



合一生科技股份有限公司

4743 TW

Science · Integrity · Transparency

Oct 12th, 2021

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Agenda

- Executive Summary & Company Highlight
- Value Creating Pipeline
 - Diabetic Foot Ulcers
 - Chronic Dermatological Disease – Atopic Dermatitis
 - Chronic Immunological Disease – Asthma
 - Viral Infection – SARS-CoV-2
- Important Milestone: 2021-2023
- Our Commitment in ESG
- Financial

Executive Summary & Company Highlight

Executive Summary

- Oneness aim to develop first-in-class new drugs to fulfill unmet medical needs, at the same time to maximize shareholder's value.
- Proprietary diabetic foot ulcer (DFU) new drug *Fespixon* was launched in Taiwan in May 2021, and is expected to launch in China in 2022, globally by 2025
- In April 2020, proprietarily developed monoclonal antibody FB825 for atopic dermatitis (AD) and asthma, licensed out global rights to LEO Pharma for US\$ 530 million
- Our pipelines consists of multiple projects across all clinical stages, targeting chronic dermatological, immunological and infectious diseases. Multiple milestones and approvals will be achieved globally in short-to-mid term.



Company Highlight

- Establishment: 2008
- Ticker: 4743 TT
- Market Cap: US\$ 2.4bn (2021/10/08)
- 155 Employees
- NDA obtained: Taiwan FDA approved DFU new drug ON101 (***FESPIXON***)
- Global Partnership: Antibody new drug FB825 licensed out to LEO Pharma
- Headquarters: Taipei, Taiwan
- Research Site: Nangang, Taipei
- PIC/s GMP certified Manufacturing Site: Pingtung, Taiwan.
- Capacity: 25mn tubes of *Fespixon Cream* /year

Fespixon Cream (Approved)

- Best DFU new drug in 20+ years
- Market exclusivity till 2043
- Clinical trials undergoing for indications expansion
- 10 year leading advantage in global market

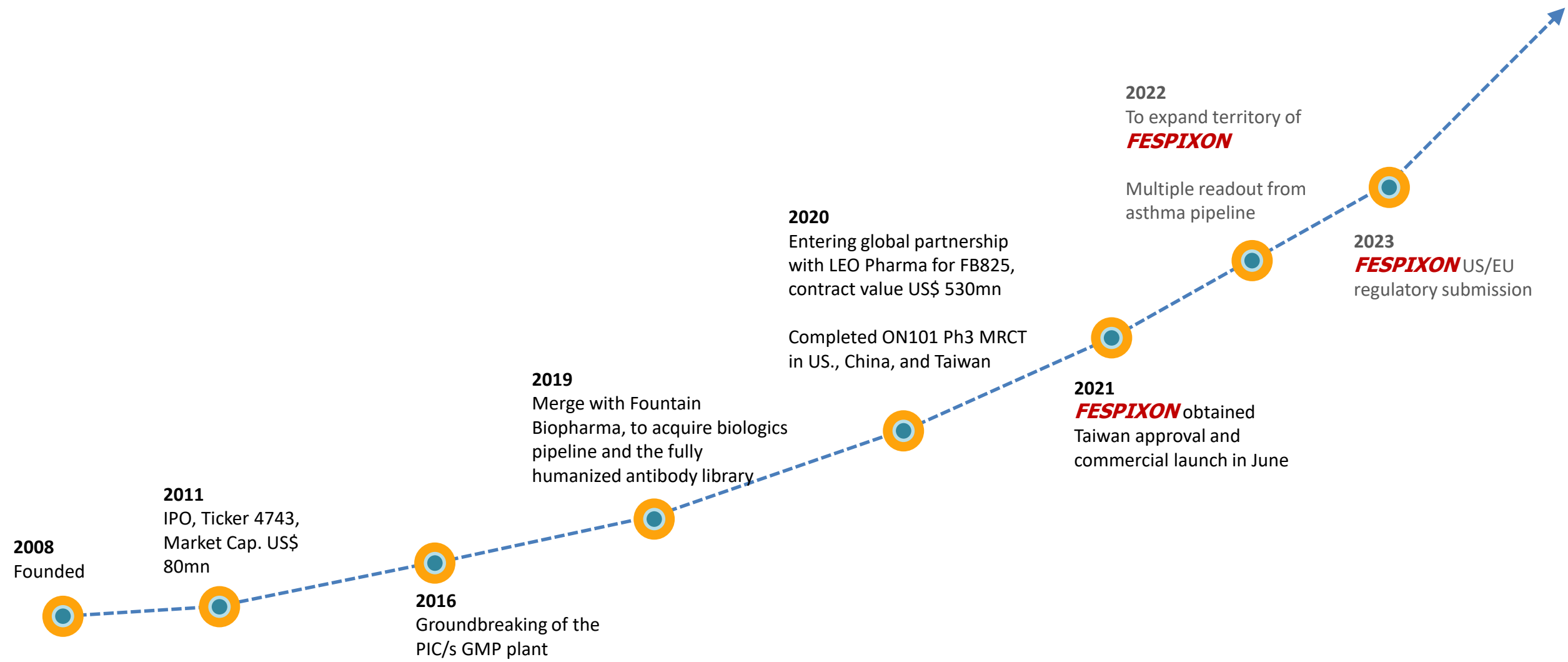
FB825 (out licensed)

- First-in-class mAb for allergic disease
- Successful licensing of \$530MM to LEO pharma
- Comparable efficacy with dosing advantage to current AD blockbuster

Asthma

- First-in-class new drugs: FB825, FB704A & FB918 address 70% Asthma unmet need, including allergic asthma, neutrophilic asthma and eosinophilic non-allergic asthma.

Company Milestones



Our Pipeline

	Product	Target	Category	Patent	Indication	Discovery/ Pre-clinical	Phase 1	Phase 2	Phase 3	Regulatory submission ⁴	Key milestones
Dermatology	<i>FESPIXON</i> (ON101 ¹)	M1/M2 Φ	Botanical	Global	Diabetic Foot Ulcer	Taiwan					2021: APAC launch, US trial initiation 2022: US PIII complete enrollment 2023: Complete US PIII trial
						CN, SG					
						US					
Immunology	FB825 ²	CεmX	mAb	Global with LEO Pharma	Atopic Dermatitis (AD)	US					2021: Initiate Phase IIa study in allergic asthma (AA) 2022: Complete Phase IIa study in AD; Complete Phase IIa study in AA
					Allergic Asthma (AA)	Taiwan, US IND					
	FB704A	IL-6	mAb	Global	Neutrophilic Asthma	Taiwan, US IND					2022: Complete Phase II trial
					Chronic Kidney Disease						
	OB318	Multiple	NCE	Global	Hepatocellular carcinoma ³	Taiwan, US IND					2022: Complete Phase I study
	FB918	IL-33	mAb	Global	Non-allergic eosinophilic asthma						2023 IND filing
Infection	SNS812	Virus	Nucleic Acid	Global with MBS	COV-Flu						

¹ON101 is approved by TFDA for Diabetic Foot Ulcer, product launch in May 2021, while pre-NDA meeting has been held with the NMPA. We aim to submit China NDA by the end of 2020. ON101 can potentially be used for treatment of venous leg ulcers and pressure ulcers in the future. ² China right has been licensed to Microbio Shanghai ³ Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer ⁴ Regulatory submission includes NDA submission and pre-NDA submission. AD: atopic dermatitis; AA: allergic asthma

Diabetic Foot Ulcers – ***FESPIXON*** (ON101)

Best new drug approved for diabetic foot ulcers in 20+ years

Diabetic Foot Ulcers

Importance of diabetic foot ulcers

- Diabetic foot Ulcer (DFU) is the leading cause to disability and death of diabetes mellitus patients.
- There are 30mn DFU patients worldwide, it is expected the DFU population will exceed 40mn by 2037. The disease is causing > US\$100bn medical burden globally, with an estimation of over US\$ 20bn in immediate medicine/treatment needs.
- DFU is the most expensive treatment among diabetes mellitus complications, almost as expensive as cancer treatments
- Every 20 seconds, a lower limb amputation is processed on diabetes mellitus patients due to lack of effective treatment for DFU wound care.
- The 5-year survival of DFU amputees is less than 60%

Current treatment and unmet needs

- Most of the DFU treatments are physical therapy, which are including negative pressure wound therapy and hyperbaric oxygen therapy
- Patients can also choose a Aquacel® Hydrofiber® Dressing or bioengineered tissue for wound care
- However, none of the above-mentioned treatments is recommended by international treatment guidelines
- There have been no new drugs approved by the US FDA for 20+ yrs. Phase 3 trials under FDA's IND were with no success. Due to the global unmet medical needs and life threatening illness of DFU, **FESPIXON** has received fast track designation from the US FDA

Mechanism of the disease

- Hyperglycemia causes dermatological immunopathy on DM patients
- Immunity issue triggers imbalanced M1/M2 Φ in diabetic skin
- Tissue damage cases excessive M1 Φ in the lesion & prolongs inflammation stage
- Chronic inflammation delays M1/M2 Φ transition & stalls wound healing

FESPIXON (ON101) – the Best Treatment for DFU

- Approved first-in-class and best new drug for DFU, can reduce healing period to improve life quality for DFU patients
- Global clinical trial data suggests **FESPIXON** can significantly improve wound closure in a wide range of categories of patients, and largely reduce cost of current care of DFU patients.
- Comprehensive patent protection through 2038, plus 5 years extension after approval. Oneness has exclusive know-how in extraction methods and exclusive control of API
- Our PIC/s GMP manufacturing facility in Pingtung, Taiwan is ready for global supply (25M tubes/yr)



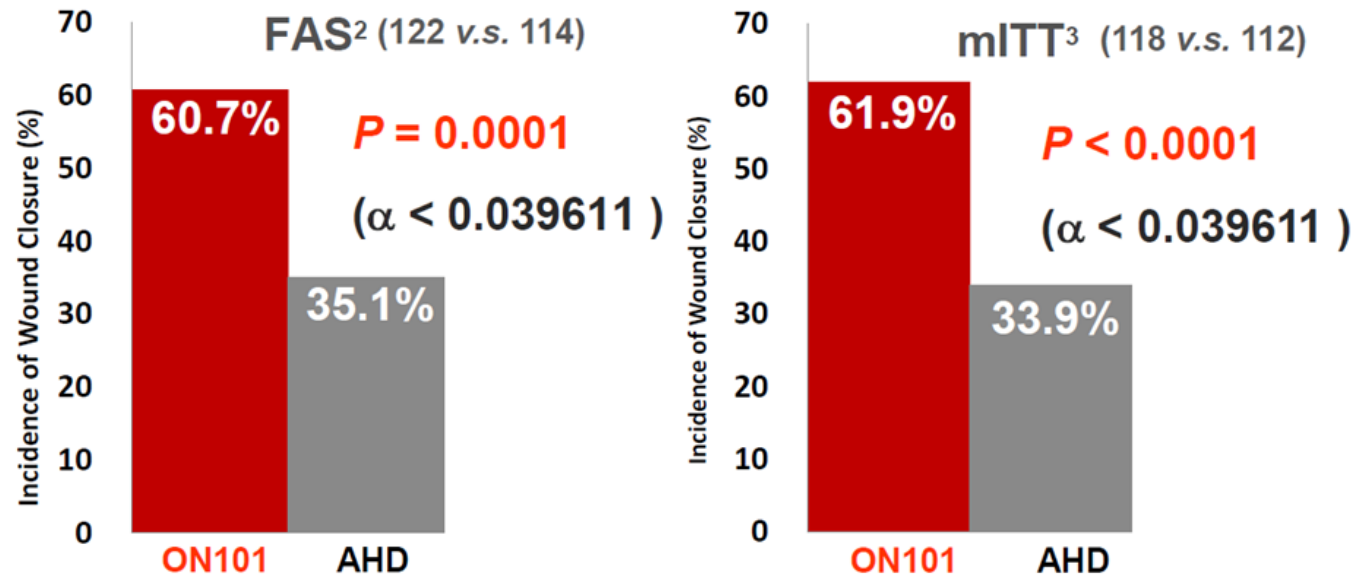
FESPIXON Phase III MRCT (US, CN, TW) Results

Fespixon stands out in both primary and secondary endpoint

Primary endpoint

Incidence of Wound Closure (16 wks)¹

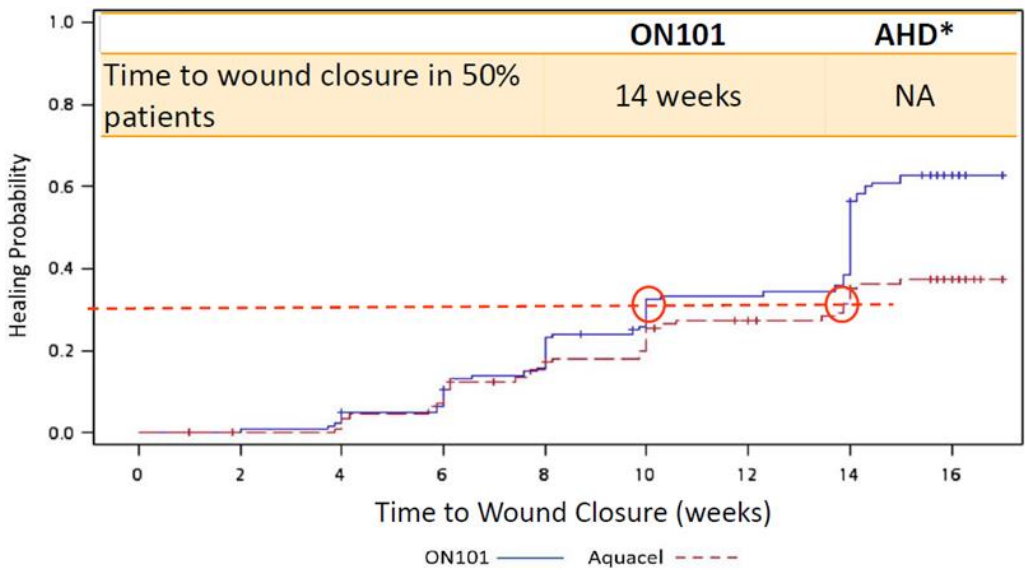
ON101 v.s. AHD*



Secondary endpoint

Time to Wound Closure (FAS)

Hazard Ratio 1.80 | 95% CI 1.23-2.65 | $P=0.002$



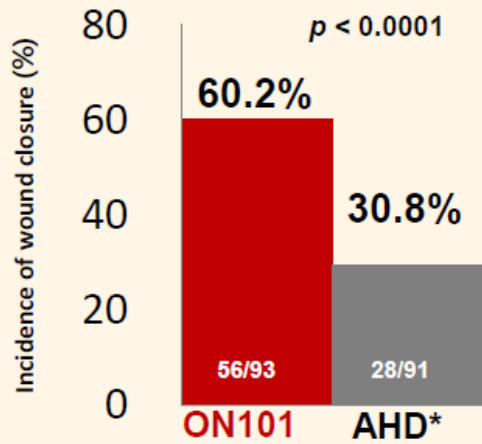
¹ wound closure: Per US FDA guidance, complete reepithelization without drainage or requirement of dressing for consecutive 2 weeks.

AHD*: Aquacel® Hydrofiber® Dressing

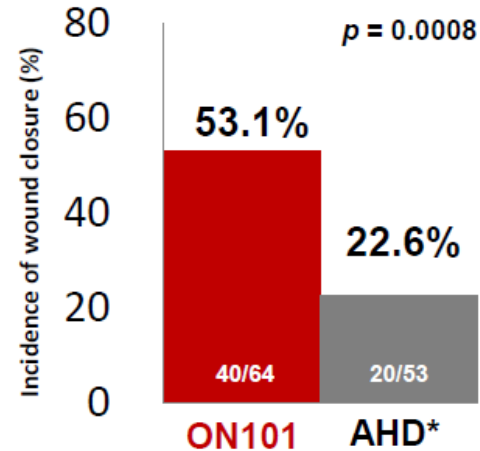
² Full analysis set | ³ Modified intention to treat

Robust Efficacy Across Hard-to-heal Ulcers (FAS)

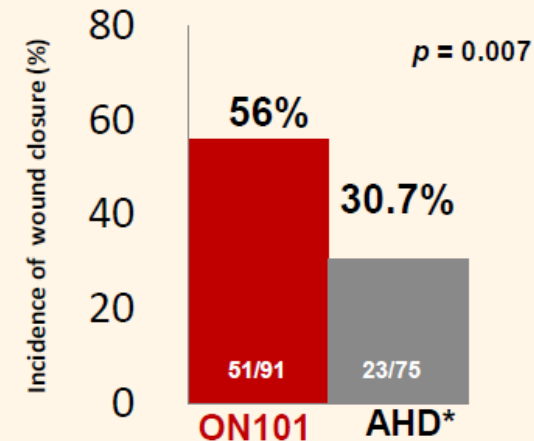
Wagner Grade 2 Wounds



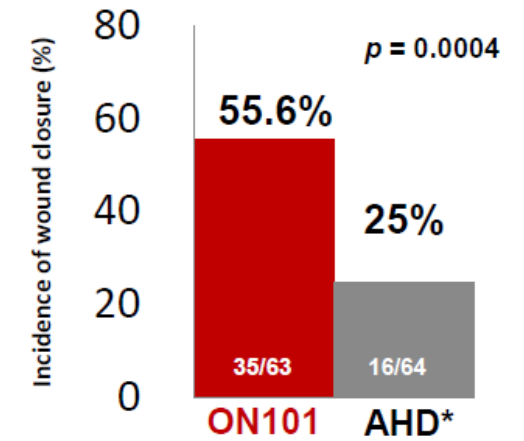
Plantar Wounds



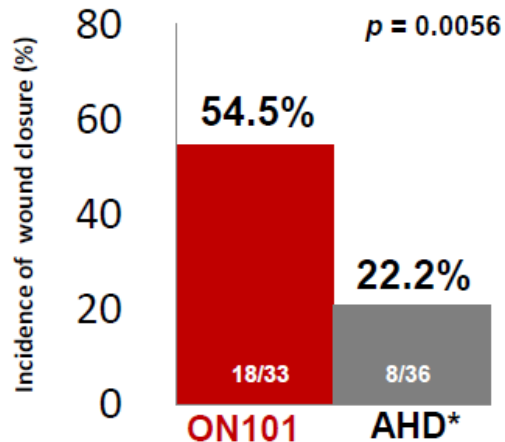
HbA_{1c} >7%



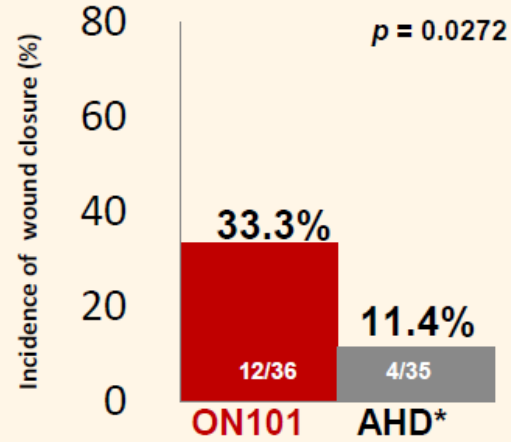
BMI ≥ 25



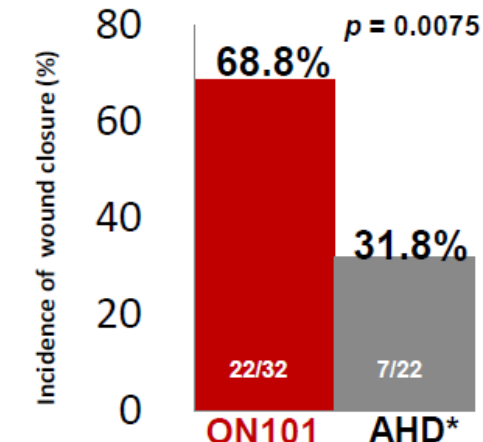
> 5 cm² Wounds



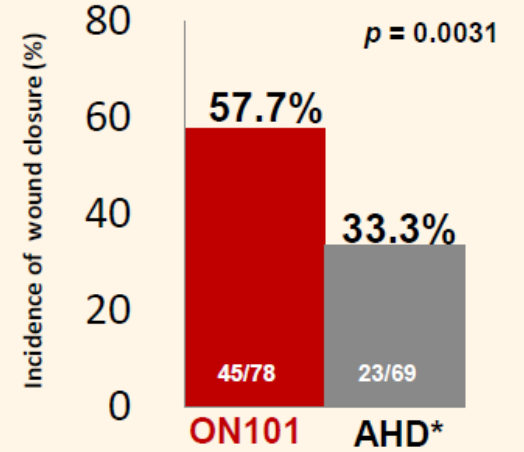
≥ 6 m Duration



Current Smokers

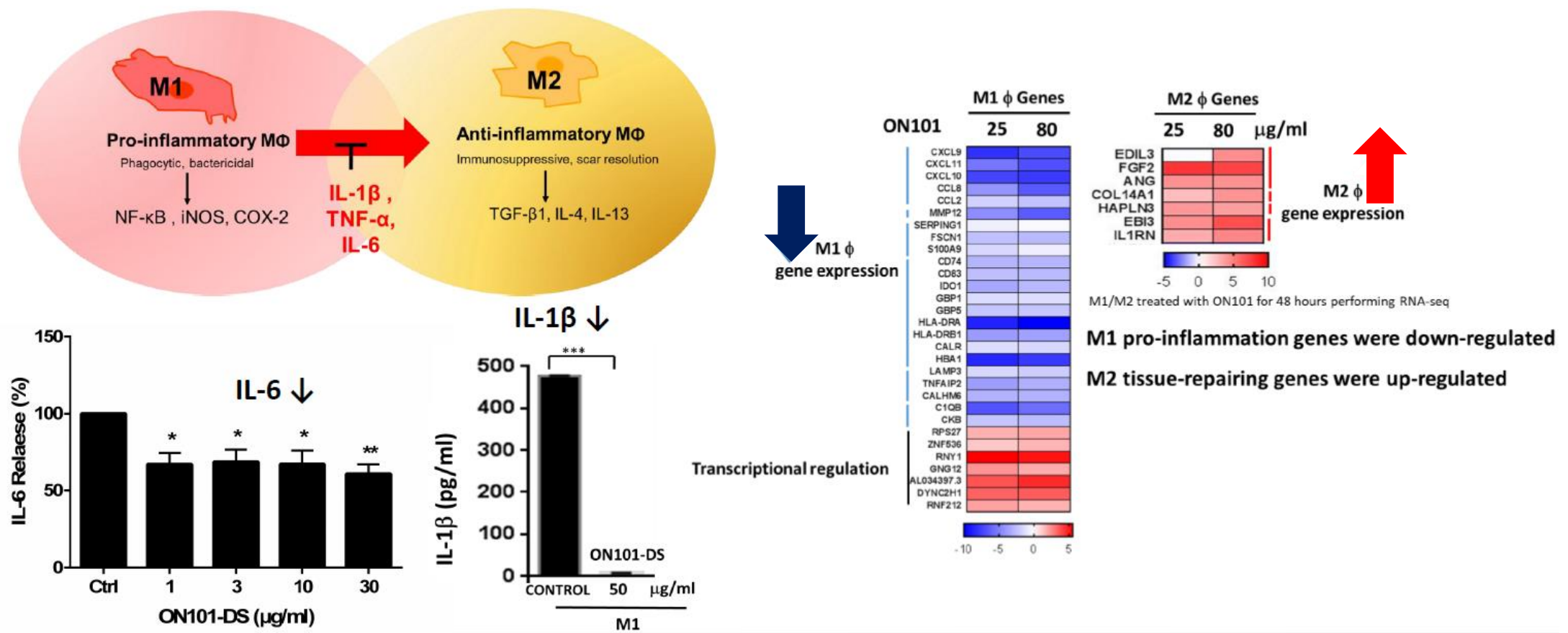


Neuropathy



MOA – First-in-class New Drug to Resolve DFU Chronicity

ON101 Treatment Suppressed M1 Φ and Activated M2 Φ



Competitive for Global Market

Product					
Category	New Drug	New Drug PDGF	Medical Device	Medical Device	Medical Device Bioengineered Tissue
Treatment	2-5 tubes	3 tubes	10-20 sessions	20-80 sessions	~ 6 grafts
Unit Price (USD)	\$300 – 600 (TBD) /15g/tube	\$1,200 /15g/tube	\$200 /session	\$250 /session	\$1,600 /graft/25cm2
Per Treatment Cycle Cost (USD)	\$600-3,000 (TBD)	\$3,600	\$2,000-4,000	\$5,000-20,000	\$1,600-9,600
Usage/Storage	Home use Room temp.	Home use 2°C-8°C	Home/ Hospital use Consumables	Hospital Use 90mins/session	Hospital Use -75°C ± 10°C

FESPIXON Can Reduce > 60% Annual Cost for DFU Care

Ulcer Size	Est. Healing time	Tube #	Daily expenditure (NTD)
≤ 2cm ²	64 days	2	306
2-3 cm ²	73 days	3	403
3-4 cm ²	75 days	4	523
4-5 cm ²	80 days	5	613
5-10 cm ²	80 days	7	858

- A 15-year follow-up study published on *Diabetes Care* 2020 has calculated medical costs in treat diabetic foot ulcers in Taiwan and found the average annual cost per DFU is approximately NT\$ 141,000
- Taking the median number of tube consumption of **FESPIXON** per patient, a treatment course of **FESPIXON** is approximately NT\$ 49,000, which comparatively heal the ulcers faster to avoid ulcer progression as well as reduce at least 60% medical burden
- Our first launch in Taiwan is expected to improve access to treatment and effectively lower medical burden in patient community and society

FESPIXON Channel Penetration in Taiwan

	Contracted Pharmacy	Passed through the Pharmacy & Therapeutics Committee	Collaborations
Medical Center	21	7	21
Regional Hospital	75	5	75
Local Hospital	65	3	65
Clinic/ Pharmacy			198
	Total		359

	Cumulative collaborations	Growth Rate
Jun	164	
Jul	263	+60%
Aug	336	+28%
Sep	359	+7%

The World Discovers **FESPIXON**

JAMA Network | **Open**



Original Investigation | Diabetes and Endocrinology

Effect of a Novel Macrophage-Regulating Drug on Wound Healing in Patients With Diabetic Foot Ulcers A Randomized Clinical Trial

Yu-Yao Huang, MD, PhD; Ching-Wen Lin, PhD; Nai-Chen Cheng, MD, PhD; Shawn M. Cazzell, DPM; Hsin-Han Chen, MD; Kuo-Feng Huang, MD; Kwang-Yi Tung, MD; Hsuan-Li Huang, MD; Pao-Yuan Lin, MD; Cheng-Kang Perng, MD, PhD; Bimin Shi, MD; Chang Liu, MD; Yujin Ma, MD; Yemin Cao, MD; Yanbing Li, MD; Yaoming Xue, MD; Li Yan, MD; Qiu Li, MD; Guang Ning, MD, PhD; Shun-Cheng Chang, MD

Abstract

IMPORTANCE Delayed healing of diabetic foot ulcers (DFUs) is known to be caused by dysregulated M1/M2-type macrophages, and restoring the balance between these macrophage types plays a critical role in healing. However, drugs used to regulate M1/M2 macrophages have not yet been studied in large randomized clinical trials.

OBJECTIVE To compare the topical application of ON101 (Hydrofiber; ConvaTec Ltd) when treating

DESIGN, SETTING, AND PARTICIPANTS A clinical trial was performed in 21 clinical sites from November 23, 2012, to May 11, 2020. Eligible patients had DFUs for at least 4 weeks and with Wagner grade 1 or 2 ulcers.

INTERVENTIONS Twice-daily application of ON101 or standard care dressing for 16 weeks, with a 12-week follow-up.

Key Points

Question Can the topical application of ON101 cream demonstrate a superior therapeutic benefit in wound healing among patients with diabetic foot ulcers (DFUs) compared with standard care?

DFU New Drug approved by Taiwan FDA (March 2021)
US Fast Track designation granted (March 2021)



Ph3 MRCT with 236 subjects demonstrated the efficacy of ON101 ($P=0.0001$)

ON101 (trade name: Fespixon) is a topical new drug with macrophage regulation novel mechanism for treating diabetic foot ulcers. A Ph3 MRCT was completed with 60.7% wound closure incidence in the ON101 treatment group in 16 weeks versus 35.1% in the comparator, a standard care dressing.

ON101 can be accessed via the Expanded Access Program (EAP) under IND 079526 in the US. A licensed physician may inquire by contacting this email: EAPrequest@onenessbio.com.tw



ONENESS www.onenessbio.com.tw/en EAPrequest@onenessbio.com.tw
Breakthrough for unmet need 11F, No.236, Sec. 4, XinYi Rd., Da'an Dist., Taipei 106, Taiwan, R.O.C.

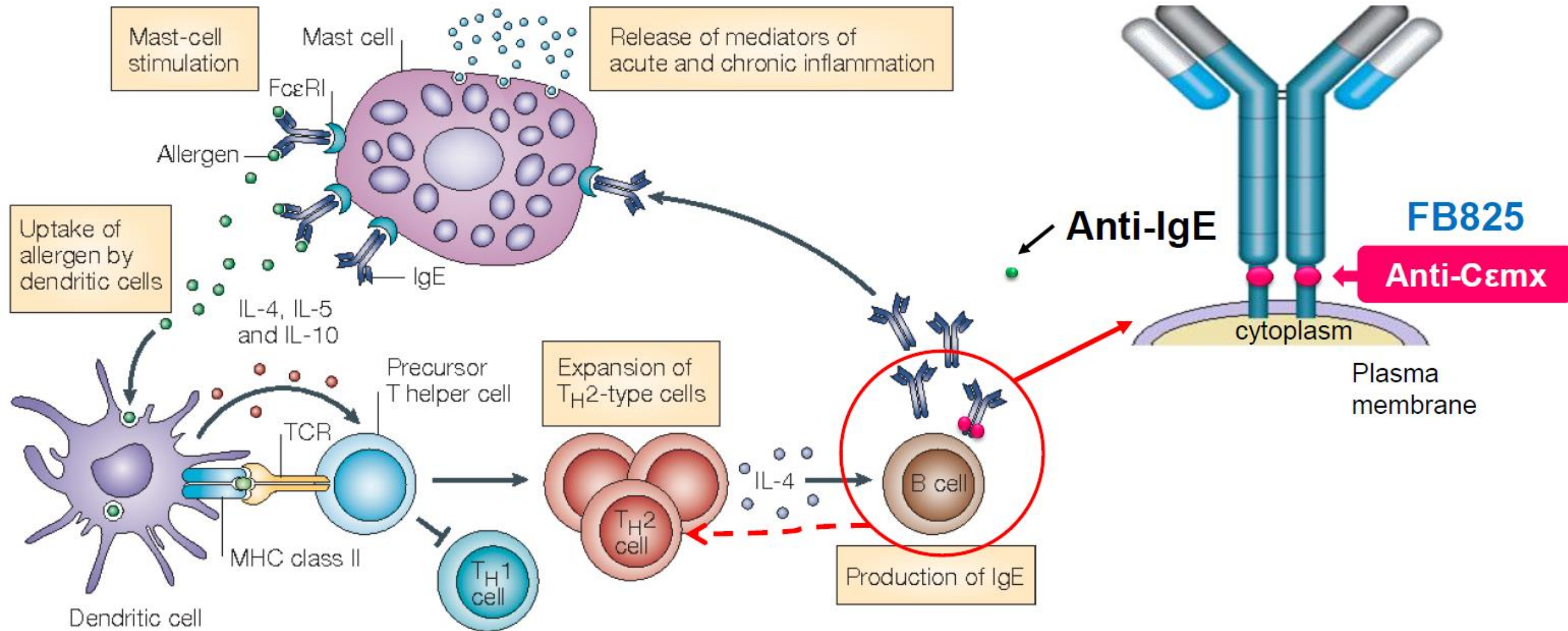
- The company published the Phase III trial data of **FESPIXON** in the JAMA Network Open on 3rd Sept, 2021. Two follow on articles to discuss the findings of the MOA will be published in top notch journals in the following months.
- Designed the Exceptional Access Program (EAP) commercials on the 2021 Sep/Oct issue of the Journal of the American Podiatric Medical Association, targeting 14,000 subscribed members of the journal.
- Initiated “Named Patient Program” in EU, UK, Russia, South America, North Africa and Middle East, from Sep, 2021.

Atopic Dermatitis – FB825

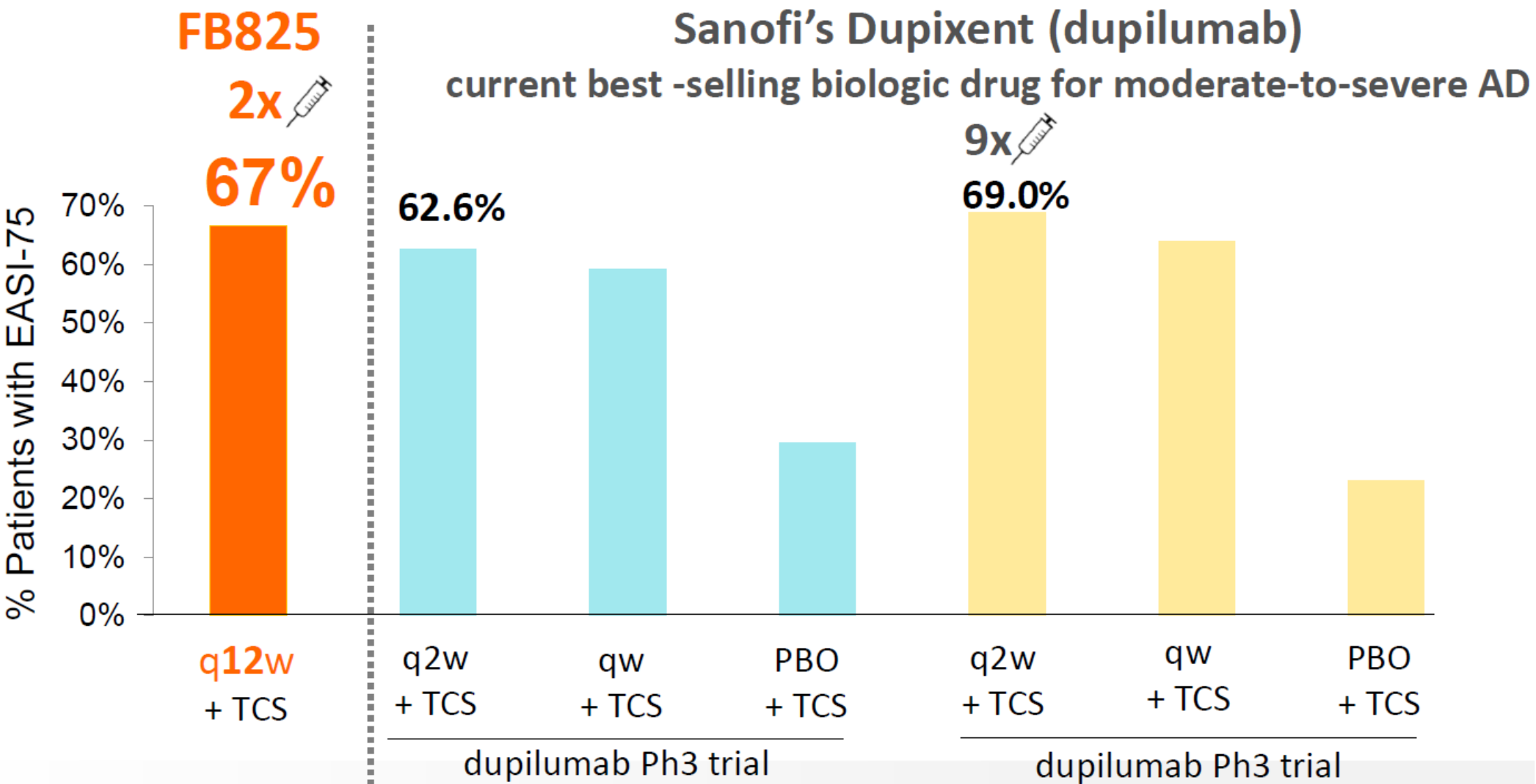
Global Partnership with LEO Pharma, contract value US\$ 530mn

*“Having seen the first-in-human data of FB825 and the reduction in Eczema Area and Severity Index scores (an indicator of AD severity), we feel that we are welcoming **a promising novel drug candidate** into our development pipeline” – Executive Vice President, Global Research & Development, LEO Pharma*

Promising Biologic for Allergic Disease – AD and Asthma



Efficacy vs Dupixent



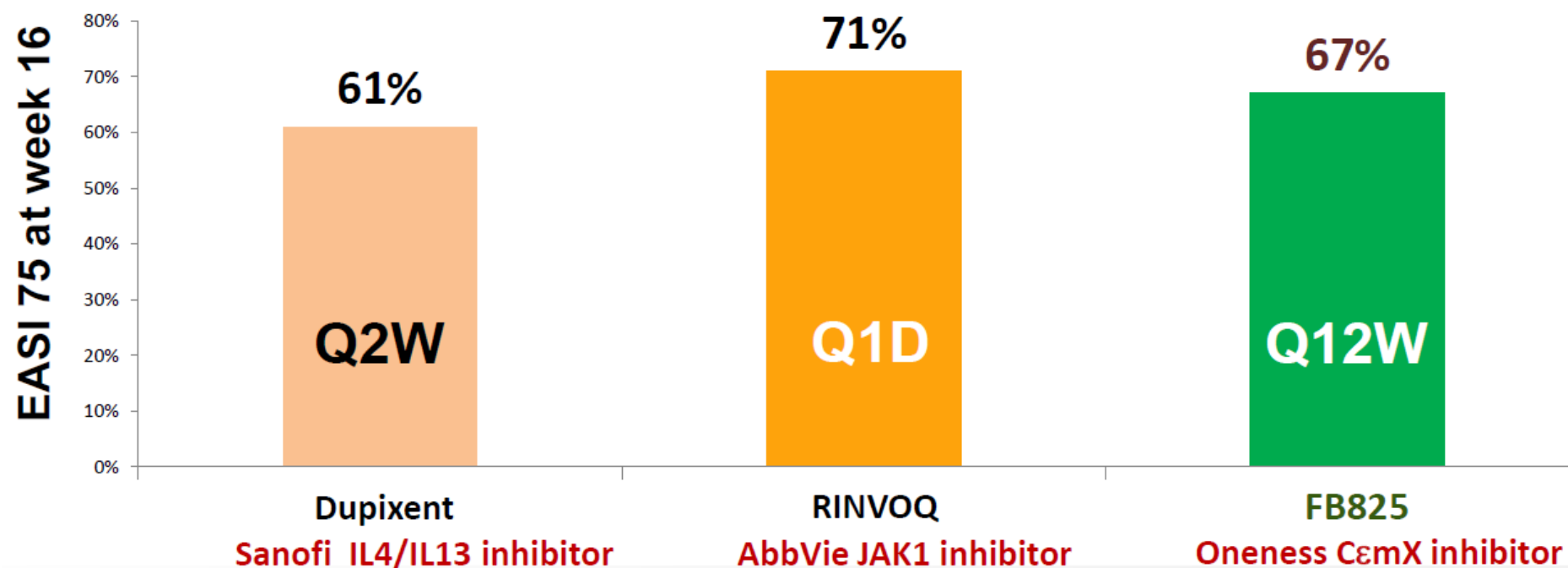
Comparison between trials: FB825 first-patient trial (NCT0358716) vs. 2 Phase III trial of Dupixent

Advantage among Global Competitors

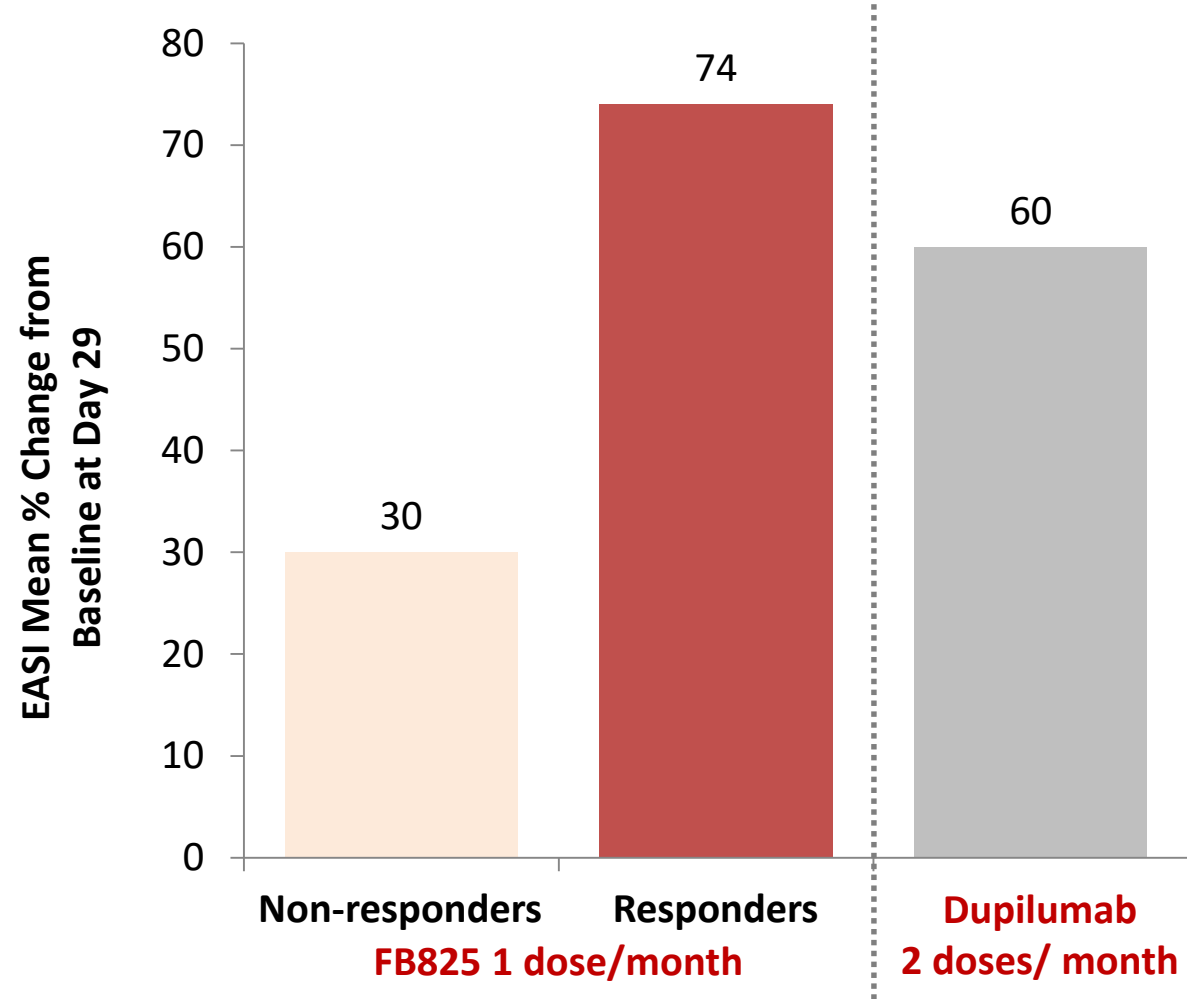
FB825 vs

AbbVie JAK1 inhibitor (RINVOQ)

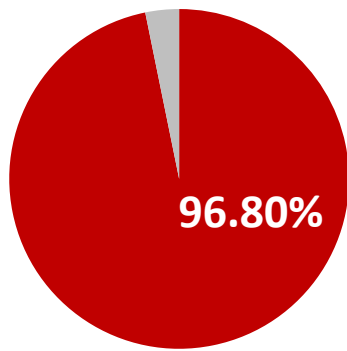
Sanofi IL4/IL13 inhibitor (Dupixent)



FB825 – AD Biomarker Ensures Outperforming Efficacy



**96.8% of US Ph IIa Study
Responders carry biomarker**



- Oneness is analyzing FB825 response related biomarkers
- The biomarkers will further improve the efficacy of FB825

Superior Treatment to Blockbusters

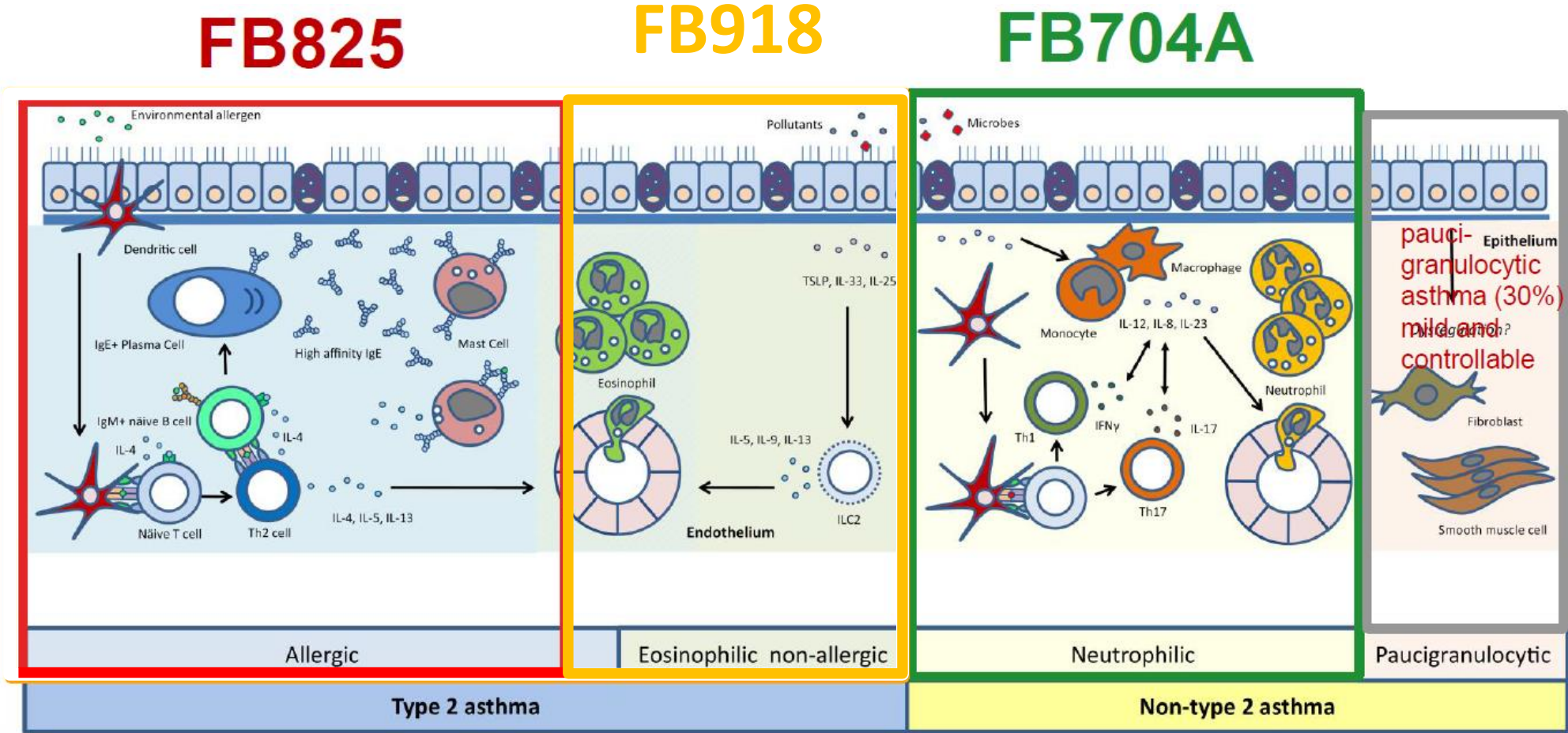
Product	FB825 	Dupixent 	RINVOQ 
Indication	Atopic dermatitis, Asthma	Atopic dermatitis, Asthma	Rheumatoid arthritis, Atopic dermatitis
Administration	SC	SC	Oral
Dose	13 doses/ year (every 4 weeks)	26 doses / year (every 2 weeks)	365 tablets / year (daily dose)
Side effect	No major side effects	Allergic reactions/ eye problems Blood vessel inflammation Cold sores	Common side effects: nausea, headache, and chest infections. Black-box Warning: “increased risk of serious infections, malignancy, and thrombosis”
Cost	N/A	US\$ 1,555 / dose US\$ 40,430 / year	US\$ 59,860 / year (upadacitinib’s annual list price for RA ¹)
Target	C&mX	IL-4Ra	JAK1
2020 Global sales	N/A	US\$ 3.5bn (AD approved in 2017, Asthma approved in 2018)	US\$ 0.7bn (RA only, approved in 2019)

¹ [https:// icer.org/news-insights/press-releases/jak_inhibitor_evidence_report](https://icer.org/news-insights/press-releases/jak_inhibitor_evidence_report)

Asthma – FB825/ FB704A/ FB918

Most comprehensive pipeline to cover 70% of asthma types

Oneness' Asthma Pipeline Addresses 70% Asthma Types



Source: Allergy 2018, 73:2290-2305; Respiriology 2006, 11:54-61

FB825 for Allergic Asthma

Rationale

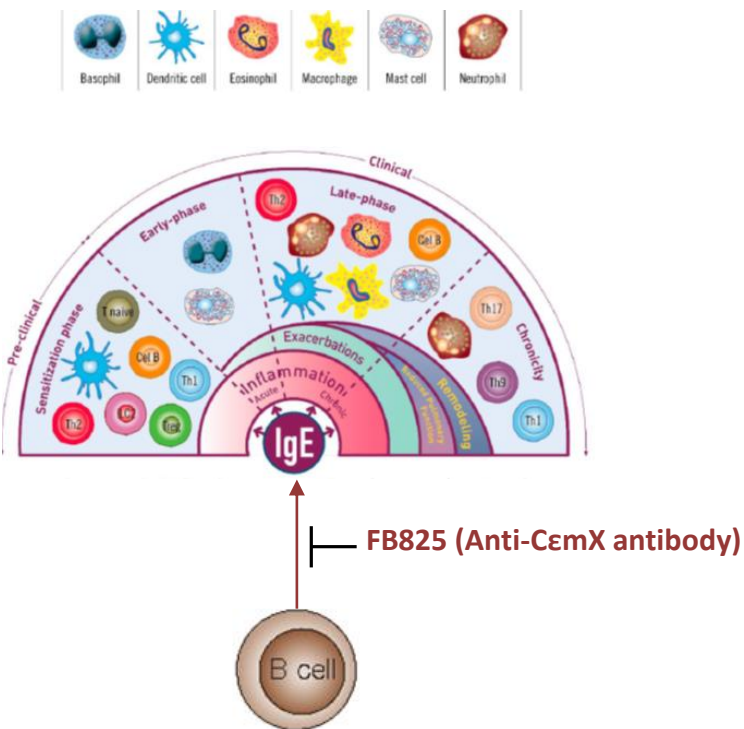
- The immunoglobulin E (IgE) has a central role in the continuum cascade of allergic reaction and participates in all phases.
- The IgE antibody is necessary for the initiation of the allergic cascade, and IgE is produced and released exclusively by memory B cells and plasma cells.
- Our Anti-CεmX antibody FB825 can block the upstream production of IgE, to relief allergic asthma symptom
- Only 1 biologic drug was approved back in 2003

About the Phase IIa trial

- Initiation in 2021 and recruit 100 subjects
- Targeting Phase IIa readout in 2022

FB825 Allergic Asthma Phase IIa Trial Design

Indication	Enrollment (FB825 vs Placebo)	Treatment duration	Site location
Allergic Asthma (AA)	100 (50 vs 50)	36 weeks	Taiwan

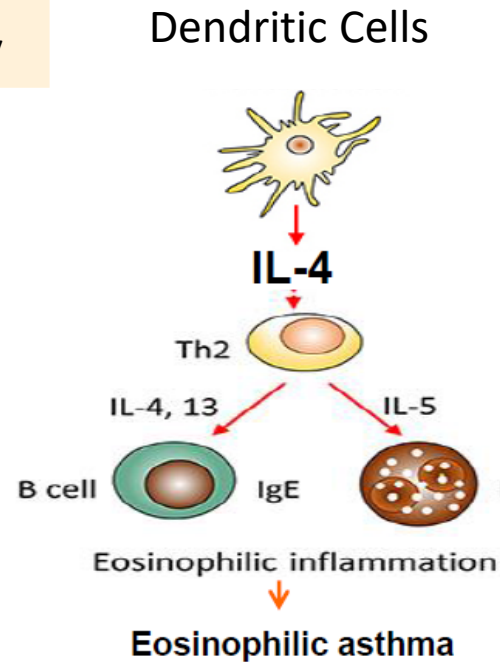


FB704A - First-in-class anti-IL6 mAb for Neutrophilic Asthma

Eosinophilic Asthma

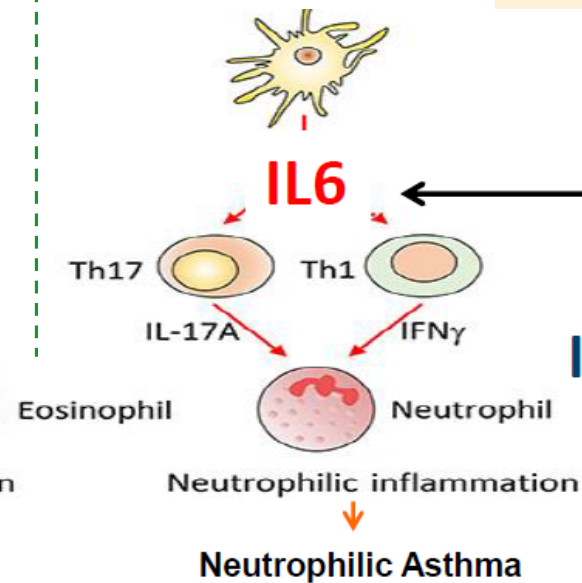
All of the biologic drugs are targeting Eosinophilic Asthma/ Allergic Asthma related pathway

Mepolizumab	IL-5
Reslizumab	IL-5
Benralizumab	IL-5
Dupilumab	IL-4R
Omalizumab	IgE



Neutrophilic Asthma

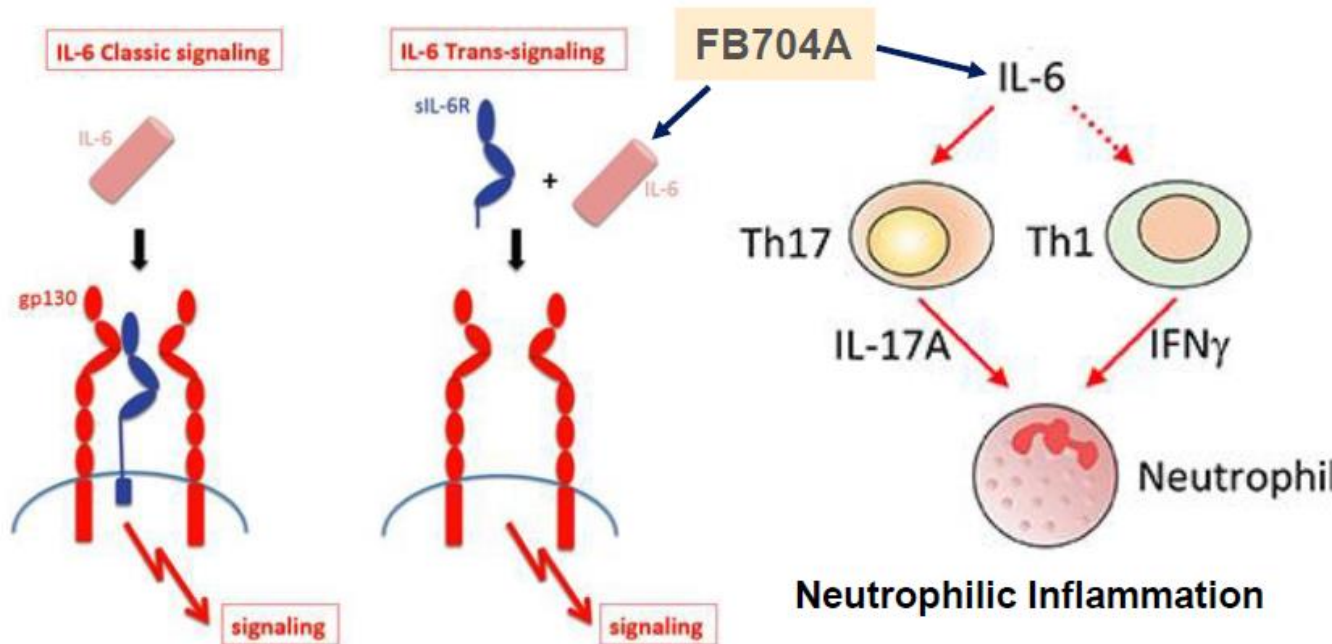
Oneness' FB704A is the only novel treatment targeting Neutrophilic asthma pathway



FB704A

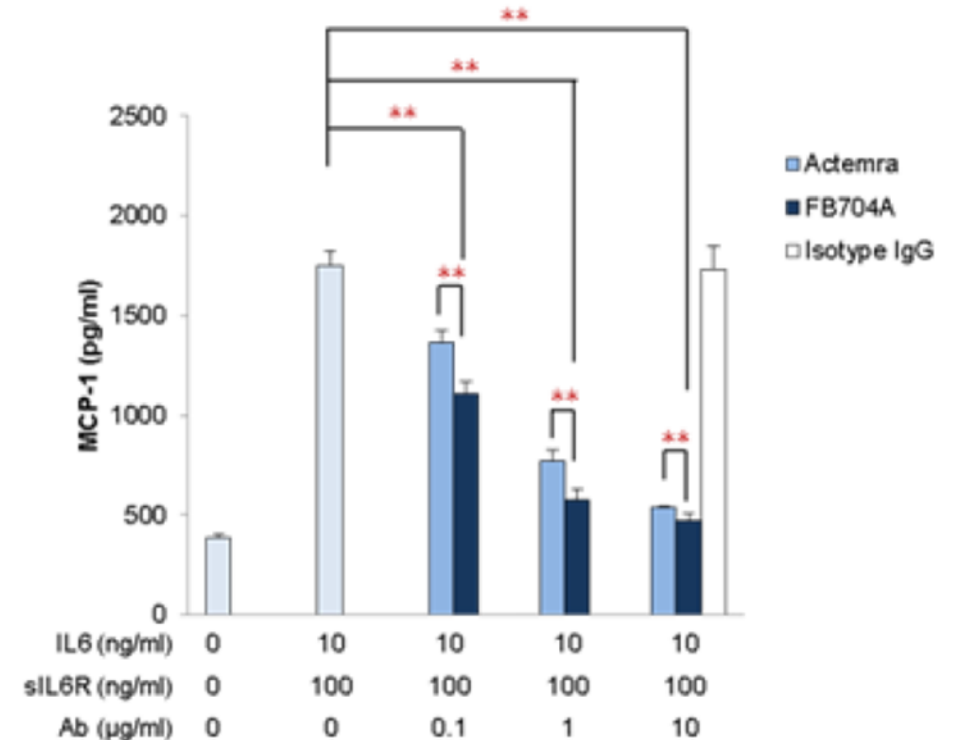
IL6 is a key cytokine to neutrophilic asthma

FB704A - First-in-class anti-IL6 mAb for Neutrophilic Asthma



- FB704A targets patients with no response to the current treatments
- Current biologics focus on Th2 pathway where there is no effective treatment for neutrophilic asthma patients
- IL6/IL6R trans-signaling pathway is key to neutrophilic asthma

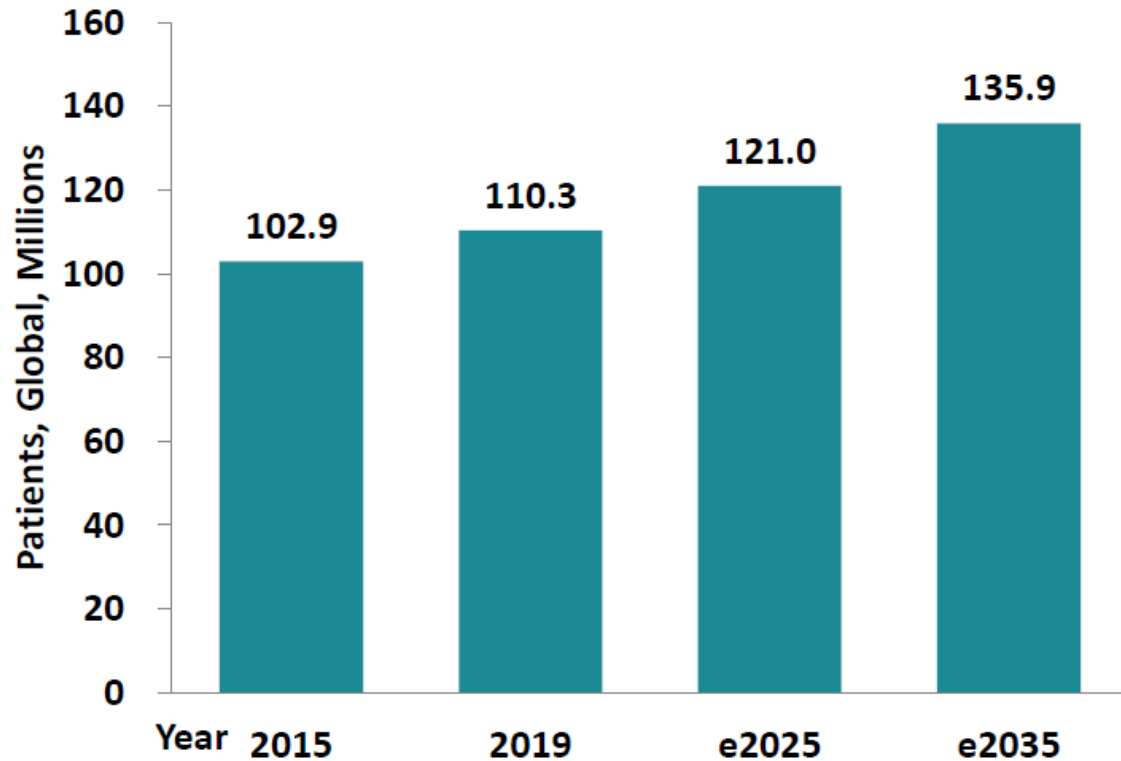
FB704A can effectively block trans-signaling pathway and is more efficacious than Actemra (Roche)¹



1. Actemra (Roche) is an anti-IL-6R antibody, mainly for the treatment of rheumatoid arthritis and systemic juvenile idiopathic arthritis

Global Neutrophilic Asthma Market

Approx. 110 million¹
Neutrophilic Asthma (NA) patients

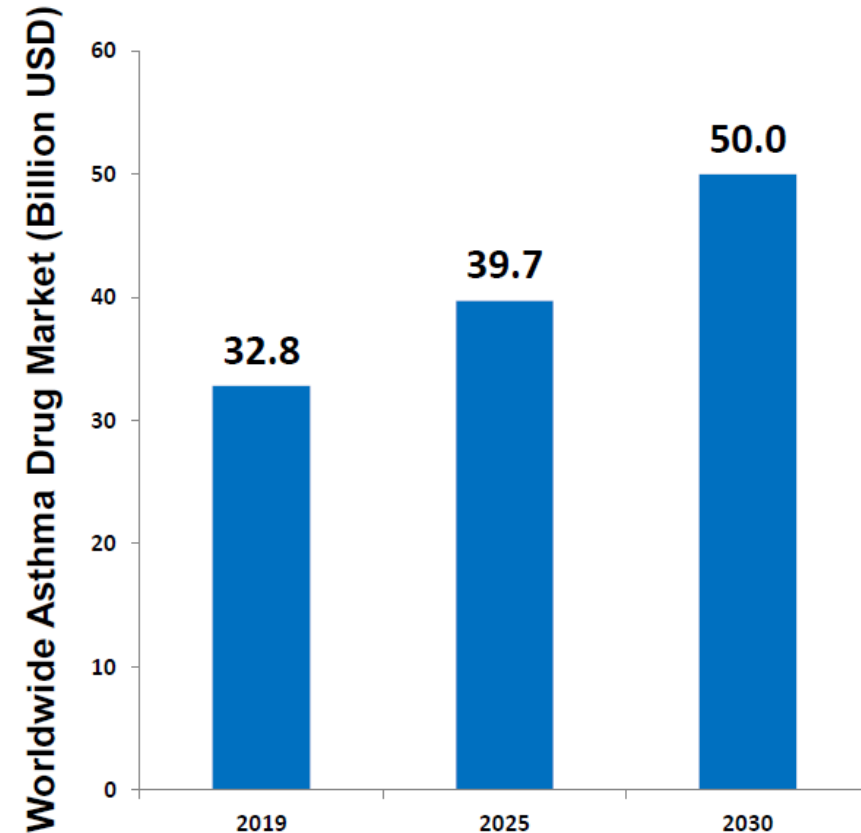


Severe Neutrophilic Asthma Market

- Severe neutrophilic asthma affects 5.5 million patients worldwide
- Remain unmet medically
- Effective biologic treatment can create billion market potential

Biologics for 40% Asthma Drug Market

- Biologics administered via subcutaneous injection, and available as pre-filled syringes or vials, accounted for 20% of global asthma market value in 2019
- Biologics set to double value share over the next decade
- Biologics will account for US\$ 20bn in worldwide asthma drug market in 2030



FB704A New Indication – CKD

Approximately 700 million people worldwide live with chronic kidney disease (CKD) which correlates with chronic inflammation. 50% CKD patients are with complication of cardiovascular diseases. Inflammation of CKD is correlated to the elevation of IL6. C-reactive protein (CRP) is the key indicator of inflammation.

IL-6 neutralizing antibody has been shown clinical efficacy in treatment for residual inflammatory cardiovascular risk in patients

- FB704A reduced CRP in the phase I study. Oneness is evaluating the potential in treatment of CKD as the second indication.
- New indication is a risk-management strategy which maximize the potential value of the drug

SARS-CoV-2 Infection – SNS812

Broad-spectrum inhibition against α strain, γ strain, ε strain and δ strain

SNS812 (siRNA) for SARS-CoV-2

- SNS812 was co-developed by Oneness Biotechnology and Microbio Co. (Shanghai), and filed the global patent in Dec 2020
- Targeting the conservative region of SARS-CoV-2 genome for siRNA design. The design covers 99.8% of over 200,000 SARS-CoV-2 sequences collected and published by the National Center for Biotechnology Information (NCBI)
- The completed *in vitro* experiments suggested that SNS812 has full inhibition capability against wild type, α strain, γ strain, ε strain and δ strain
- In the δ strain hACE2 mice challenge studies, SNS812 demonstrated significant efficacy suppressing the viral count in lung tissues, no matter it is a pre-exposure prophylaxis (PrEP), or an administration after infection
- The pathological section of the lung tissue of hACE2 mice demonstrated SNS812 can reduce: 1) lung injury; 2) Immune cell infiltration; and 3) thrombosis
- Already obtained US FDA Pre-IND Number and start preparation for IND Package in 4Q2021.

Future Prospect

Important Milestones: 2021-2023

Important Milestone: 2021-2023

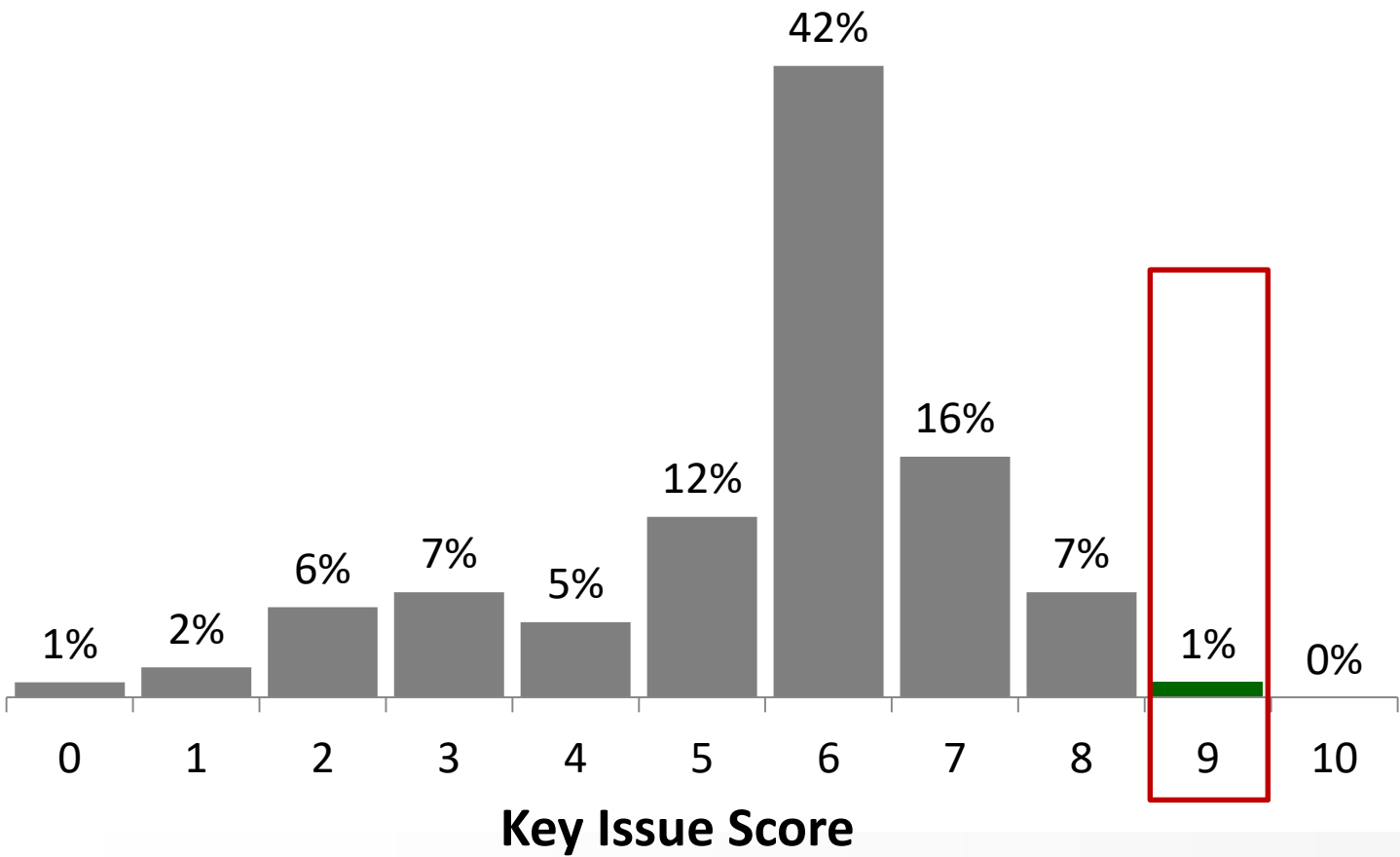
US\$	TAM	2021	2022	2023
FESPIXON (Diabetic Foot Ulcers)	24bn	- Product Launch in Taiwan - Regulatory submission in China - US Phase III initiation	- Market entry into ASEAN - New indication expansion - Out-licensing deals	- Complete US Phase III trial - US/EU regulatory submission
FB825 (Atopic Dermatitis)	18bn	40M upfront received - Phase IIa data readout	Phase IIb AD initiation	Phase IIb AD
FB825, FB704A, FB811 (Asthma)	20bn	- FB825 Phase IIa Asthma initiation - FB704A Phase IIa Asthma initiation	- FB825 Phase IIa asthma data readout - FB704A Phase IIa asthma data readout	FB704A licensing

Our Commitment in ESG

First rated by MSCI in Mar. 2021

Outstanding Performance in MSCI ESG Rating

Oneness was scored 9.1 in Product Safety & Quality Key Issue



2021.3.15	Score	Weight
Product Safety & Quality Key Issue Score	9.1	27%
Exposure Score	3.9	
Business Segment Exposure Score	7.1	
Company-Specific Exposure Score	0.7	
Management Score	6.0	
Management Score (Excluding Controversies)	6.0	
Practices Score	1.9	
Performance Score	10.0	
Controversies Deduction	0.0	

Financials

5-year Income Statement

NT\$ Million	2016	2017	2018	2019	2020	1H21	YoY (%)					
							2016	2017	2018	2019	2020	1H21
Sales Revenue	5.7	2.6	18.9	13.5	41.6	23.7	(27.3)	(54.6)	628.9	(28.5)	208.8	(32.1)
Gross Profit	2.9	1.4	8.2	(3.5)	23.7	16.5	(4.5)	(52.1)	502.8	(142.9)	(770.7)	(21.3)
Operating Profit	(113.2)	(139.1)	(132.2)	(311.7)	(673.2)	(446.2)	-	-	-	-	-	-
Income before Tax	(14.3)	(155.9)	(244.9)	(326.3)	(249.9)	(353.5)	-	-	-	-	-	-
Net Income to Parent	(14.3)	(155.4)	(235.4)	(322.2)	(241.9)	(355.5)	-	-	-	-	-	-
EPS (NT\$)	(0.07)	(0.80)	(1.20)	(1.28)	(0.68)	(0.94)	-	-	-	-	-	-

Key Financial ratio (%)

Gross Margin	50.0	52.8	43.6	(26.2)	56.9	69.4
Operating Margin	(1,984.1)	(5,376.6)	(701.0)	(2,313.4)	(1,618.0)	(1,881.7)
Opex ratio	2,034.1	5,429.4	744.7	2,287.2	1,674.9	1951.2
Net Margin	(250.0)	(6,008.7)	(1,248.6)	(2,421.2)	(604.9)	(1499.5)

5-year Balance Sheet

NT\$ Million	2016	2017	2018	2019	2020	1H21	YoY (%)					
							2016	2017	2018	2019	2020	1H21
TOTAL ASSETS	2,556	2,521	2,335	6,980	15,384	15,067	(9.0)	(1.3)	(7.4)	198.9	120.4	43.1
Cash	194	244	286.5	1202.2	6524.9	6,117	(72.0)	25.6	17.3	319.7	442.7	412.4
NR & AR	0.7	0.2	1.0	1.7	443.9	10.7	(6.8)	(70.8)	354.6	71.4	26,277.8	(97.7)
Inventory	41	41	50	48	50	65	27.9	(1.1)	23.7	(4.0)	3.8	38.9
Fixed Asset	175	456	561	640	727	717	642.7	160.8	23.1	14.2	13.5	15.6
TOTAL LIABILITIES	31	27	170	521	1,625	1,610	(24.7)	(15.7)	541.0	207.1	211.9	0.8
Bank Loans	-	-	-	-	-	-	-	-	-	-	-	-
NP & AP	0.2	0.1	0.5	0.6	48.4	2.3	(18.5)	(53.6)	450.0	15.2	7,865.1	(95.5)
TOTAL EQUITY	2,524	2,495	2,166	6,459	13,760	13,457	(8.7)	(1.2)	(13.2)	198.2	113.0	50.6
A/R turnover days	49	67	12	36	2,028	1,750						
Inventory turnover days	4,563	12,167	1,659	1,074	1,659	1,456						
A/P turnover days	25	39	9	8	830	640						
ROE (%)	(0.54)	(6.38)	(10.75)	(7.56)	(2.48)	(5.23)						
ROA (%)	(0.53)	(6.12)	(9.69)	(6.87)	(2.20)	(4.67)						