ONENESS

合一生技股份有限公司 (TPEx: 4743)

法人說明會

3:00 ~ 3:50 簡報/Q&A

陳菀均博士, 研發副處長

108年12月27日

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免責聲明

The statements and contents included in this presentation that are not historical in nature are "forward-looking statements". These forward-looking statements, which may include statements regarding our future results of operations, performance, financial condition, development or marketing of our products or business prospects, are subject to risks and uncertainties and are based on our current expectations. Actual results may differ materially from those expressed or implied in these forward-looking statements for a variety of reasons. Please be cautioned not to place undue reliance on these forward-looking statements which are based on information currently available. Our forward-looking statements at this time does not create any duty of disclosure beyond that which is imposed by law, and we expressly disclaim any obligation to publicly update or revise any forecasts or forward-looking statements, whether as a result of new information, future events or otherwise.

ONENESS
合一生技股份有限公司

大綱

- 新合一簡介
- 新合一特色
- 重磅藥物介紹
- 未來五年里程碑
- 結語

ONENESS
合一生技股份有限公司

新合一生技

From Biotech to Pharma

2019 & before

- Became listed in Taipei Stock Exchange
- Acquired Fountain Biopharma (4159 TT)
- Established PIC/s GMP facility

2020

- ON101 NDA approval in TW
- Launching 1st new drug
- ON101 Ph3 in US
- FB825 Ph2a studies complete

2021 & beyond

- ON101 launch in China & Asia
- FB825 Ph2b studies start

106~108Q3損益表

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(單位：新台幣仟元)

106-108 Q3 Financials

項目	108年前三季	107年度	106年度
營業收入	11,100	18,856	2,587
研究發展費用	124,157	94,436	65,432
本期淨損	(152,898)	(244,941)	(155,923)
資產總額	7,225,806	2,335,421	2,521,393
負債總額	576,204	169,643	26,464
權益總額	6,649,602	2,165,778	2,494,929

2018-2019 Chart (NTD)

Previous Close	Day's Range	52-week Range	Market Cap
29.35	29.25-29.5	26.2-35.2	103億

(20 Dec, 2019) (Currency in NTD)

簡明資產負債表

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(單位：新台幣仟元)

項目	108/09/30	107/12/31	106/12/31
流動資產	1,737,780	745,176	1,237,325
不動產、廠房及設備	627,199	561,012	455,714
無形資產	2,278,502	51,925	23,106
其他資產	2,582,325	977,308	805,248
資產總額	7,225,806	2,335,421	2,521,393
負債總額	576,204	169,643	26,464
股本	3,524,908	1,957,522	1,957,522
資本公積	3,751,668	799,295	764,582
保留盈餘	(232,523)	(254,379)	(155,446)
其他權益	(394,451)	(336,660)	(71,729)
權益總額	6,649,602	2,165,778	2,494,929

新合一生技

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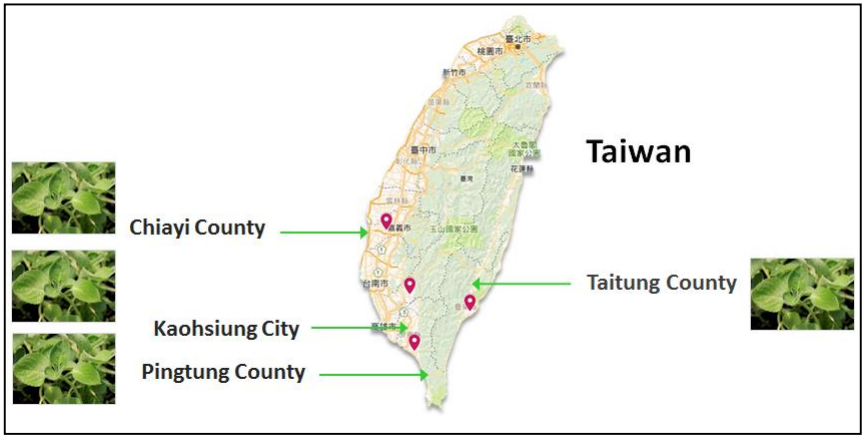
From drug discovery to production

	Code	Target	Discovery / Preclinical	Ph 1	Ph 2	Ph 3	NDA Submission	Market Launch
Diabetes	ON101	Multiple	Diabetic Foot Ulcer			China	TW	2020 TW 2021 China 2023 US 2024 EU
			Diabetic Foot Ulcer			US		
Immune Disease	FB825	CεmX	Atopic Dermatitis			US		
			Allergic Asthma			US/CN		
			HIES (Orphan Drug Designation)			US		
	FB704 A	IL-6	Rheumatoid Arthritis			US		
	OB318	Multiple	HCC			US/CN		
	FB918	IL-33	Atopic Dermatitis					

全球上市優勢

From cultivation to production

44-acre GACP 種植基地



全球供貨

- **GACP種植基地掌控藥材**
  In compliance with US FDA"Botanical Drug Development - Guidance for Industry" (2016.12)

- **PIC/s GMP生產廠(第一階段可供應2,500萬條)**

PIC/s GMP 生產廠

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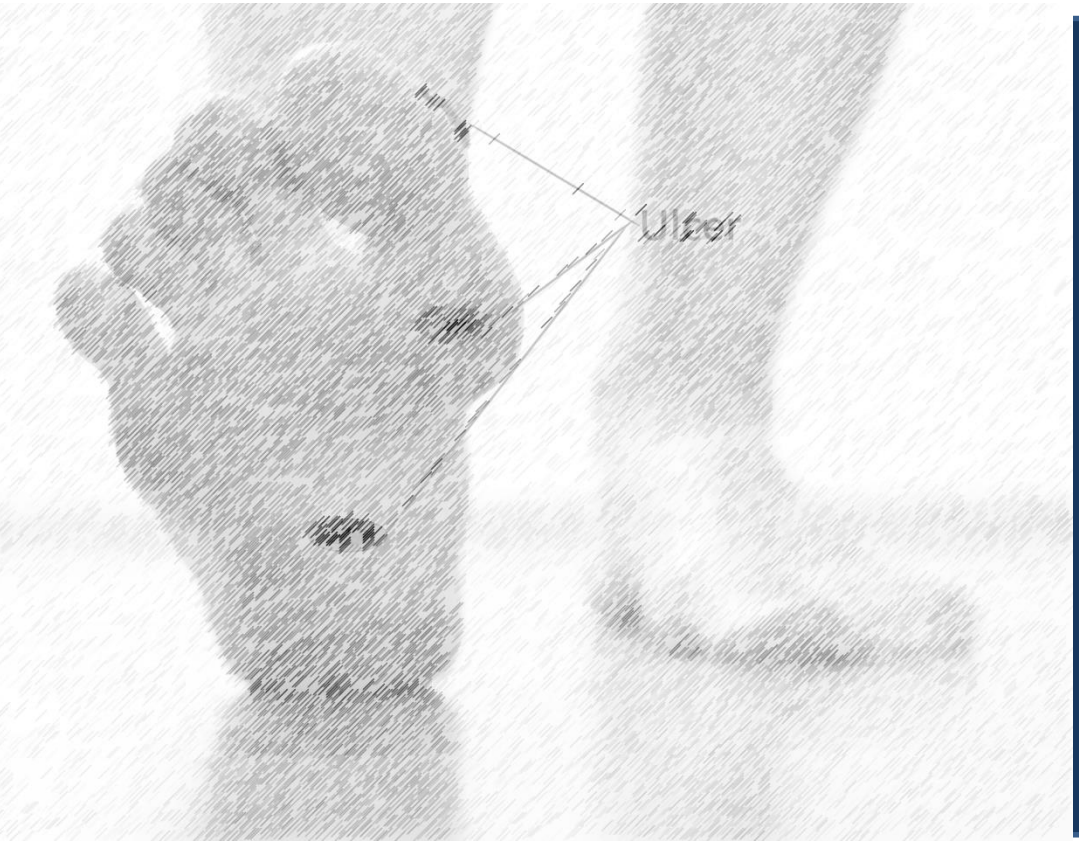
核心新藥-ON101



全球
醫療迫切需求

The Best-in-class for DFU

(糖尿病足部傷口潰瘍)

DFU(糖尿病足部潰瘍傷口)

一、全球未滿足的醫療需求(Unmet Medical Need)

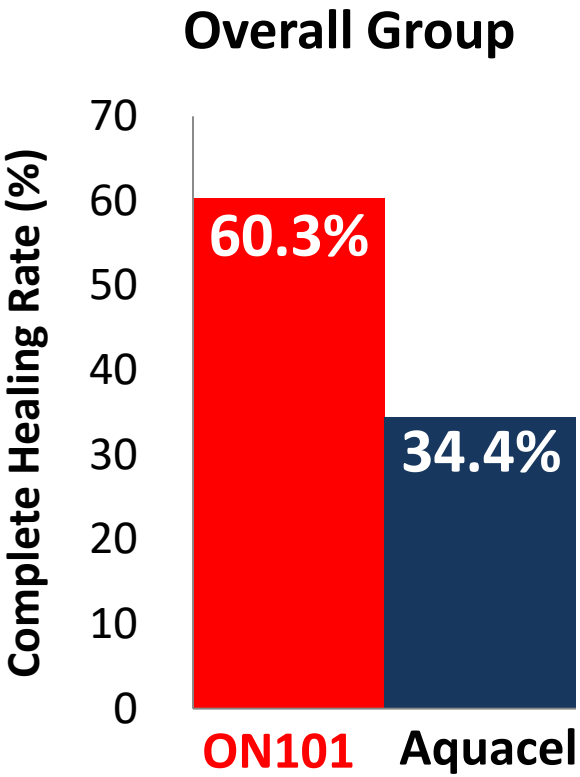
二、全球醫療需求超過600億美元

三、過去20年全球三期臨床試驗全部失敗

四、病患截肢後五年存活率僅50~60%

ON101臨床療效穩健性 (一)

主要療效指標: 傷口完全癒合率(FAS)



傷口完全愈合率：

ON101組 60.3%

Aquacel組 34.4%

全球唯一第三期試驗

達到60%完全癒合率

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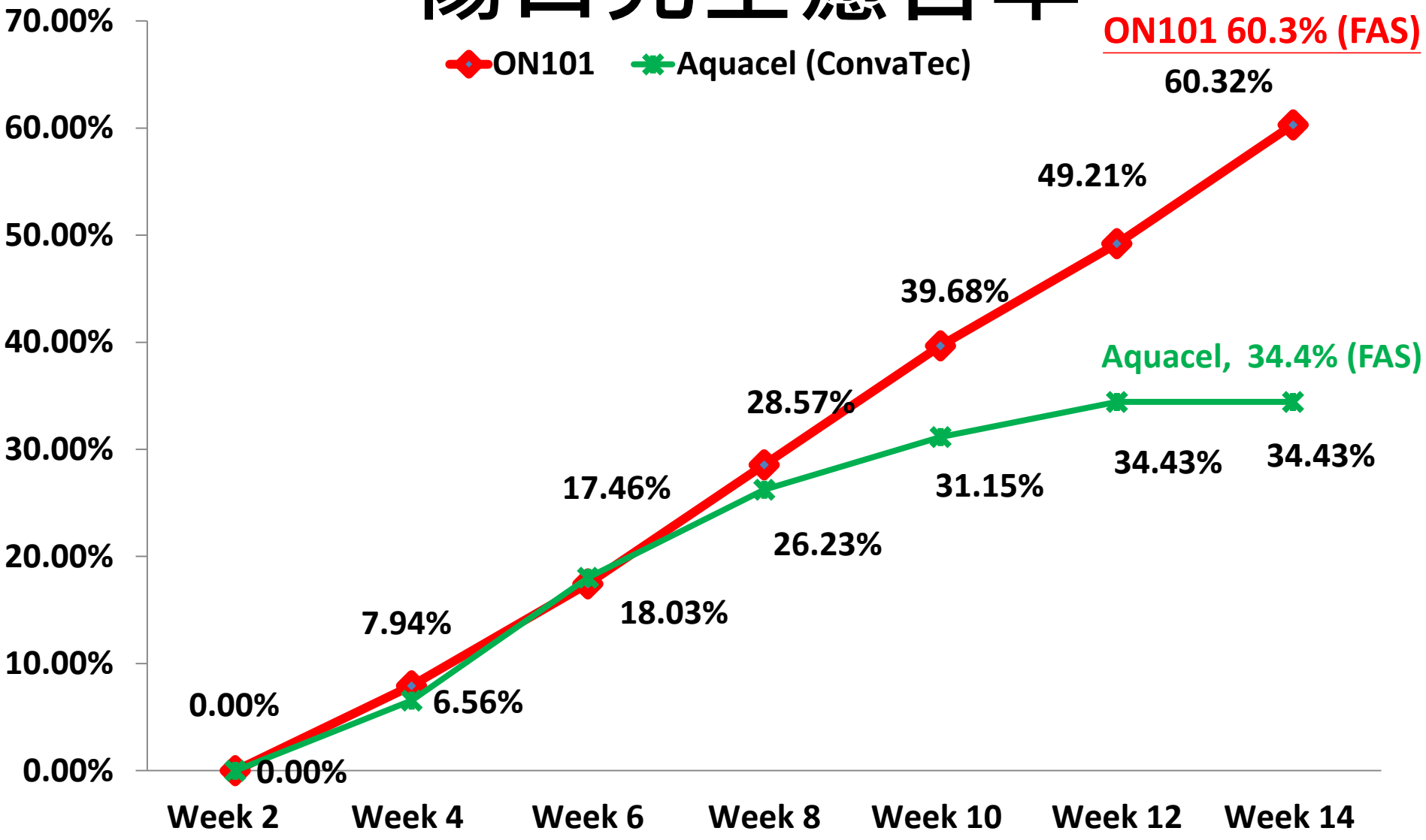
傷口完全癒合率



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ON101臨床療效穩健性(二)

困難癒合傷口次族群分析

	ON101 : Aquacel
• 足底傷口癒合率	60.0% : 26.7%
• 大於 5 cm^2 (大傷口) 癒合率	53.3% : 5.9%
• Wagner Grade 2 癒合率	63.0% : 32.7%
• HbA1c > 7% 癒合率	50.0% : 30.0%

三期試驗

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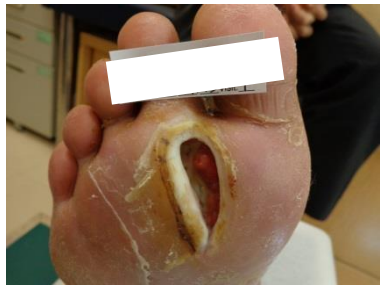
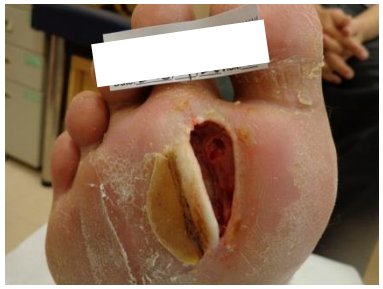
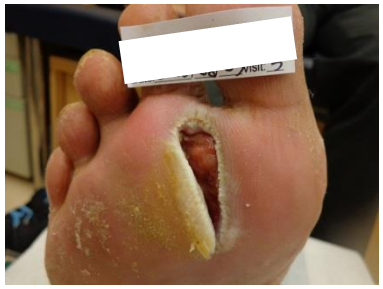
Ulcer duration 1.2 month; Plantar wound size 3.23 cm^2;
Completely healed in 10 weeks



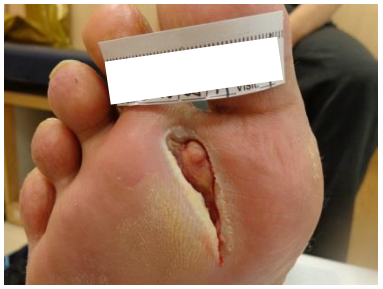
V1 2016/07/13
G2 Area: 2.85 cm^2



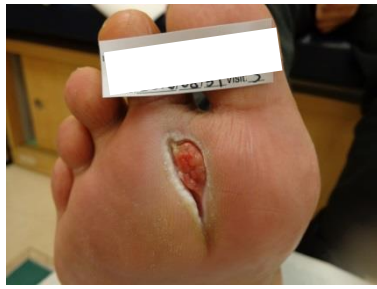
V2 2016/07/20
G2 Area: 3.23 cm^2



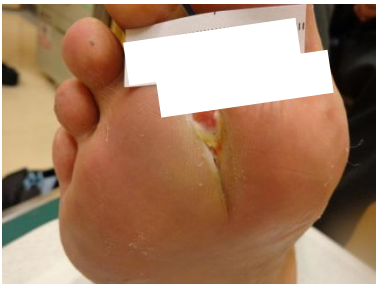
V3 2016/08/03
G2/G1 Area: 2.30 cm^2



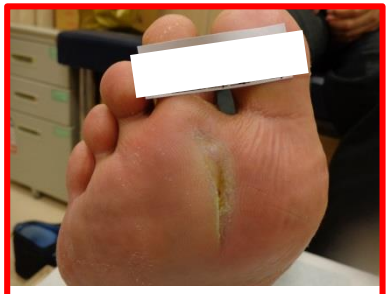
V4 2016/08/17
G1 Area: 1.77 cm^2



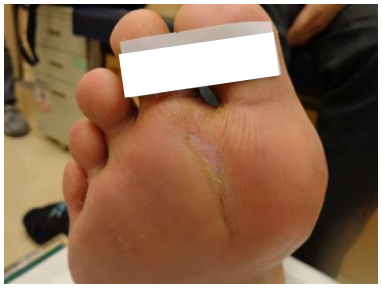
V5 2016/08/31
G1 Area: 1.49 cm^2



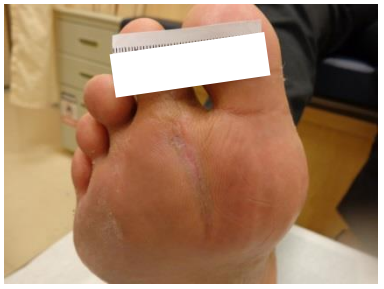
V6 2016/09/14
G1 Area: 0.48 cm^2



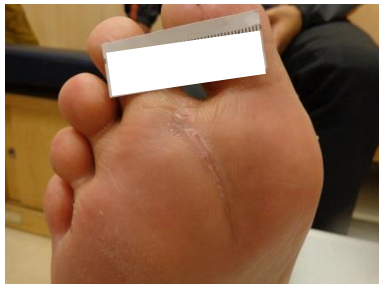
V7 2016/09/28
Healing
G0 Area: 0.00 cm^2



V8 2016/10/12
Healing
G0 Area: 0.00 cm^2



V10 2016/10/26
G0 Area: 0.00 cm^2



V11 2016/11/09
G0 Area: 0.00 cm^2

ON101 研發計劃

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生產製造

- 已於台灣 PIC/s GMP 規格廠，進行量產測試
- 已取得台灣到手香萃取物原料藥(PA-F4)藥品證明

臨床開發

- 於台灣進行NDA 藥品查驗登記審查
- 於中國執行三期臨床試驗
- 於美國 執行第二個三期臨床試驗

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核心新藥-FB825

With Revolutionary Mechanism in Atopic Dermatitis

The First-in-class for AD

(異位性皮膚炎)

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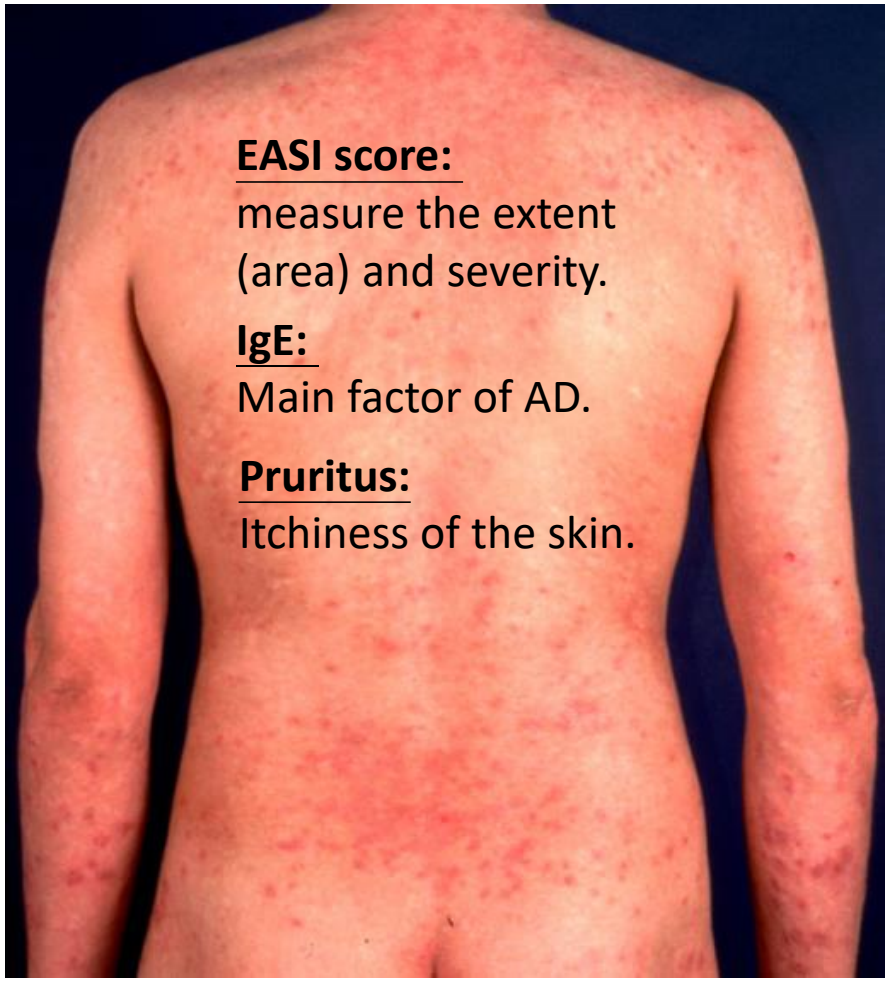
異位性皮膚炎 (AD)



>28 million

全球重度 AD 病人數

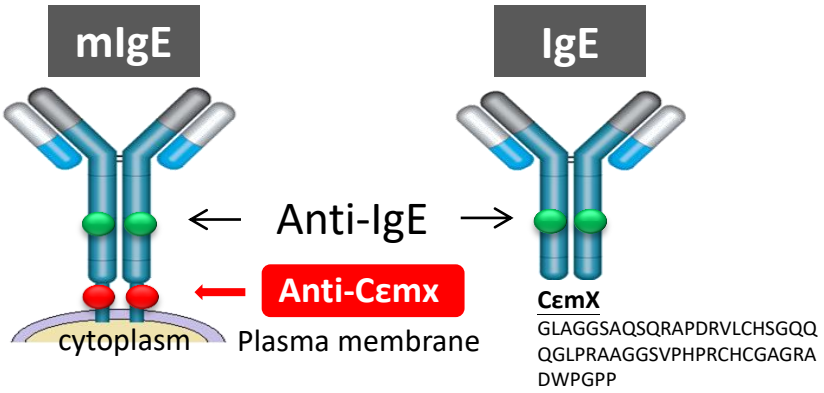
>15.7 million

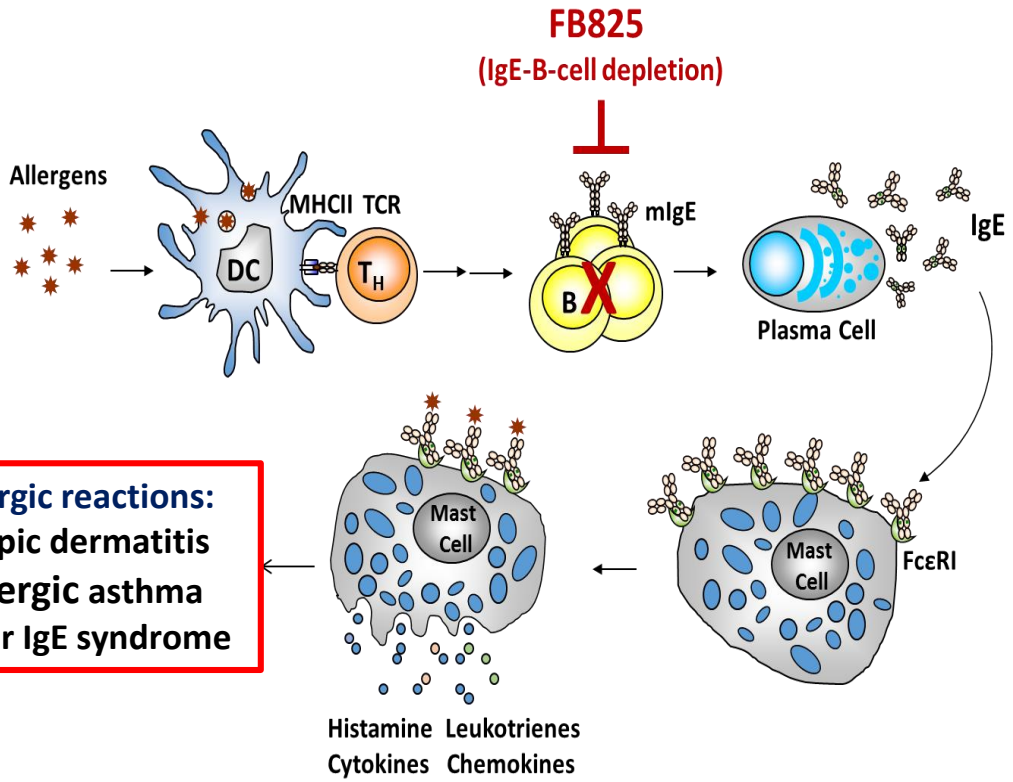
無法有效控制病情人數

>18 billion

未來五年預估市場

FB825 作用機制





- **CεmX 表現在 mIgE B 細胞表面**
- **IgE 與多種過敏性疾病有密切關聯**

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FB825 臨床結果 (IIS)

In 24 weeks (2 doses),

- EASI score reduction by 72%
- IgE level reduction by 46%
- Pruritus reduction by 46%
- AD-related inflammatory cytokines reduced.

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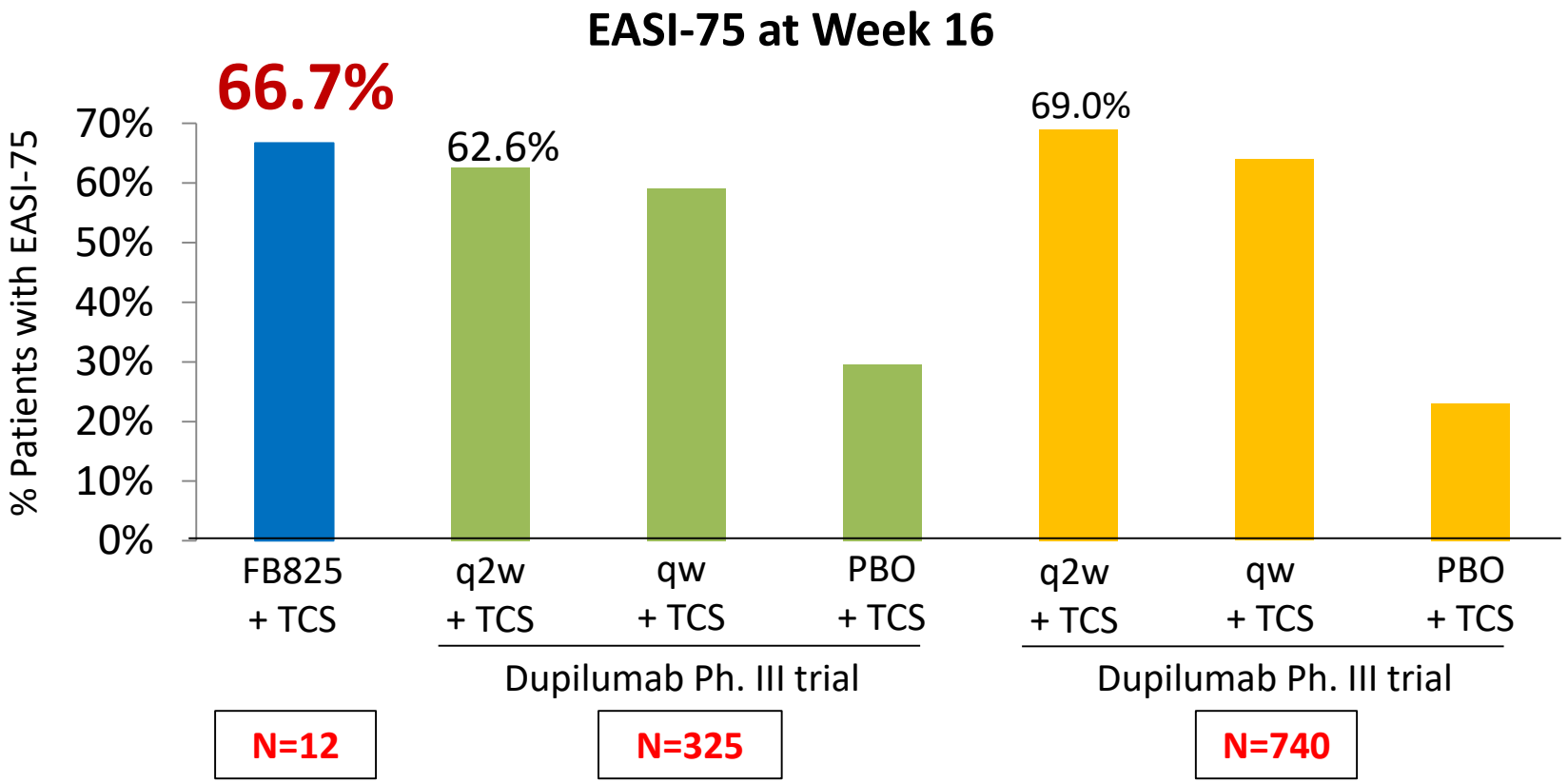
FB825 vs. Dupilumab

Dupilumab (Sanofi)為目前唯一核准 AD 抗體新藥 ，在 2017 年第二季上市，2019 年至第三季銷售金額已達到 US$ 15 億元。



FB825臨床優勢

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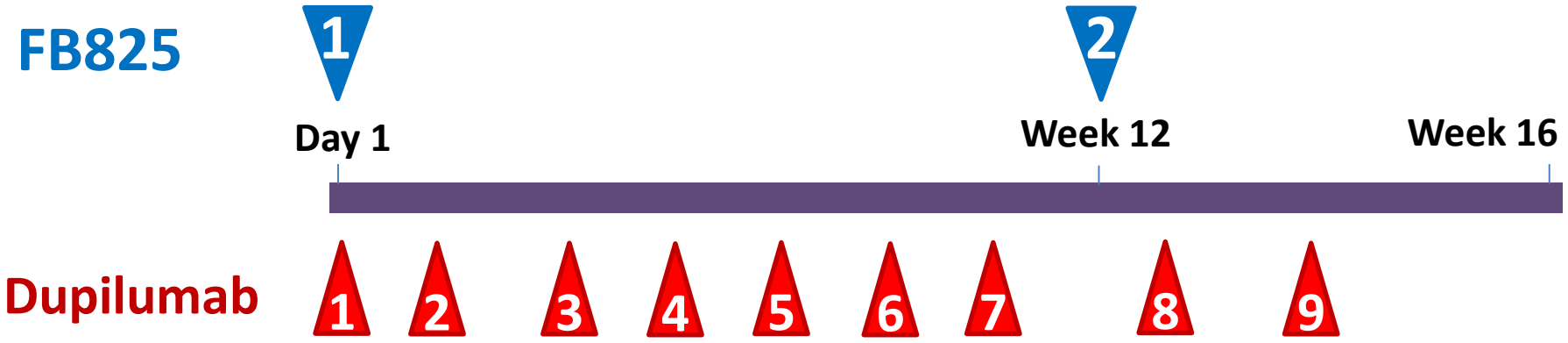
2 劑效果相當於唯一核准上市的 Dupilumab (Sanofi) 9 劑



全新藥物機制

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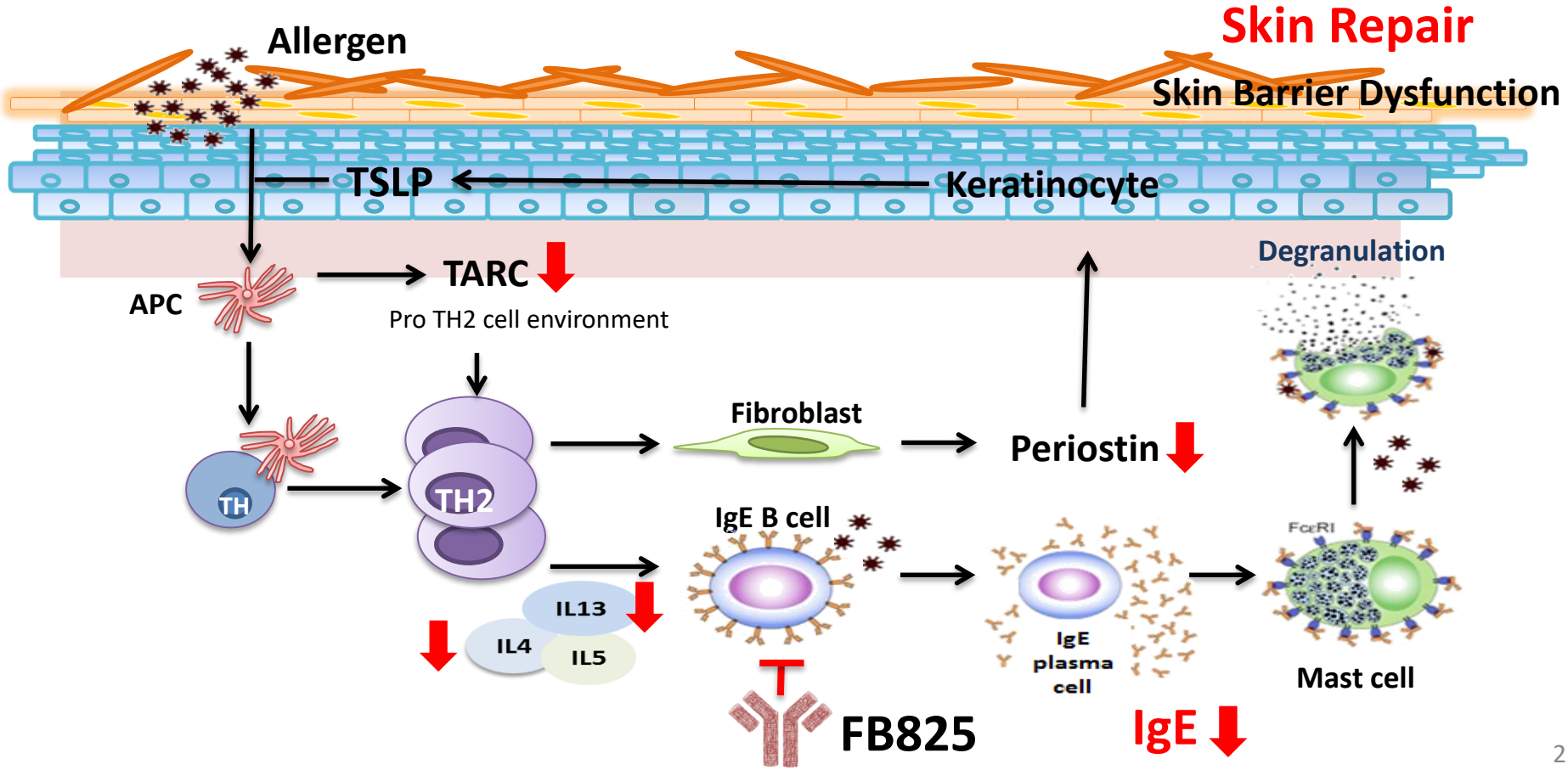
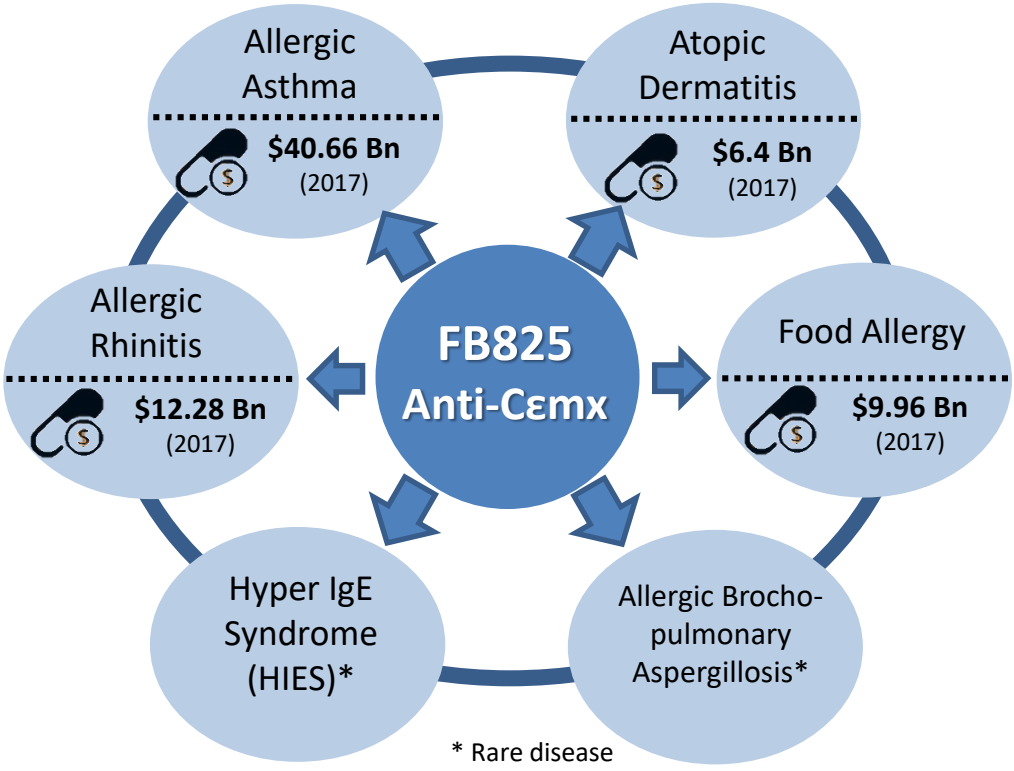


全球唯一治療高 IgE 疾病新藥

- 目前針對高 IgE (>1,500 IU/mL) 疾病之唯一治療藥物
- 針對各種過敏性疾病之長效型抗體沒有臨床顯著副作用，病人依從性佳
- 3% 病人使用 FB825 可創造之市場價值約 US$80億元



FB825 研發計劃

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生產製造

- 美國 CMO 已完成 3 批次cGMP 藥物生產

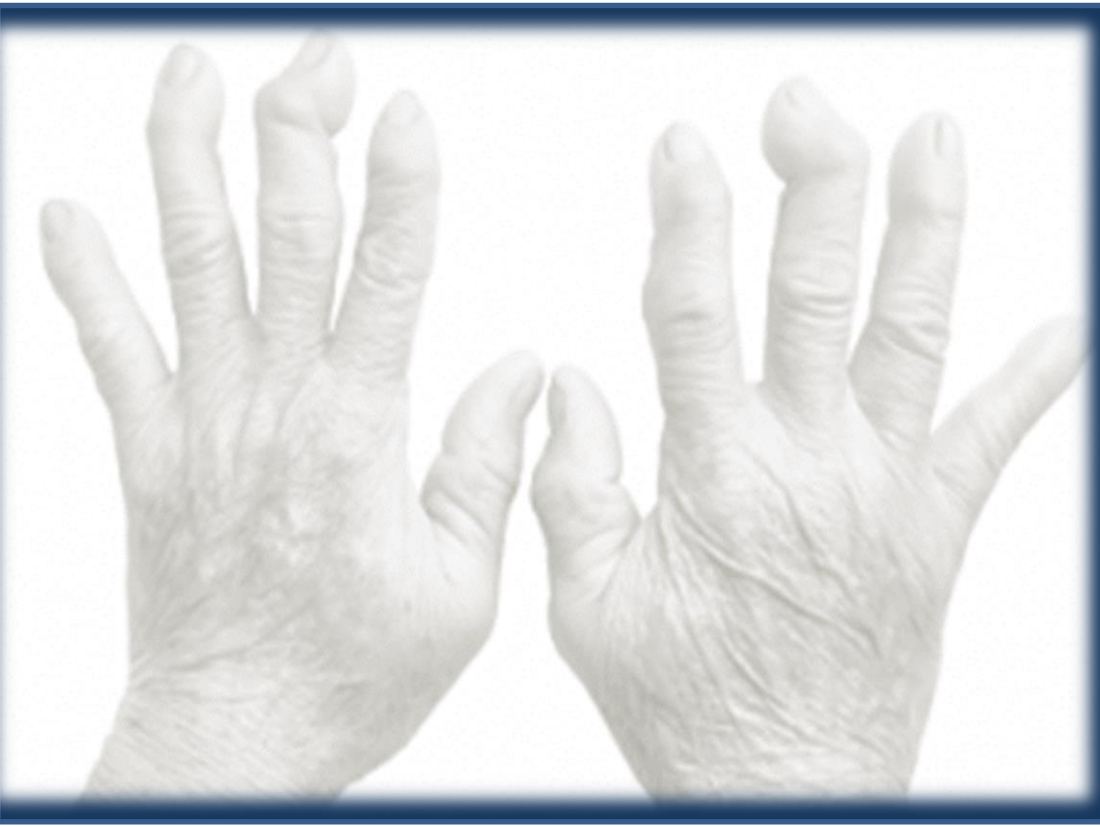
臨床開發

- 於美國 執行異位性皮膚炎二期臨床試驗
- 於中國 進行過敏性氣喘二期臨床試驗

國際佈局發展策略

- 完成探索性試驗， FB825具極佳療效與藥物優勢
- 與國際藥廠積極進行全球授權中

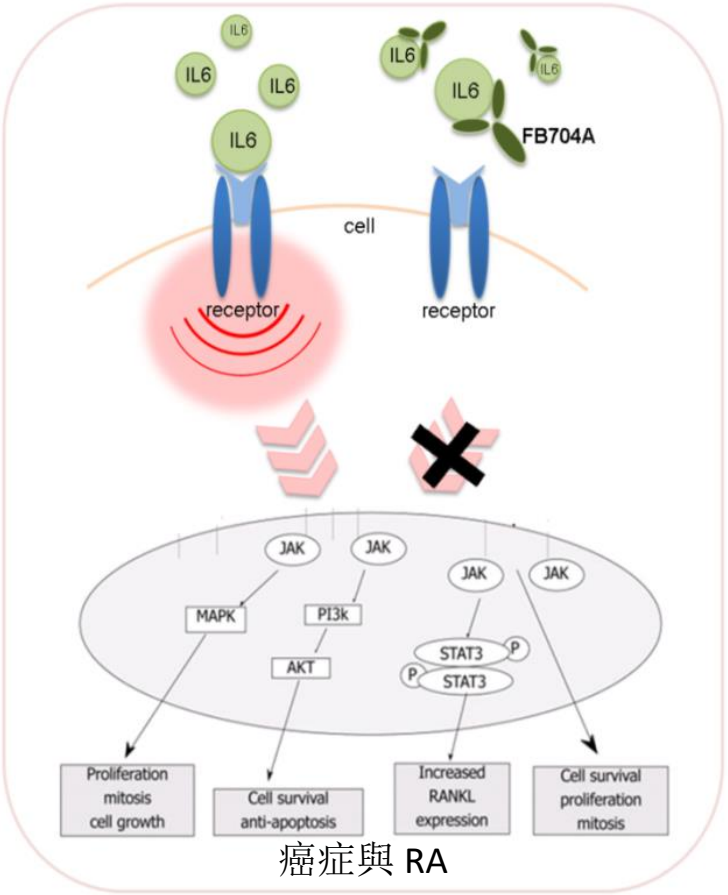
核心新藥-FB704A



抗 IL6 全人單抗新藥

The Best-in-class for RA
(風濕性關節炎)

FB704A 靶點 IL6 相關應用



癌症與 RA

Name	Disease	Targets	Company
Tocilizumab (Approved)	Rheumatoid arthritis Castleman disease Giant cell arteritis	IL-6R	Roche
Siltuximab (Approved)	Castleman disease	IL-6	Janssen
Sarilumab (Approved)	Rheumatoid arthritis	IL-6R	Sanofi
FB704A	**Rheumatoid arthritis Inflammatory Bowel Disease (IBD) (unmet medical need)**	IL-6	Oneness

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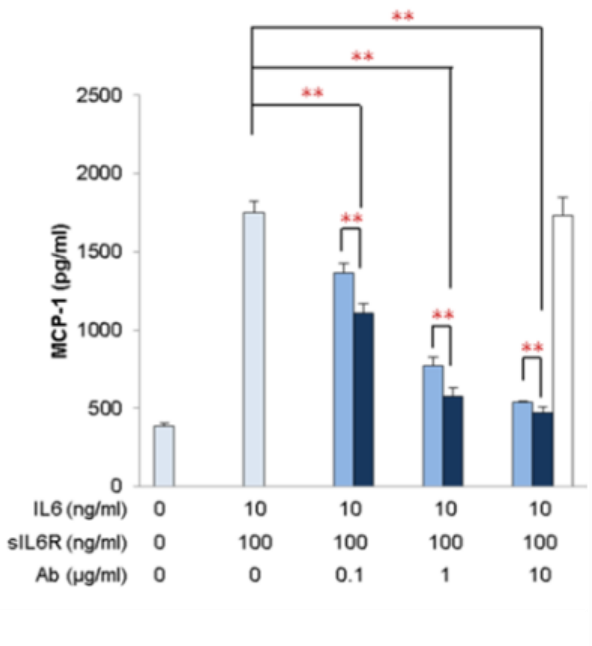
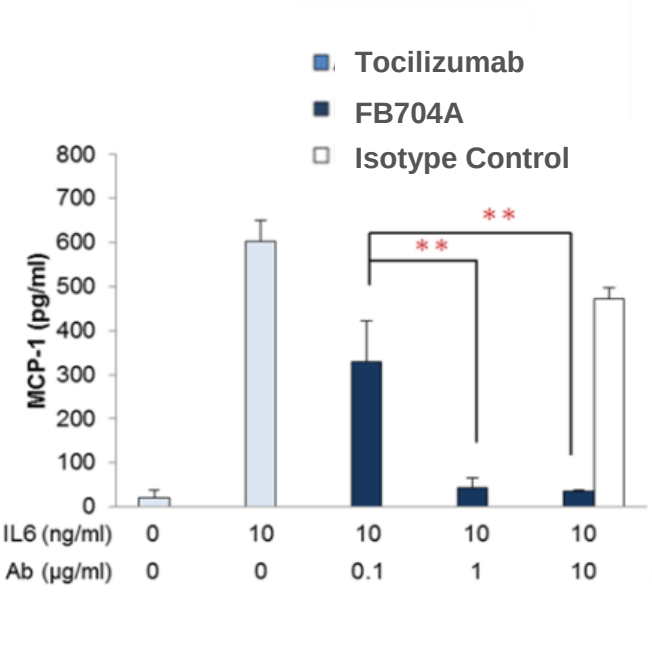
FB704A vs. Tocilizumab (Roche)

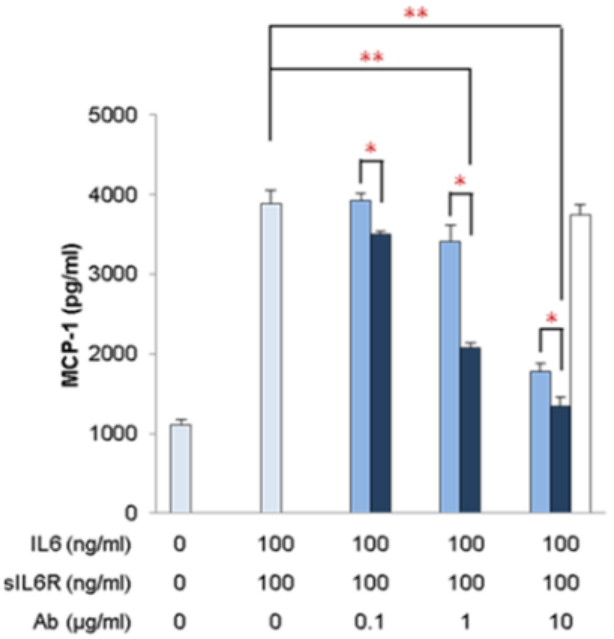
HUVEC cells



Human PBMC



Fibroblast-like synoviocytes (RA-FLS)



FB704A 研發計劃

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生產製造

- 美國 CMO 完成 cGMP 藥物中試生產

臨床開發

- 已於美國完成健康受試者一期臨床試驗
- 於美國 執行類風濕性關節炎一期臨床試驗

國際佈局發展策略

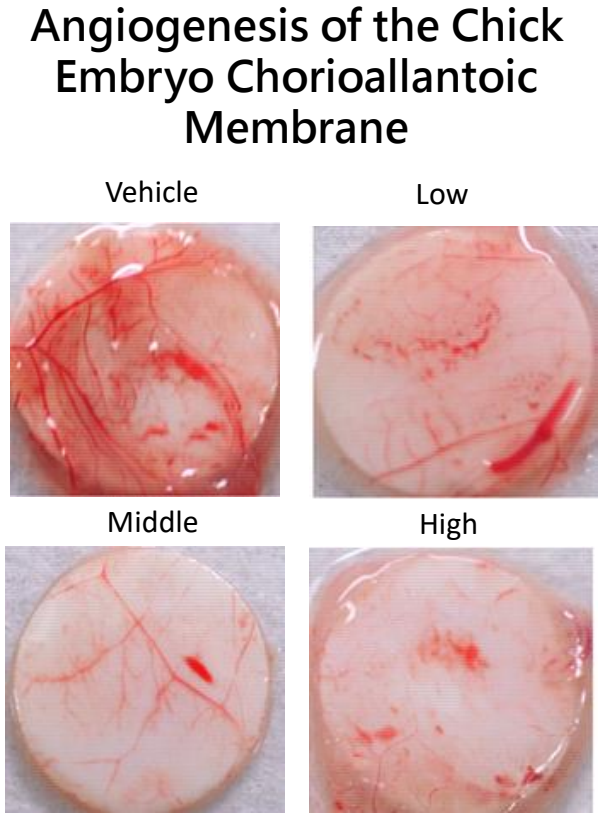
- 完成療效性試驗後，驗證療效與藥物優勢
- 進行國際授權 / 共同開發

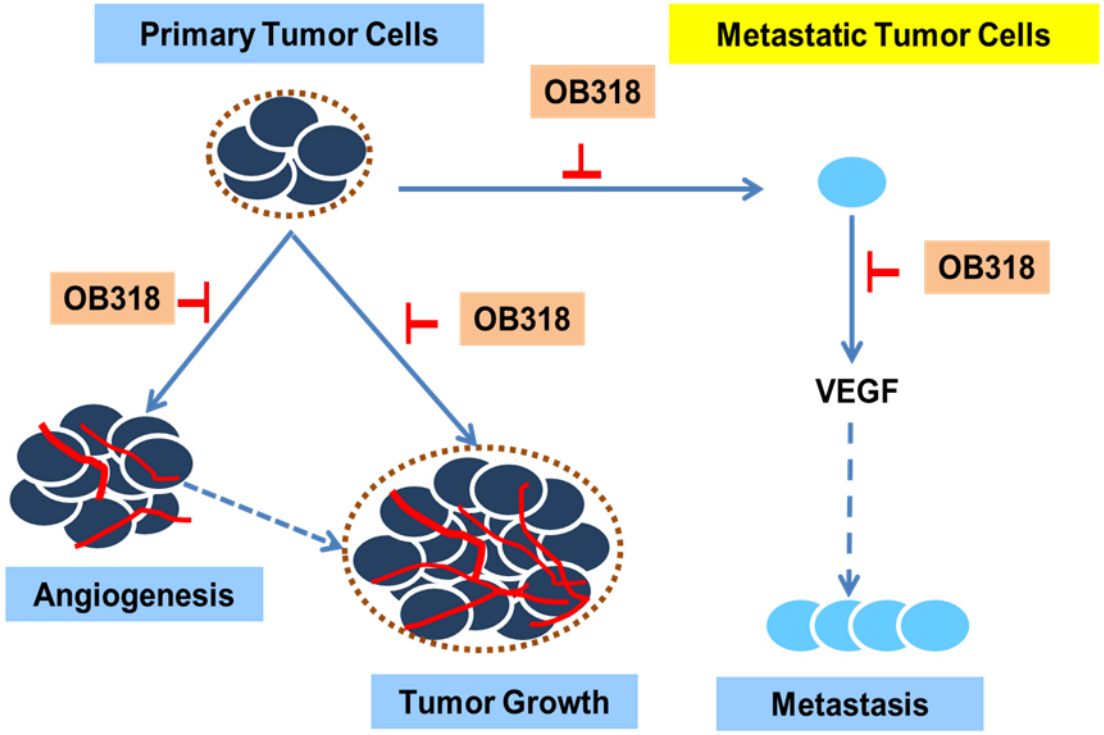
核心新藥-OB318

全球
醫療迫切需求

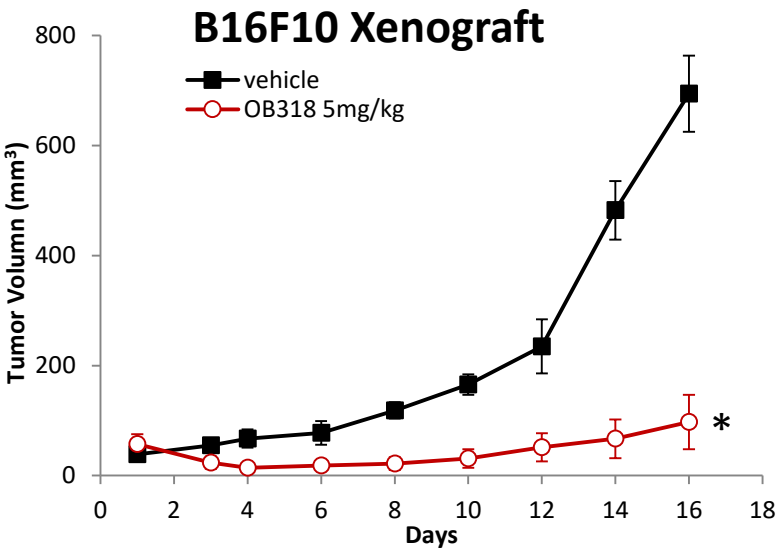
肝癌新藥

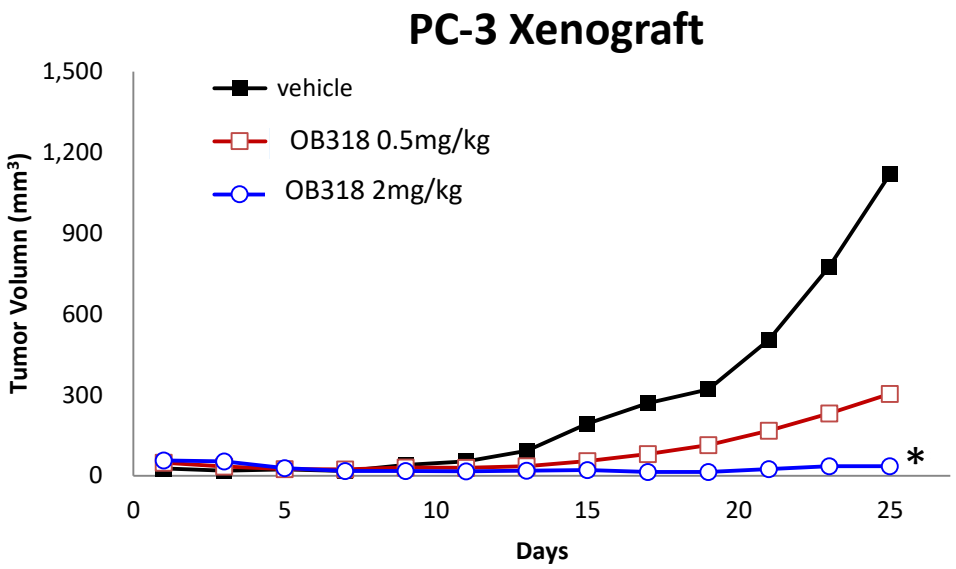
OB318 藥理機制


Angiogenesis of the Chick Embryo Chorioallantoic Membrane
Vehicle
Low
Middle
High


Primary Tumor Cells
Metastatic Tumor Cells
OB318
OB318
OB318
OB318
VEGF
Angiogenesis
Tumor Growth
Metastasis

OB318臨床前動物實驗





OB318 dramatically inhibits the *in vivo* tumor growth of various kind of cancers.

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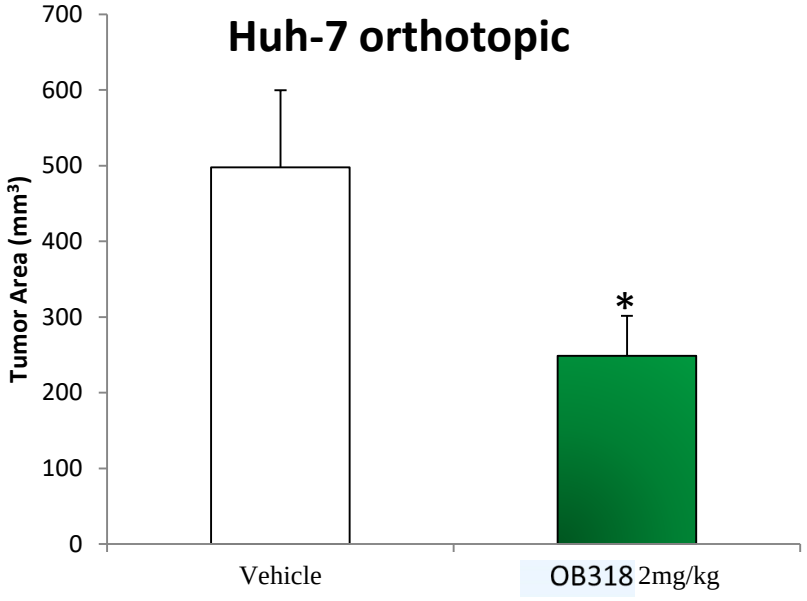
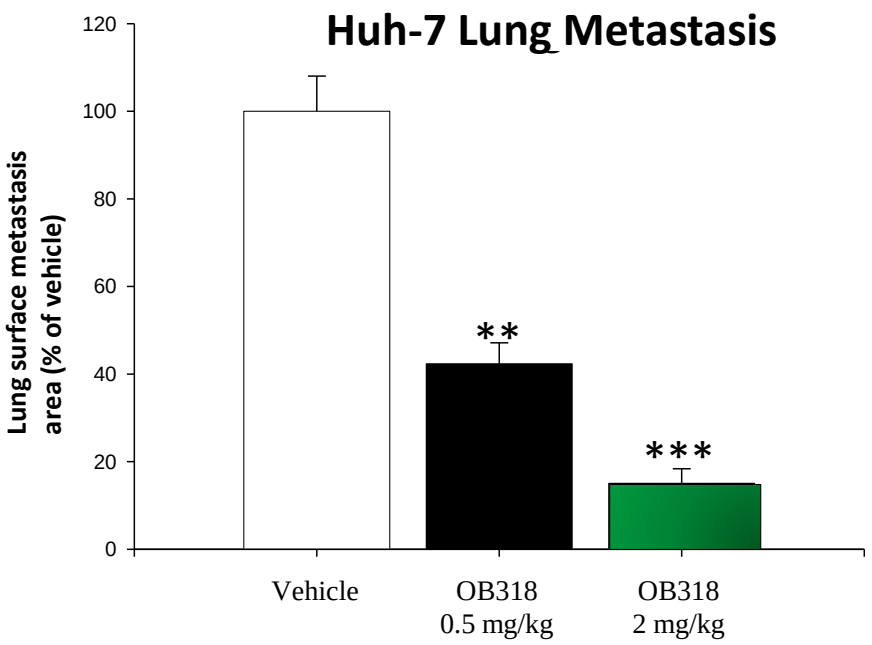
OB318臨床前動物實驗





OB318 inhibits the orthotropic growth of malignant liver cancer that is the most difficult to tackle with among oriental people, and lung metastasis.

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OB318 研發計劃

臨床開發

- 已取得美國以及台灣IND許可
- 完成發酵產量優化及製程控制
- 2020年Q1於美國 執行一期臨床試驗
- 2021年完成療效驗證性試驗後，決定對外授權

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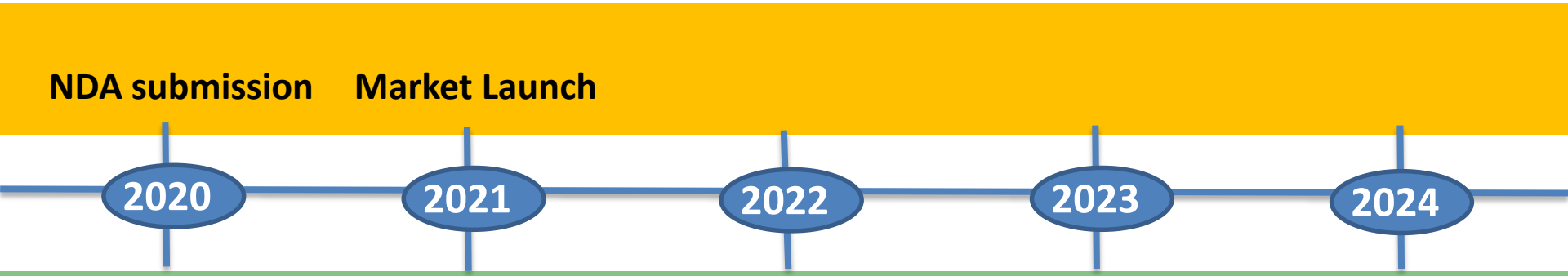
未來五年里程碑



ON101 (Asia)

Market Launch

ON101 (US/EU)

Out-license

FB825 (US/EU)

Out-license

FB704A (US/EU)

Out-license

OB318 (US/Asia)

P2 trial

FB918 (US/EU)

P2a AD (US)

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合一生技股份有限公司

Transformation from Innovation

蛻變的鳳凰