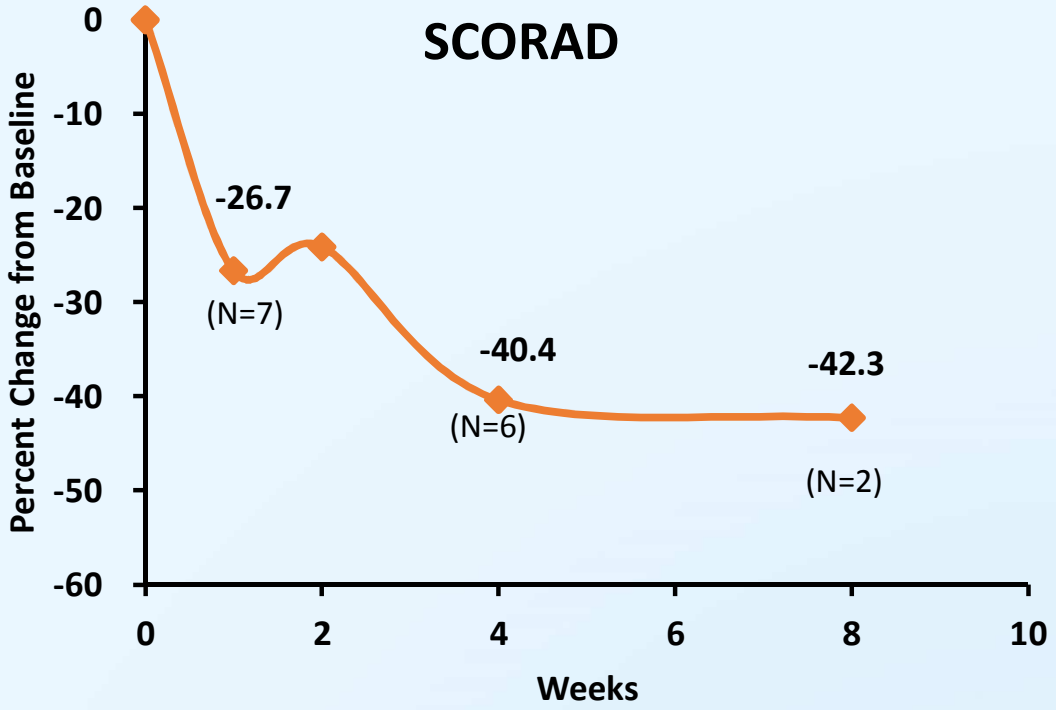
	EASI Score Change from Baseline							給藥頻率
	W1	W2	W4	W8	W12	W13	W16	
FB825	-40%	-45%	-53%	-70%				每12週一針
Dupilumab*	-15%	-35%	-55%	-66%	-70%	NA	-70%	每2週 一針

*三期試驗結果, Dupilumab為目前唯一核准之異位性皮膚生物製劑.

FB825在第一週EASI指數改善率為 Dupilumab之260%
第八週FB825注射一針與 Dupilumab注射四針效果相當

FB825 疾病指數明顯下降





FB825注射一針第八週後 EASI指數下降70%
SCORAD指數下降42%

FB825
在異位性皮膚炎取得突破性進展

- **藥效作用快**
  - **注射一針在第一週就能使EASI 指數下降40%**
- **長效作用**
  - **注射一針藥效持續達2 個月**
  - **FB825注射 1針 的效果與dupilumab 注射 4 針相當** (根據目前已知結果)
- **低副作用**
  - **未觀察到注射部位的局部反應**

FB825

尋求策略合作夥伴

- 藥物授權
- 共同開發

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Thank You Very Much