ONENESS
Oneness Biotech Co., Ltd

Investor Presentation 4743.TT

40th Annual J.P. Morgan Healthcare Conference

10:00AM on 13th Jan 2022 (EST)

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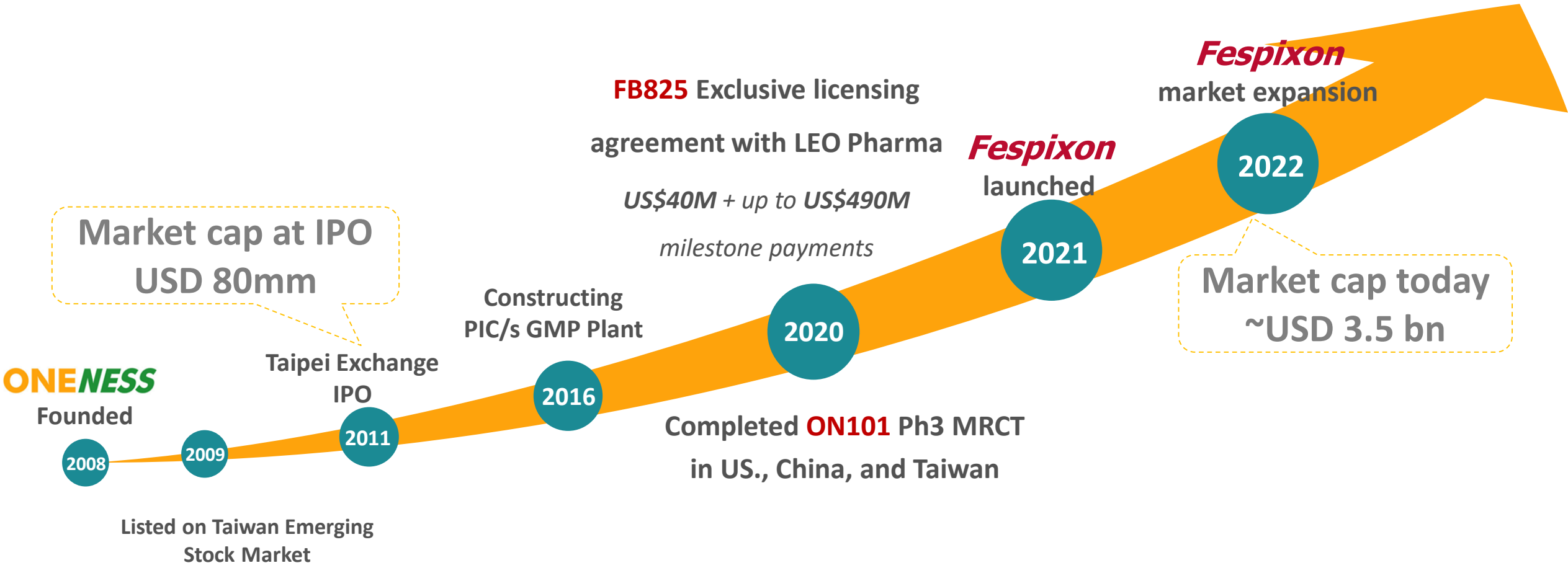
Oneness at a Glance

- **Ticker: 4743 TT** (IPO in 2011; MSCI Global Standard Indexes)
- **Market Cap:** ~US$ 3.5 bn (as of 2021/12/30)
- **Headquarter & Research Site : Taipei, Taiwan**
- **Focus in chronic dermatological, immunological diseases**
- **Pipeline across pre-clinical to NDA/market stages**
- **PIC/s GMP certified Manufacturing Site: Pingtung, Taiwan**
- **170+ Employees** (as of 2021/12/30)

Milestones of Innovation



Investment Highlights

Leading Biotech	• Largest biotech company in Taiwan in terms of market cap • Multiple pipeline under development across pre-clinical and clinical stages
Value-added strategy	• Each pipeline under development of multiple indications to maximize the value of the assets and mitigate the risk of development
Strong financial standing	• Sufficient cash flow to support upcoming development of new drugs • Anticipated profitability from the launch of Fespixon and the licensing of new drugs

Pipeline

Pipeline for Unmet Medical Needs

	Product	Target	Category	Patent	Indication	Discovery/ Pre-clinical	Phase 1	Phase 2	Phase 3	Regulatory submission [4]	Key milestones
Dermatology	***FESPIXON*** (ON101[1])	M1/M2 Φ	Botanical	Global	Diabetic Foot Ulcer					Taiwan	2022: China NDA, US PIII complete enrollment 2023: Complete US PIII trial
										CN, SG, MY	
										US	
	FB825 [2]	CεmX	mAb	Global with LEO Pharma	Atopic Dermatitis (AD)					US	2022: Complete Phase IIa study in AD; 2023: Complete Phase IIa study in AA
Immunology					Allergic Asthma (AA)					Taiwan, US IND	
	FB704A	IL-6	mAb	Global	Neutrophilic Asthma					Taiwan, US IND	2023: Complete Phase II trial
					Chronic Kidney Disease						
	OB318	Multiple	NCE	Global	Hepatocellular carcinoma[3]					Taiwan, US IND	2023: Complete Phase I study
Infection	SNS812	Virus	Nucleic Acid	Global with MBS	COV-Flu						2022: File IND

[1] ON101 has been completed a Phase 3 clinical trial and is undergoing another one (one for China and Taiwan registration, the other for U.S. registration). Drug approval has been obtained in Taiwan. NDA submitted to the NMPA and health authorities in South East Asia.. 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 and worldwide exclusive license jointly licensed with Micorbio Shanghiai to LEO Pharma | [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

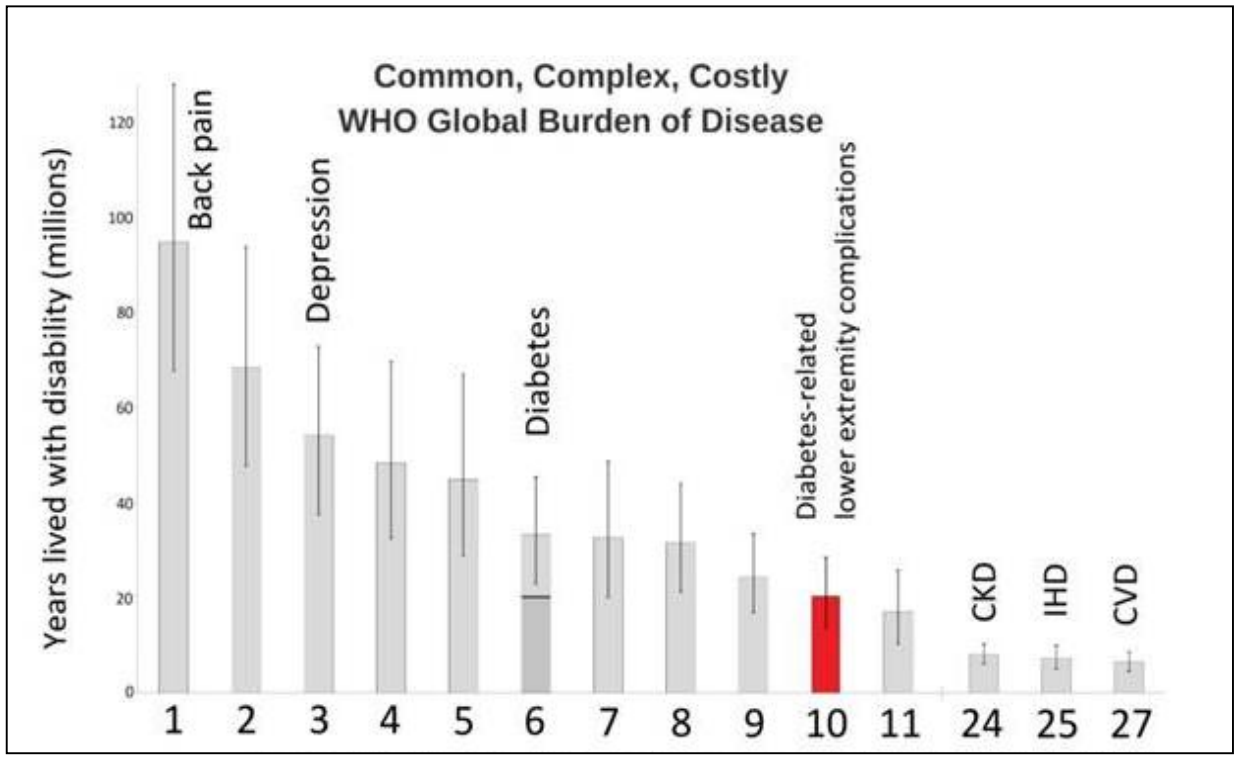
Fespixon® (research code: ON101)

First-in-class MΦ Regulating New Drug for Diabetic Foot Ulcers

Billion market potential

DFU – Top 10 Costly Disease

DFU has caused huge medical burden worldwide



>30 mn DM patients with a foot ulcer worldwide[1]

19-34% life-time incidence on DM patients[2]

30-40% recurrence on DM patients within 1 yr[3]

1/3 medical costs spent on lower limbs[4]

[1] Zhang P, et al. Ann Med. 2017 Mar;49(2):106-116. |[2] N Engl J Med 2017;376:2367-75 | [3] Zhang Y, et al. Diabetes Care 2020 May; 43(5): 964-974. | [4] J Foot Ankle Res. 2020 Mar 24;13(1):16.

Fespixon, a Novel Macrophage-regulating Drug Showed Superiority to Standard Care in a Phase 3 MRCT

The Phase 3 data have been published on the leading journal

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; Cherng-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

Ref: JAMA Netw Open. 2021;4(9):e2122607 | MRCT : Multi-center randomized clinical trial

Balanced Baseline Characteristics

Equally-distributed baseline patient and wound characteristics

Patient Characteristics	ON101 Cream (n=122)	Absorbent Dressing (n=114)	P-value**
Characteristic, n (%)			
Age (years) (SD)	57.4(10·6)	56.6 (11·3)	0.575
Men	93 (76·23%)	82 (71·93%)	0.461
Type 2 Diabetes	121(99·18%)	113 (99·12%)	>0.999
Diabetic duration			0.158
⩽ 2 years	19 (15·57%)	14 (12·28%)	
>2 to ⩽5 years	12 (9·84%)	11 (9.65%)	
> 5 to ⩽10 years	24 (19·67%)	12 (10·53%)	
> 10 years	67 (54·92%)	77 (67·54%)	
Mean HbA_{1c}(%)(SD)#	8·1(1·5)	8·1 (1·8)	0.767
Diabetic complications			
Coronary Artery disease	16 (13.11%)	10 (8.77%)	0.307
Diabetic kidney disease	31 (25·41%)	23(20·18%)	0.356
Diabetic retinopathy	41 (33·61%)	36 (31·58%)	0.782
Smoking	55(45·08%)	44(38·60%)	0.417

Wound Characteristics	ON101 Cream (n=122)	Absorbent Dressing (n=114)	P-value**
Ulcer etiology			0.905
Neuropathy	78(63·93%)	69 (60·53%)	
Peripheral vascular disease	30 (24·59%)	30 (26·32%)	
Neuro-ischemia	7 (5·74%)	6 (5·26%)	
Other	7 (5·74%)	9 (7·89%)	
Amputation history due to DFU	56 (45·90%)	60 (52·63%)	0.362
Ankle-brachial index (SD)	1·1(0·2)	1·1 (0·1)	0.422
Ulcer location			0.366
Non-plantar	58 (47·54%)	61 (53·51%)	
Plantar	64 (52·46%)	53 (46·49%)	
Ulcer duration (months)(SD)	7·2 (13·0)	7·3 (14·4)	0.974
Ulcer severity (Wagner grade)			0.633
Grade 1	29 (23·77%)	23 (20·18%)	
Grade 2	93 (76·23%)	91 (70·82%)	
Ulcer size (cm^2)(SD)	4·70 (4.3)	4·90 (4.5)	0.693
1.01 -5	88 (72·13%)	77 (67·54%)	
>5	33 (27.05%)	36 (31·58%)	

** ANOVA test for continuous variables and Fisher's exact test for categorical variables

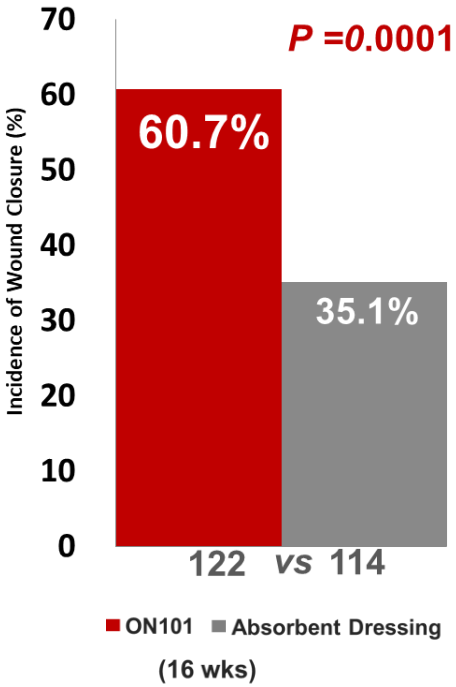
Ph3 Clinical Trial Results – Superiority to SOC

MRCT (US, China, Taiwan) in 236 subjects

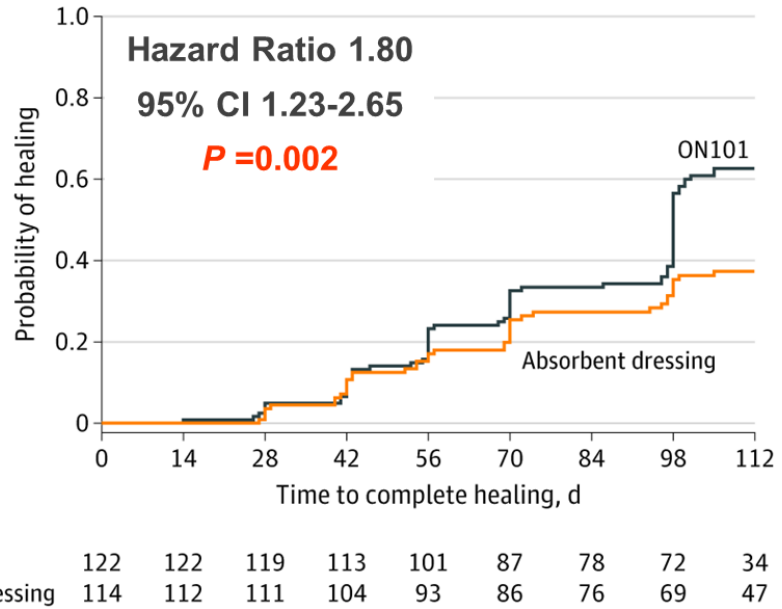
Efficacy Endpoints

FAS[2]

Primary endpoint-
Incidence of Wound Closure[1]



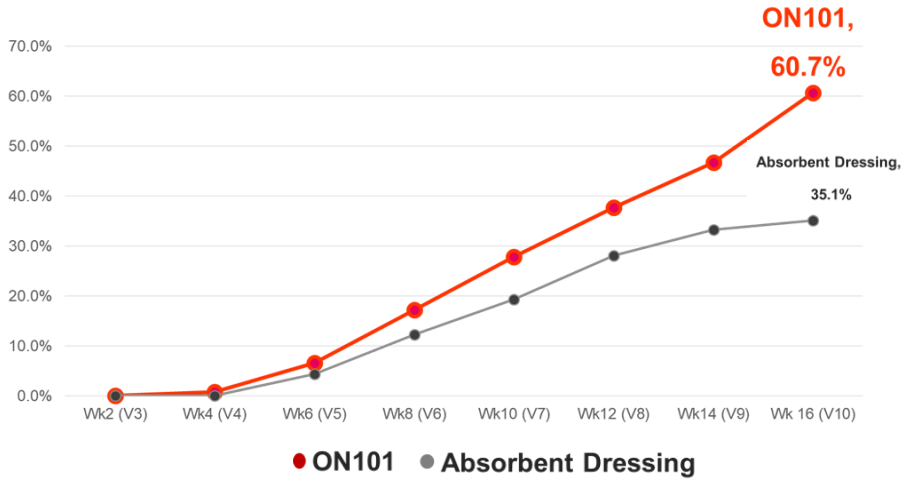
Secondary Endpoint –
Time to Complete Wound Closure



No. at risk

ON101	122	122	119	113	101	87	78	72	34
Absorbent dressing	114	112	111	104	93	86	76	69	47

Cumulated Incidence of Wound Closure



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

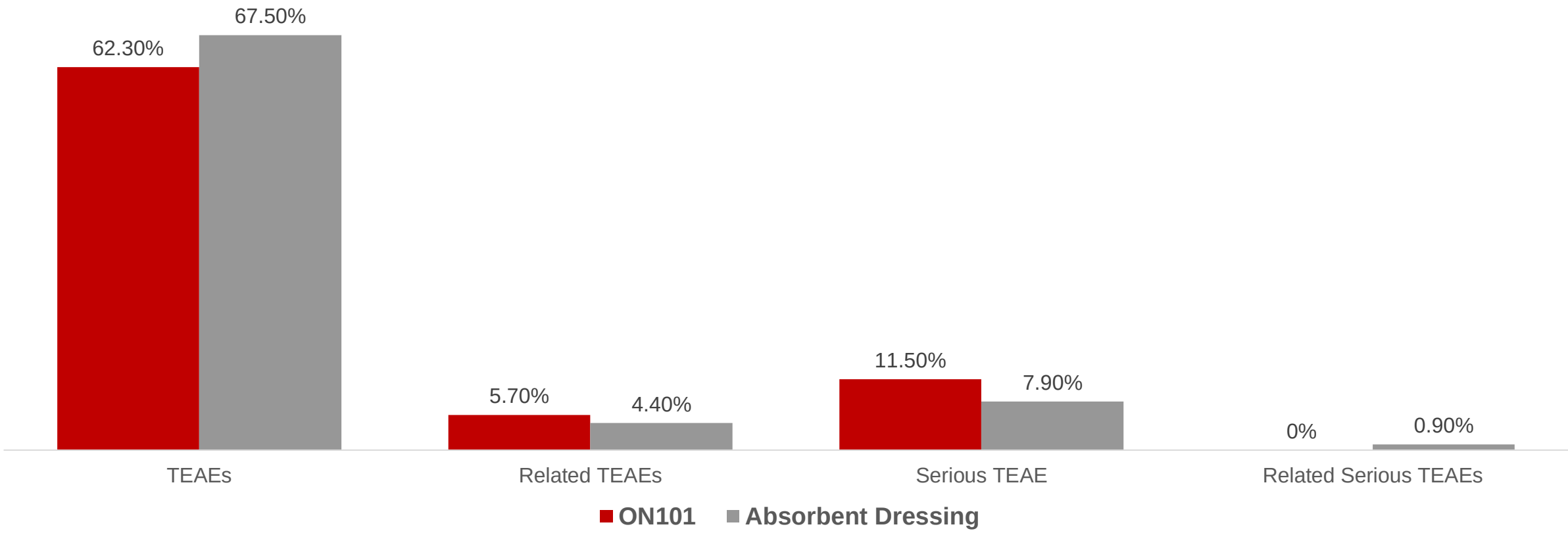
[2]Full analysis set

ON101: Trade name - Fespixon
SOC: Standard of Care

Ph3 Clinical Trial Results – Satisfactory Safety Profile

MRCT (US, China, Taiwan) in 236 subjects

Safety Endpoints

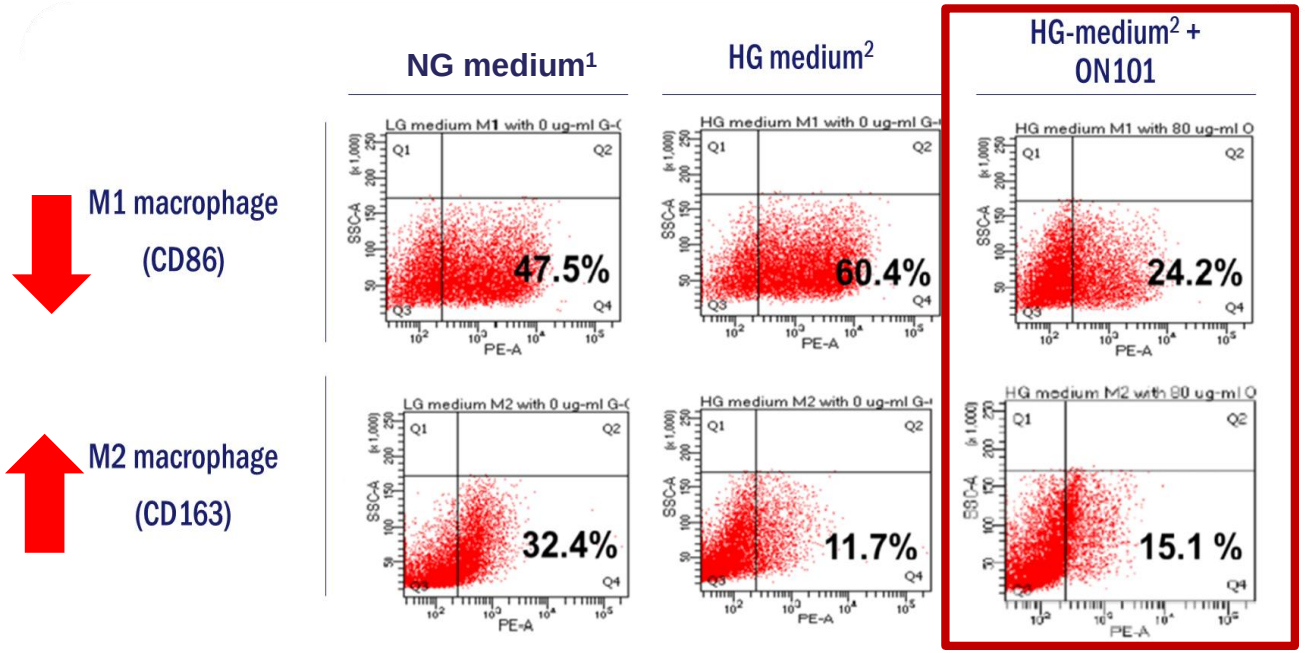


Note: ON101 trade name: Fespixon

Mechanism of Action – Mφ Regulation

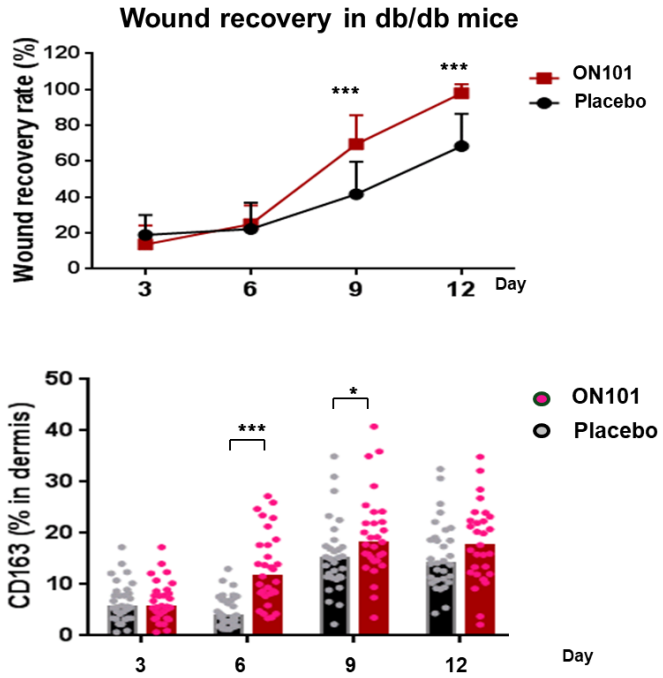
Rebalancing Macrophage Expression is the Key to Solve Ulcer Chronicity

In-vitro Proof of Concept: THP-1 Cell Assay



- ON101 (80ug/ ml) administration in HG-medium^2 during the polarization period showed a **M1 decreased** (24.2%) and **M2 increased** (15.1%) population compared to HG-medium^2 alone (M1 60.4%; M2 11.7%)
- The M1 to M2 ratio in the ON101 treatment condition is 1.6, which represents a **similar ratio to the normal-glucose (NG) medium**

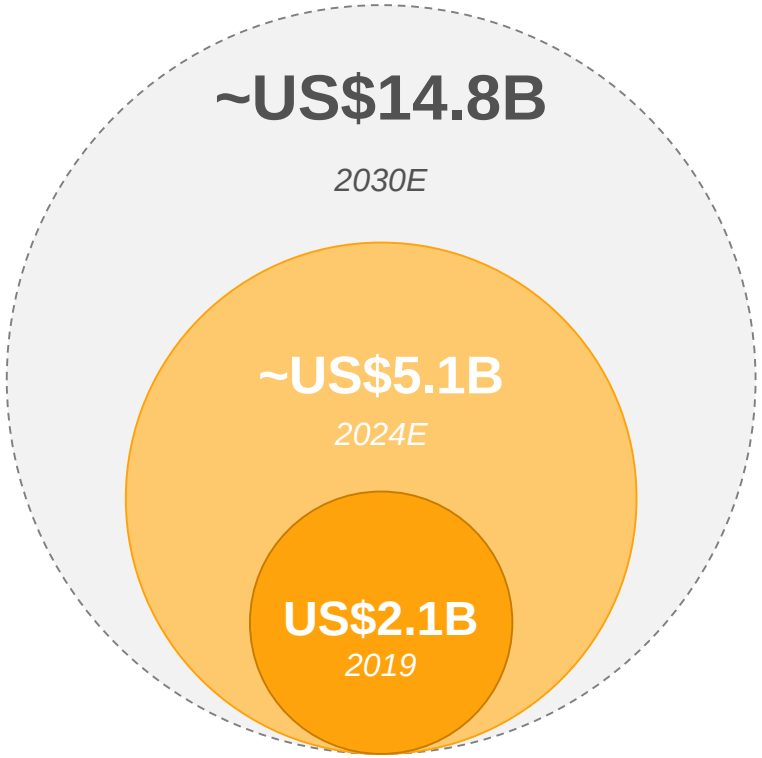
In-vivo Proof of Concept: db/db Mice Model



- ON101 and placebo cream were **applied daily from Day 3 onwards** until wound closure or mice were harvested
- The result showed that **ON101 treatment significantly promoted wound recovery at Day 9 and Day 12**
- IHC staining of the tissue also showed that **the M2 macrophages increased in alignment with the wound recovery** on the mice.

DFU Treatment Market Opportunity

DFU Unmet Medical Need Creates > US$ 14 Billion Market Opportunity for an Effective DFU New Drug



19.2%
2019-24E CAGR

>30M
DFU patients globally

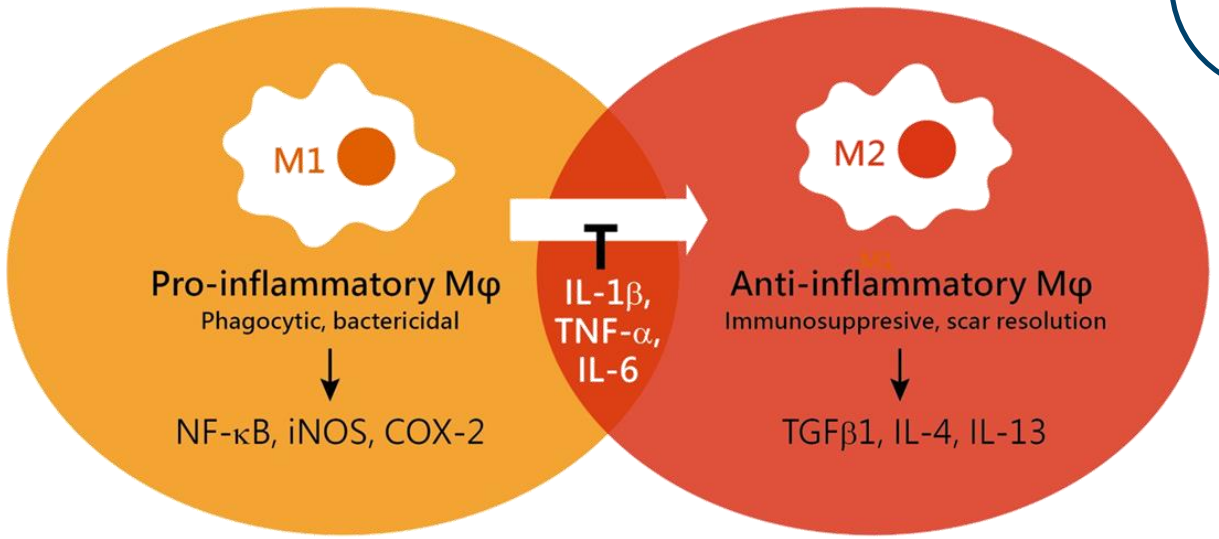
>1.2M
amputations / year

The real market demand is anticipated to be multiplied by the launch of an effective new drug

Source: Frost & Sullivan analysis, International Diabetes Federation, Diabetes Care 2014 Mar; 37(3): 651-658 | Eleftheriadou I, Tsapogas P, Tentolouris A, et al.

Expansion into Multiple Indications

Unique Mechanism for Chronic Wounds and Multi-displinary Care



Podiatry | Diabetes | Dermatology

1. Pressure ulcer
2. Venous leg ulcer
3. Scar removal
4. Radiology dermatitis

Edited from DOI: 10.1007/s11926-018-0725-5

Fespixon® for Global Market

Regulatory Planning

- Multiple NDA submissions in Asia (China, Singapore, Malaysia, Vietnam, Thailand, Philippines, Indonesia, India)
- Rolling submission for the US

Licensing and Collaboration

- Under negotiations with multiple pharma companies for regional licensing collaboration

Exclusivity & Supply

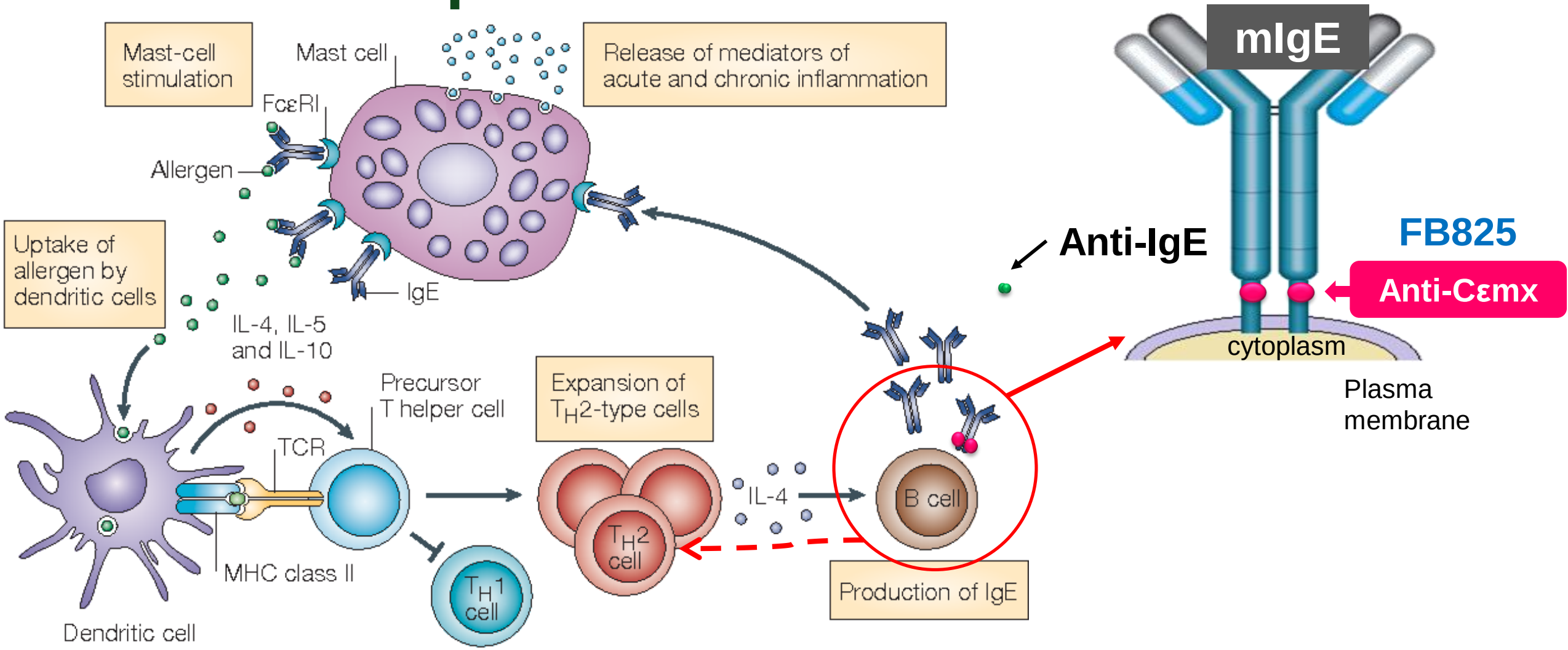
- 25 mn tubes production capacity has been established
- Latest patent protection for formulation till 2038

FB825

First-in-class anti-IgE B Cells mAb for Allergic Diseases

Development under Global Partnership

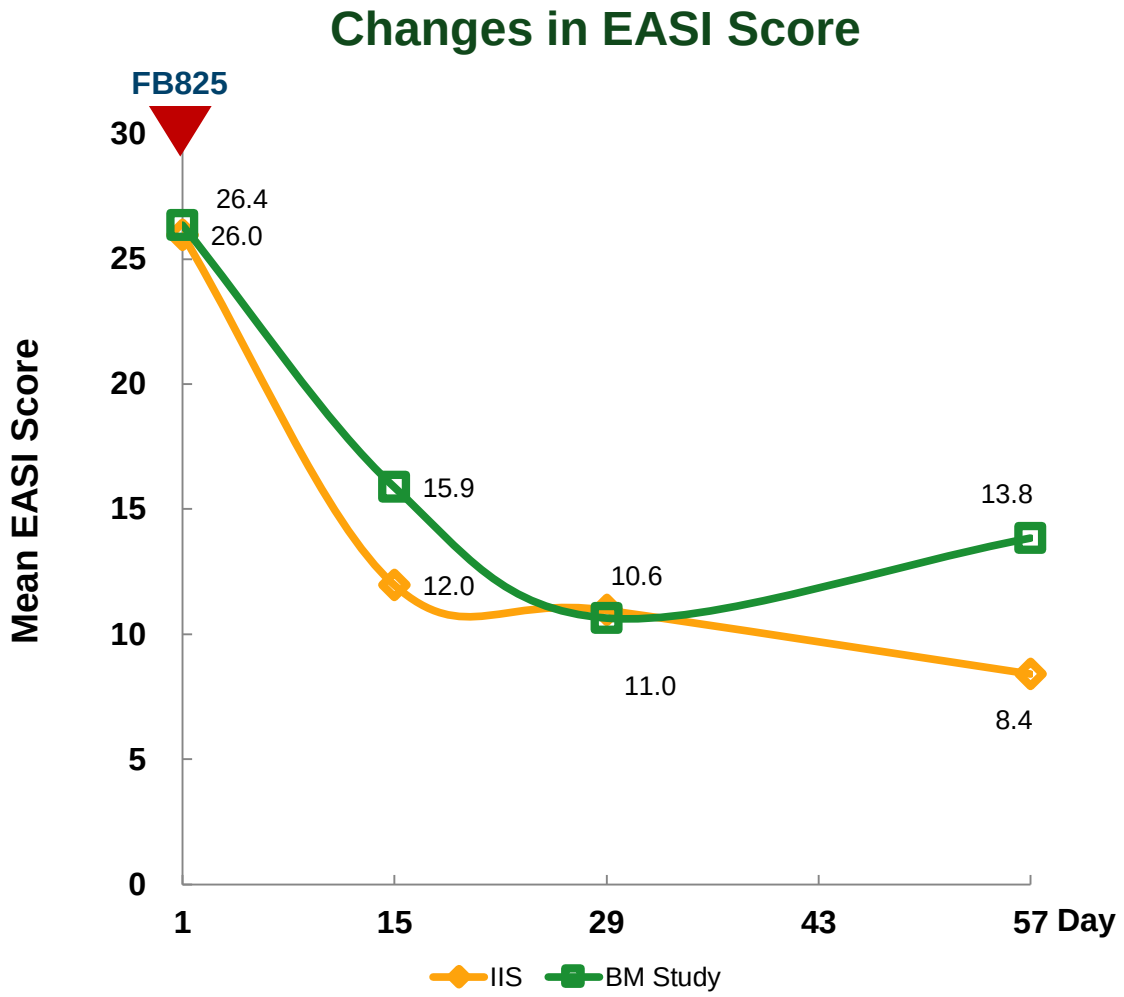
Promising Biologic for Allergic Disease – Atopic Dermatitis and Asthma



Edited from Nature Review | Immunology 2004 ; IgE: Immunoglobuin E; AD: atopic dermatitis

Outcomes in Two Exploratory Studies in AD

Reconfirmed Clinical Efficacy



- IIS with 12 moderate-to-severe AD patients (q12w) and BM study with 20 moderate-to-severe AD patients (1 dose)
- The change in EASI score has been similar in two studies

Dual Indications – 2 Ph2a Trials

Final Results Anticipated in 2022 & 2023

Indication	Enrollment	Treatment duration	Site location
Atopic Dermatitis (AD)	99	16 weeks	US

Final data and CSR anticipated in H1 2022

Indication	Enrollment	Treatment duration	Site location
Allergic Asthma (AA)	100	36 weeks	Taiwan

(FB825 *vs* Placebo : 50 *vs* 50)

Trial completion in H1 2023

(AA is Sponsored by Microbio Shanghai)

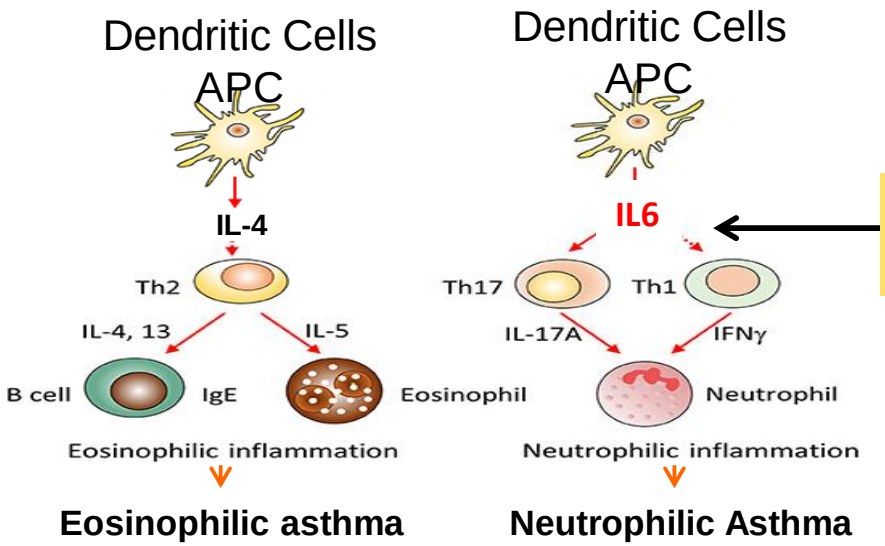
FB704A

First-in-class anti-IL6 mAb

Severe Asthma & CKD-induced CVD

IL-6 in Severe Asthma (Neutrophil High)

Severe Asthma with high neutrophils have been a large unmet need



FB704A

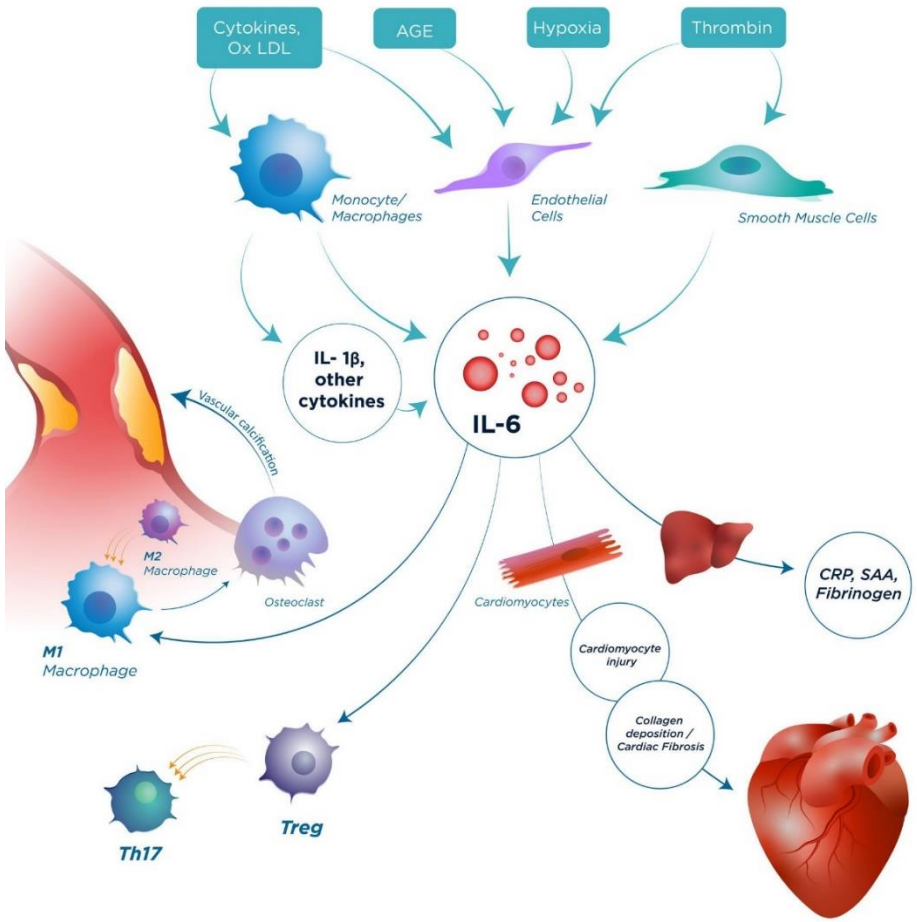
IL6 is a key cytokine to asthma (neutrophilic phenotype)

- **Severe Neutrophilic Asthma affects 5.5 million patients worldwide**
- **Remain unmet medically**
- **Effective biologic treatment can create billion market potential**

Modified from *Front Immunol.* 2018;9:2718

IL-6 in CKD-induced CVD

350 Million CKD Patients Worldwide at Risk of Having a CVD



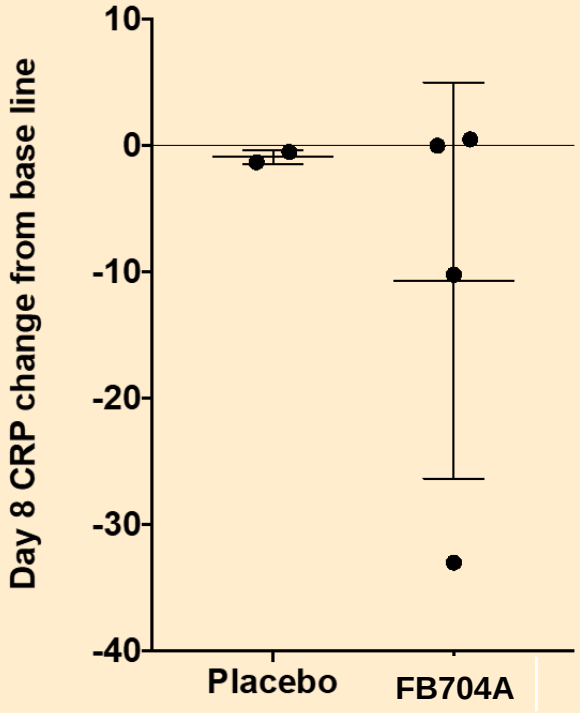
- Approx. 700 million people worldwide live with chronic kidney disease (CKD) which correlates with chronic inflammation. 50% CKD patients are with complication of cardiovascular diseases
- Inflammation of CKD is correlated to the elevation of IL6. C-reactive protein (CRP) is the key indicator of inflammation.
- “IL-6 level and CKD status should be useful as decision support for selection of patients with chronic coronary syndrome who may derive benefit from anti-inflammatory treatment with general and specific IL-6 inhibition,”

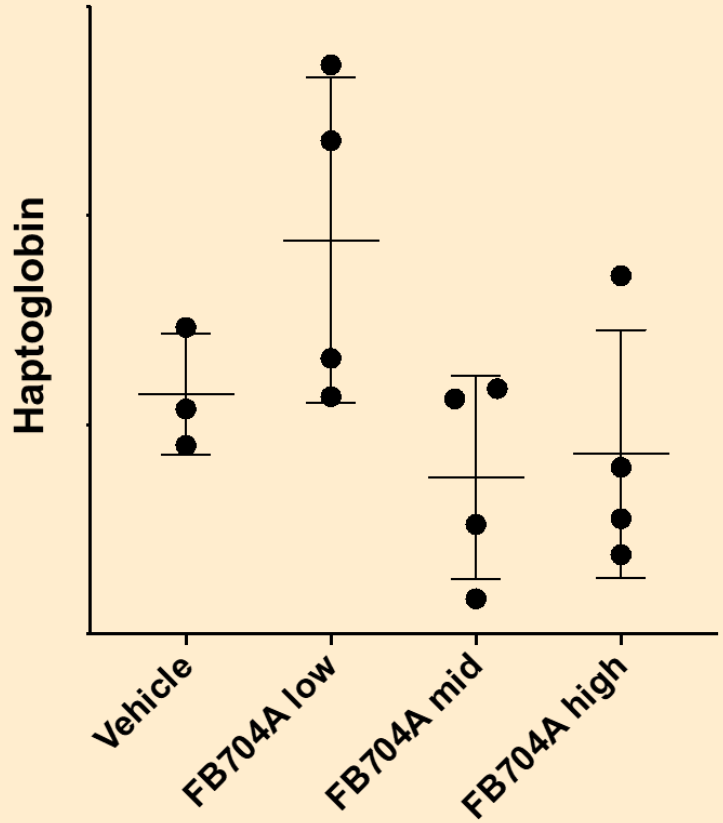
Circulation. 2020;141:787–789.

FB704A in Dual Indications

FB704A Showed Reduction in Key Indicators for Both Indications

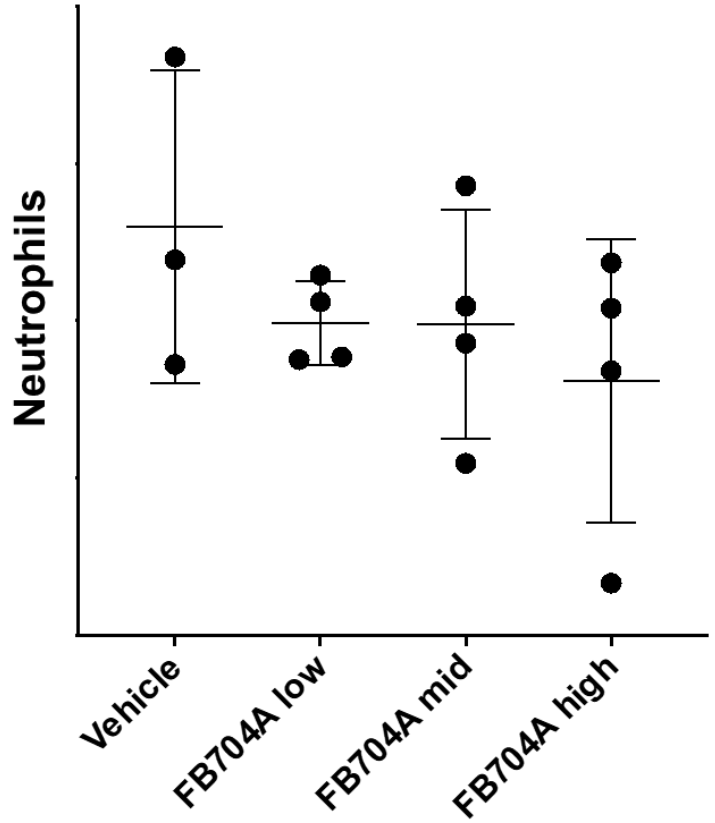
Key indicators for CKD-induced CVD





C-Reactive Protein and Haptoglobin are reduced

Key indicator for Severe Asthma



Neutrophils are reduced

Core Antibody New Drug with Strategy of Dual Indications

FB825 (anti-CεmX)

Atopic Dermatitis(IIa)/Allergic Asthma(IIa)

FB704A (anti-IL6)

Severe Asthma(IIa) /CKD-induced CVD

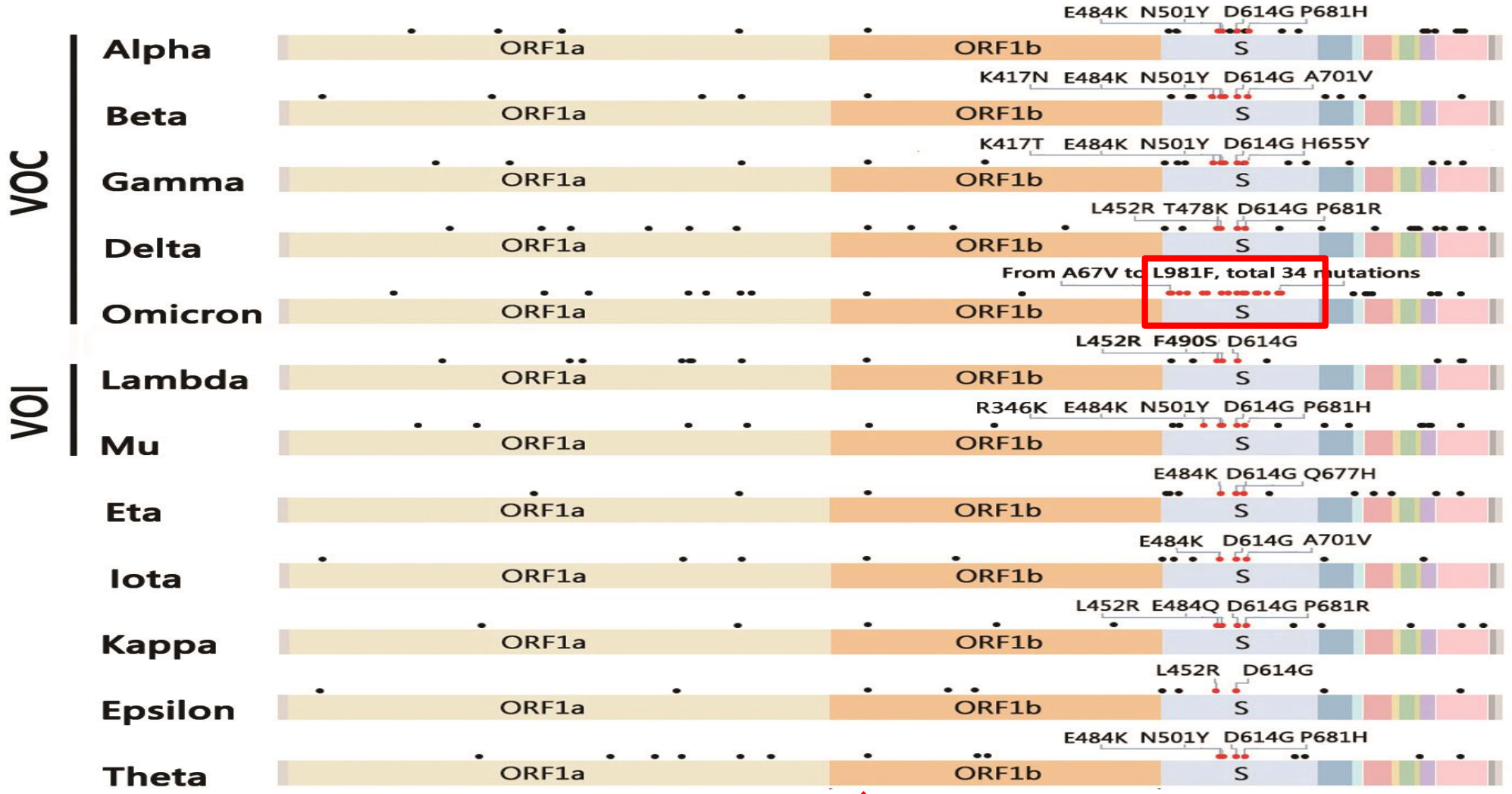
SNS812

First-in-class nucleic acid new drug for SARS-COV-2

Broad-spectrum inhibition against α, γ, ε & δ strains

SNS812 Targets All Variants

SNS812 Targets The Conserved Region And Covers 99.8% Virus Variants



SNS812 Advantages

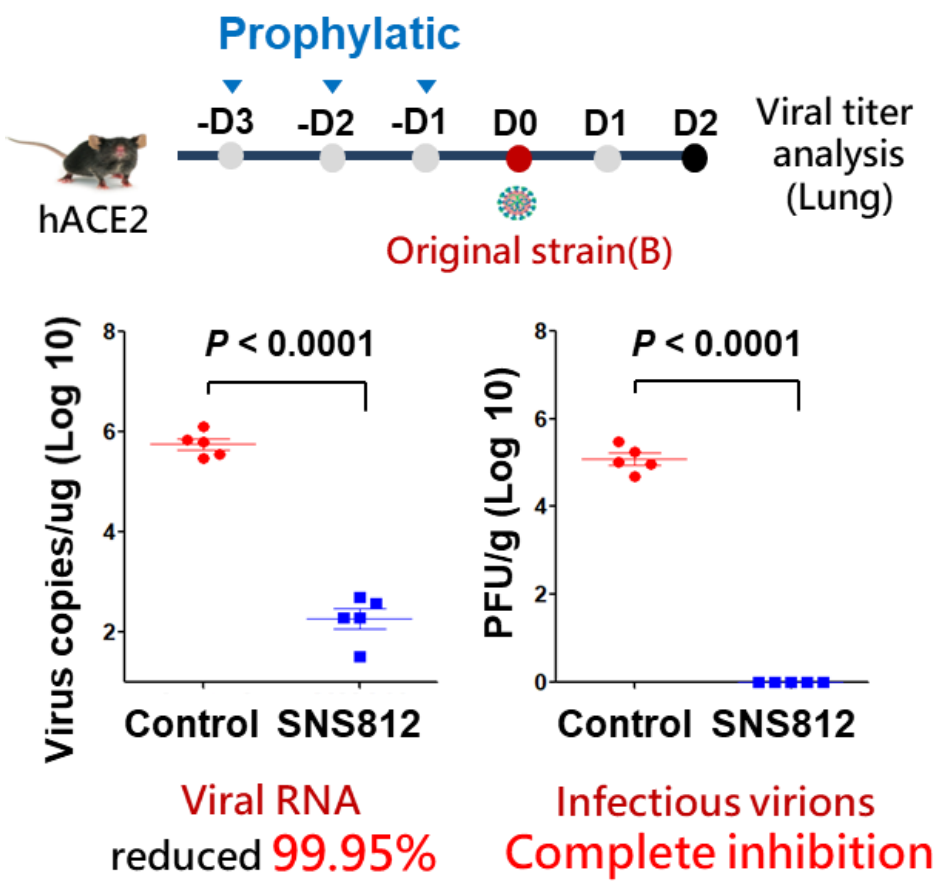
- **SNS812 covers 99.8% variants and can inhibit virus by both prophylactic and post-exposure treatment.**

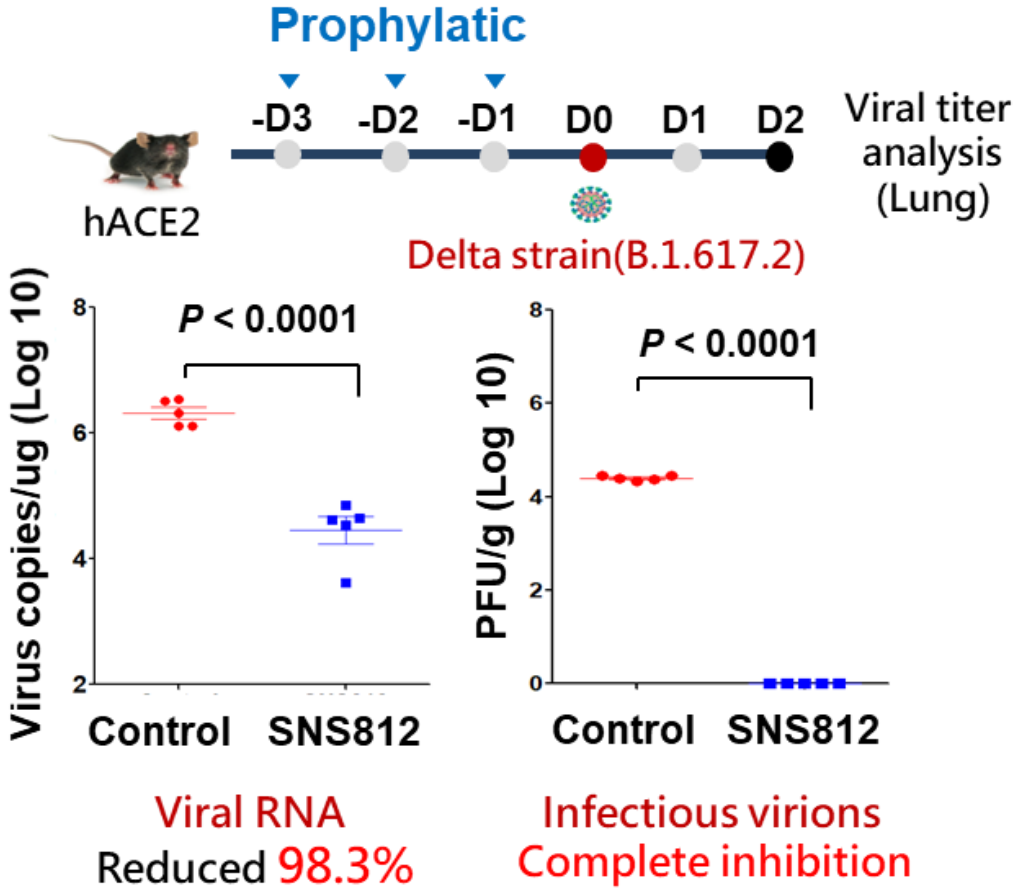
Name	SNS812	Molnupiravir	PAXLOVID
Classification	Nucleic acid/ siRNA	Small chemical/ Nucleoside analogs	Small chemical/ Protease inhibitor
API	C6G25S	MK-4482	PF-07321332 + Ritonavir
Mechanism of action	Cleavage viral RNA by siRNA targeting	Cause accumulation of mutation in viral RNA	Inhibit viral 3CL protease
Route of administration	Inhalation	Oral	Oral
Coverage rates of variants	99.80%	ND	ND
Resistant to viral mutation	Relatively resistant viral mutation	ND	ND
Pontential risk	ND	Mutagenic concern **(1)**	Potential drug–drug interactions of Ritonavir **(2)**
Animal efficacy	hACE2 transgenic mice (reduce 2.6 logs)	Human lung transplant mice (reduce 4.4 logs) **(3)**	BALB/c mice + mice adapted virus. (reduce 1.9 logs) **(4)**
Clinical reduction of severe illness	ND	50%	89%

1. β-d-N4-hydroxycytidine Inhibits SARS-CoV-2 Through Lethal Mutagenesis But Is Also Mutagenic To Mammalian Cells. J Infect Dis. 2021 Aug 2;224(3):415-419
2. Caution required with use of ritonavir-boosted PF-07321332 in COVID-19 management. The Lancet 2022 Jan 1; 399(10319): 21-22
3. SARS-CoV-2 infection is effectively treated and prevented by EIDD-2801. Nature 2021; 591: 451–457.
4. An oral SARS-CoV-2 Mpro inhibitor clinical candidate for the treatment of COVID-19. Science 2021 Dec 24;374(6575):1586-1593

SNS812 Virus Inhibition – in vivo

Prophylatic Treatment Prevented Virus Infection

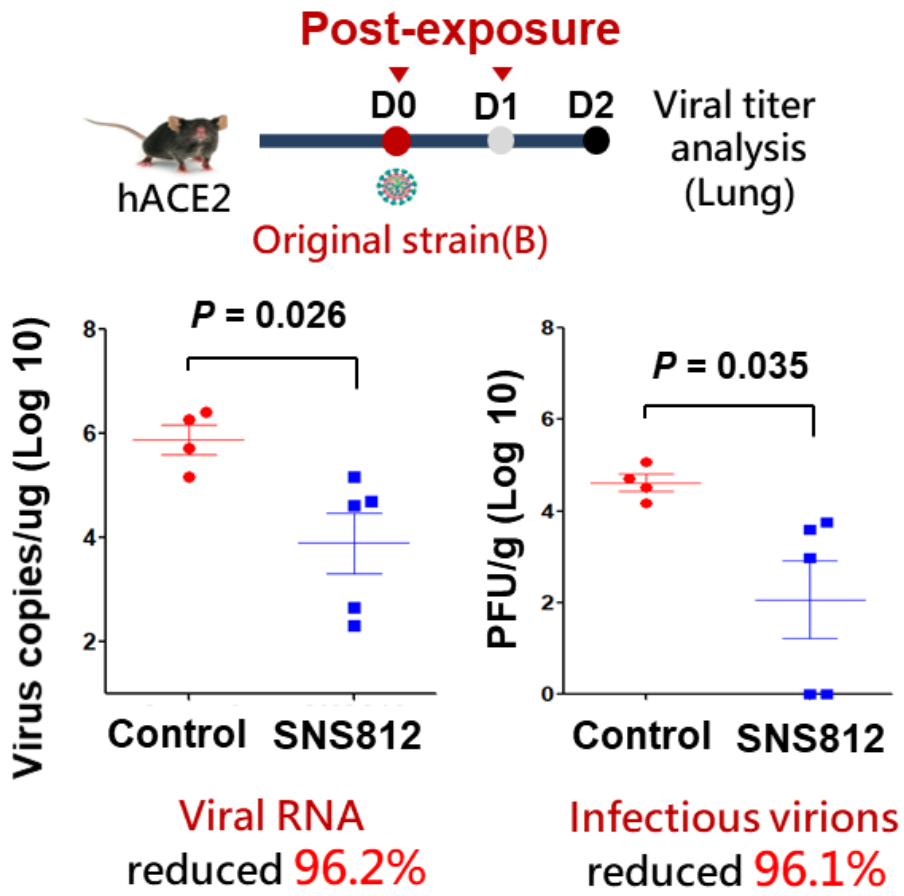


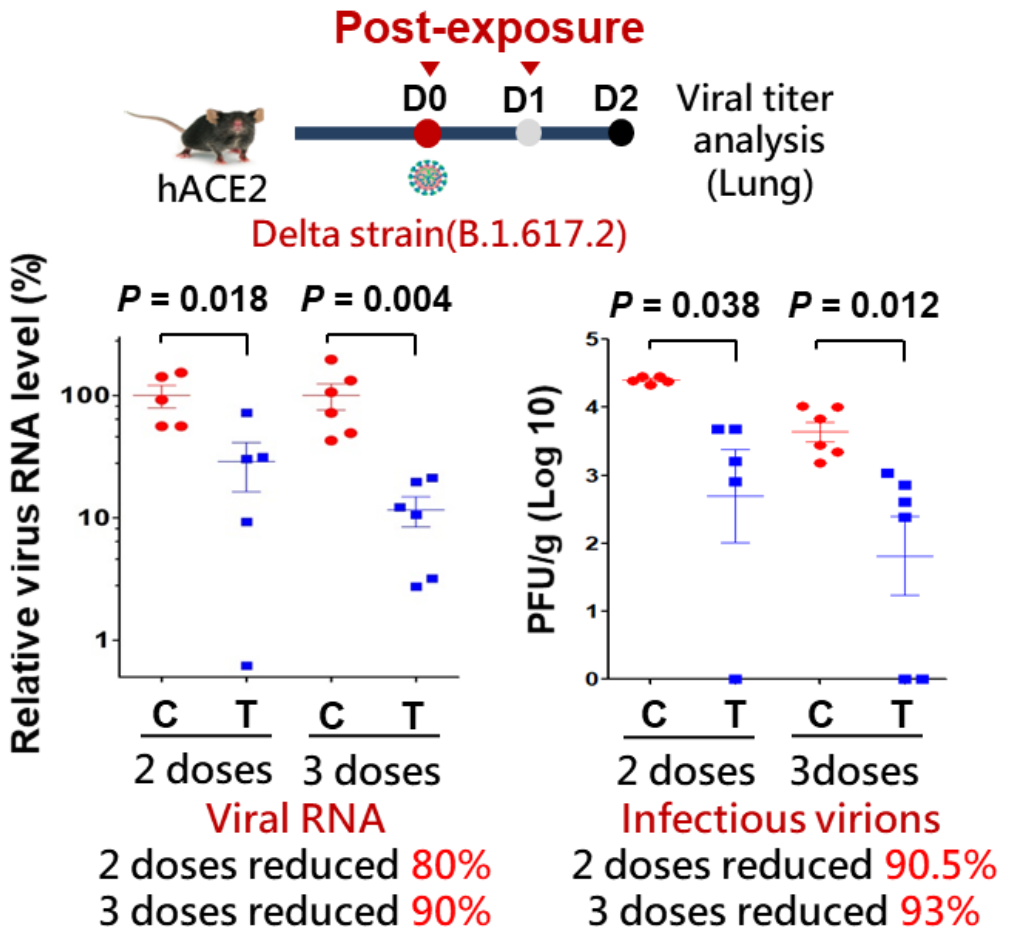


-Unpublished data-

SNS812 Virus Inhibition – in vivo

Post-exposure Treatment Showed Significant Inhibition of Viruses





-Unpublished data-

SNS812 (siRNA) Progress

- SNS812 targets the conserved region of SARS-COV-2. As of 2021.12.13, its target viral genome covers 99.8% of SARS-CoV2 strains including the Omicron variant according to NCBI database and GISAID
- Contracted with CMO & CRO to proceed with GMP production and non-clinical tox studies. Plan to submit IND in 2022.H2
- SNS812 research data and results have been submitted to a renown international journal

Upcoming 2022 and Beyond Milestones

Fespixon (ON101)	• Market entry into China • Out-license in EU/US • Initiate rolling submission in the US
FB825	• Ph2a AD completion • Ph2a AA completion
FB704A	• Ph2a severe asthma • Evaluate to initiate Ph2a CKD-induced CVD
SNS812	• Initiate first-in-patient clinical trial

Financials

5-year Balance Sheet

NT$ Million	2016	2017	2018	2019	2020	21Q3	YoY (%) 2016	2017	2018	2019	2020	21Q3
TOTAL ASSETS	**2,556**	**2,521**	**2,335**	**6,980**	**15,384**	**14,620**	**(9.0)**	**(1.3)**	**(7.4)**	**198.9**	**120.4**	**33.5**
Cash	194	244	286.5	1202.2	6524.9	5,916.5	(72.0)	25.6	17.3	319.7	442.7	401.2
NR & AR	0.7	0.2	1.0	1.7	443.9	24.4	(6.8)	(70.8)	354.6	71.4	26,277.8	(94.6)
Inventory	41	41	50	48	50	67	27.9	(1.1)	23.7	(4.0)	3.8	36.7
Fixed Asset	175	456	561	640	727	723	642.7	160.8	23.1	14.2	13.5	17.0
TOTAL LIABILITIES	**31**	**27**	**170**	**521**	**1,625**	**1,615**	**(24.7)**	**(15.7)**	**541.0**	**207.1**	**211.9**	**1.4**
Bank Loans	-	-	-	-	-	-	-	-	-	-	-	-
NP & AP	0.2	0.1	0.5	0.6	48.4	0.8	(18.5)	(53.6)	450.0	15.2	7,865.1	(98.4)
TOTAL EQUITY	**2,524**	**2,495**	**2,166**	**6,459**	**13,760**	**13,005**	**(8.7)**	**(1.2)**	**(13.2)**	**198.2**	**113.0**	**38.9**
A/R turnover days	49	67	12	36	2,028	1,352						
Inventory turnover days	4,563	12,167	1,659	1,074	1,659	1,043						
A/P turnover days	25	39	9	8	830	435						
ROE (%)	(0.54)	(6.38)	(10.75)	(7.56)	(2.48)	(5.29)						
ROA (%)	(0.53)	(6.12)	(9.69)	(6.87)	(2.20)	(4.72)						

5-year Income Statement

NT$ Million	2016	2017	2018	2019	2020	21Q3	YoY (%)					
							2016	2017	2018	2019	2020	21Q3
Sales Revenue	5.7	2.6	18.9	13.5	41.6	47.6	(27.3)	(54.6)	628.9	(28.5)	208.8	29.3
Gross Profit	2.9	1.4	8.2	(3.5)	23.7	32.1	(4.5)	(52.1)	502.8	(142.9)	(770.7)	8.8
Operating Profit	(113.2)	(139.1)	(132.2)	(311.7)	(673.2)	(659.6)	-	-	-	-	-	-
Income before Tax	(14.3)	(155.9)	(244.9)	(326.3)	(249.9)	(524.0)	-	-	-	-	-	-
Net Income to Parent	(14.3)	(155.4)	(235.4)	(322.2)	(241.9)	(531.4)	-	-	-	-	-	-
EPS (NT$)	(0.07)	(0.80)	(1.20)	(1.28)	(0.68)	(1.40)	-	-	-	-	-	-

Key Financial ratio (%)

Gross Margin	50.0	52.8	43.6	(26.2)	56.9	67.4
Operating Margin	(1,984.1)	(5,376.6)	(701.0)	(2,313.4)	(1,618.0)	(1,385.7)
Opex ratio	2,034.1	5,429.4	744.7	2,287.2	1,674.9	1,453.4
Net Margin	(250.0)	(6,008.7)	(1,248.6)	(2,421.2)	(604.9)	(1,133.2)

Globalization by Innovation