# 36<sup>th</sup> Annual J.P. Morgan Healthcare Conference



A Taiwanese Leading Biotech Since 1997



#### **MICROBIO Group Profile**

- 1997 Established with 4 listed in Taiwan
- 700 million USD Investment in R&D
- 12 New Drugs Pipeline
- 4 R&D Centers
- 2 PIC/s GMP Standard Manufacturing Plants in Taiwan
- 1 GMP Manufacturing Plant in China
- 80 In-House Scientists + 5 Research institutions



#### **Product Pipeline**

Phase 1

Phase 2

Phase 3

**Approved** 

**OB318** 

**HCC** 

**MB-110** 

**HCV** 

**FB704A** 

Anti-IL-6

**FB317** 

Anti-IgE

**SNP630** 

NASH

**SNP810** 

Analgesic and antipyretic

FB825

Anti-CemX

**ON101** 

Diabetic Foot Ulcer

MB-6

Colon Cancer

**MS-20** 

Oncology

Herbiron

Anemia

2 Approved Drugs and 8 Programs on Clinical Stage



# ON101 (DFU Cream)

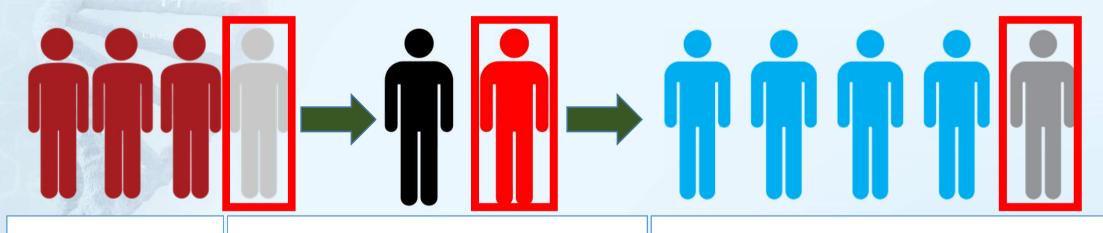
# **Outstanding Phase III Interim Result**

**Wound Healing Rate > 60%** 

#### **DFU-Unmet Medical Need**



## DM patients worldwide 425 million



25% has DFU

>50% DFU patients Infected

**20%** DFI patients amputated

DFU mortality in 5 Years 50 %

# DFU – A Major Economic Impact<sup>™</sup>



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** Phase III Interim Result



#### Overall Group



62.7%

ON101

60

50

40

30

20

10

Plantar Ulcers Group



63.6% 60 50 40 24.1% 30 20 10 ON101 Aquacel

Difference = 30.5% (p<0.001)

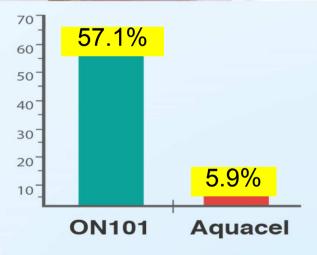
32.2%

Aquacel

Difference = 39.5% (p=0.002)

▶ Large Wound Size (> 5 cm<sup>2</sup>) Group



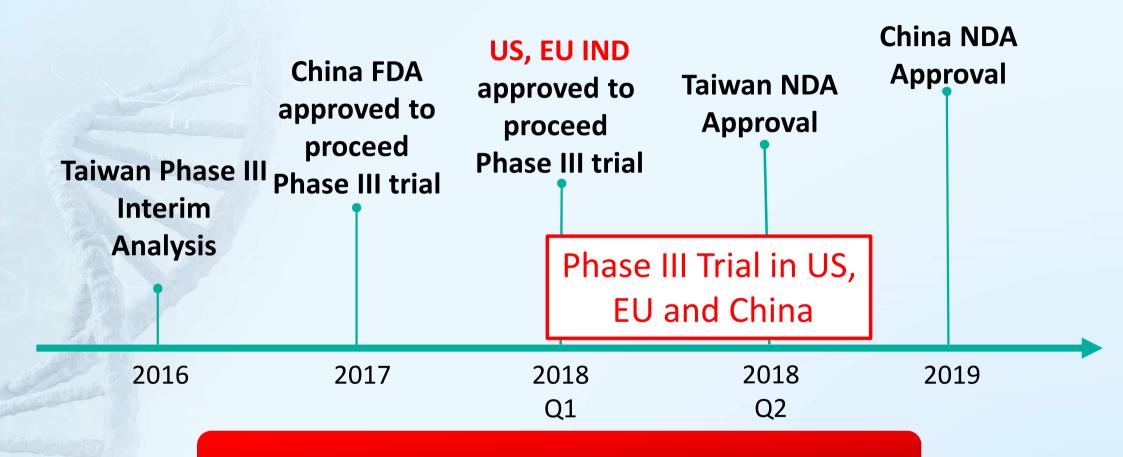


Difference = 51.2% (p=0.002)

**60% Complete Healing in 16 Weeks** 

#### **ON101** Development Plan





**Looking for Strategic Partners** 



# MS20 (Commensal bacterial metabolites)

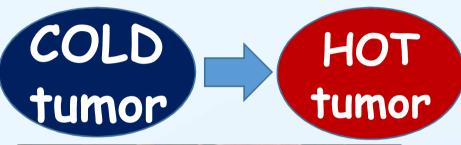
# **New Indication Development**

on Human Gut Ecosystem and PD-1 booster

# Limited Response Rate of Immune Checkpoint Inhibitors



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 %	-								





Commensal *Bifidobacterium* promotes antitumor immunity and facilitates anti-PD-L1 efficacy

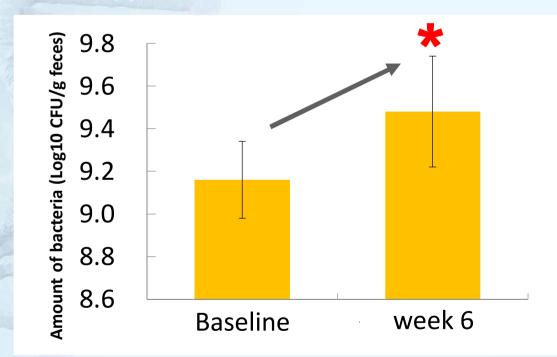
Science. 2015, 350(6264):1084-1089

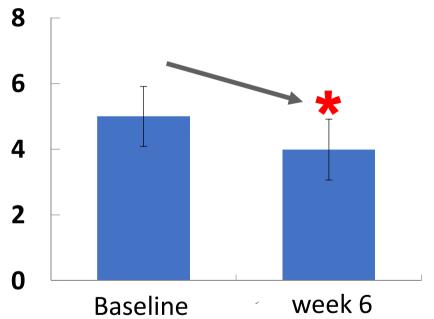


#### MS-20 Human Gut Microbiota Ecosystem

# Bifidobacterium spp. (beneficial bacteria)

# Clostridium perfringens (gut pathogen)



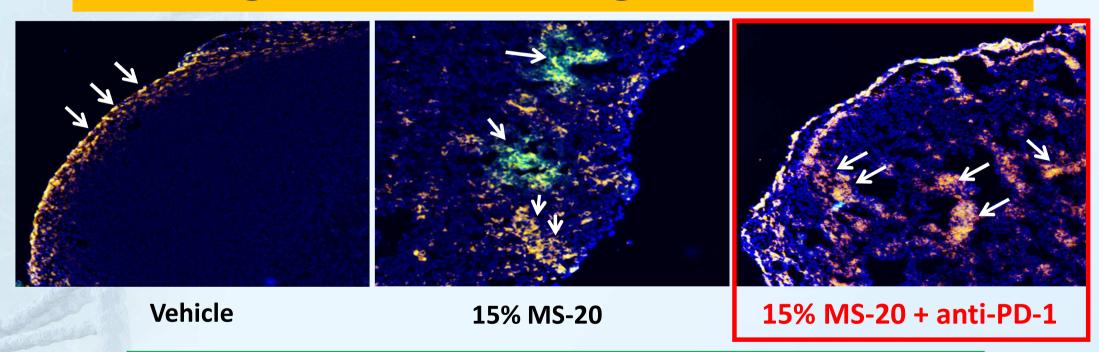


<sup>\*</sup> p<0.05 compared with baseline

#### MS-20 Turn Cold to Hot tumors



### **Boosting tumor infiltrating CD4+/CD8+ T cells**



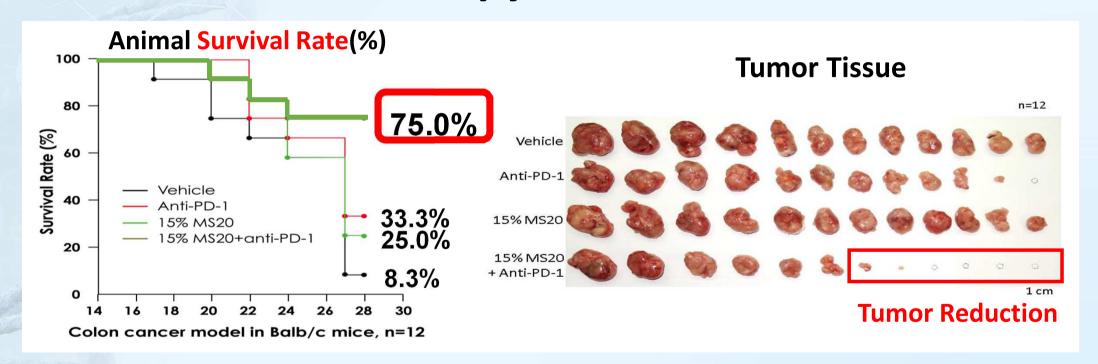
Blue: Tumor cells; Green: Dendritic cell

Yellow: CD4<sup>+</sup> T cells; Red: CD8<sup>+</sup> T cells



#### **MS-20** Enhance Anti-tumor Immunity

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



**Improved Survival Rate and Reduced Tumor Size** 



#### **MS-20** Opportunity



- 1. Market Product Modulates
  Human Gut Microbiome
- 2. Enhancement of Immune Checkpoint Blockade

**Looking for Strategic Partners** 



# FB825 (Anti-CεmX)

# First-in-Patient Data

on Moderate-to-Severe Atopic Dermatitis

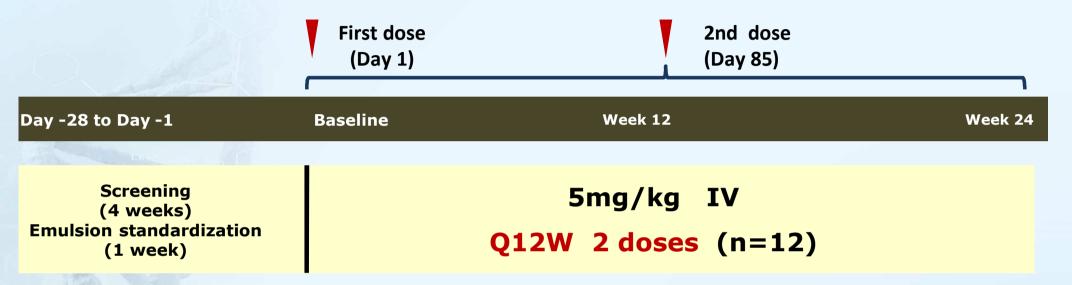
#### FB825 Clinical Site and PI



- Top Ranked Medical Center in Taiwan
  - **National Taiwan University Hospital**
- Chia-Yu Chu MD, PhD
  - CEO, National Taiwan University Hospital International Medical Service Center
  - Director, Taiwanese Dermatological Association
  - Editor-in Chief, Dermatologica Sinica
  - Chairman, 6<sup>th</sup> Euro-Asian Association of Dermatovenerologists Congress
  - Conducted global trials for Atopic Dermatitis including Anti-IL4R, Anti-IL13, JAK inhibitors, etc.

#### FB825 Clinical Design (Exploratory Study)





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

12 Weeks per Dose on Moderate-to-Severe Atopic Dermatitis

#### FB825 Compare with Dupilumab



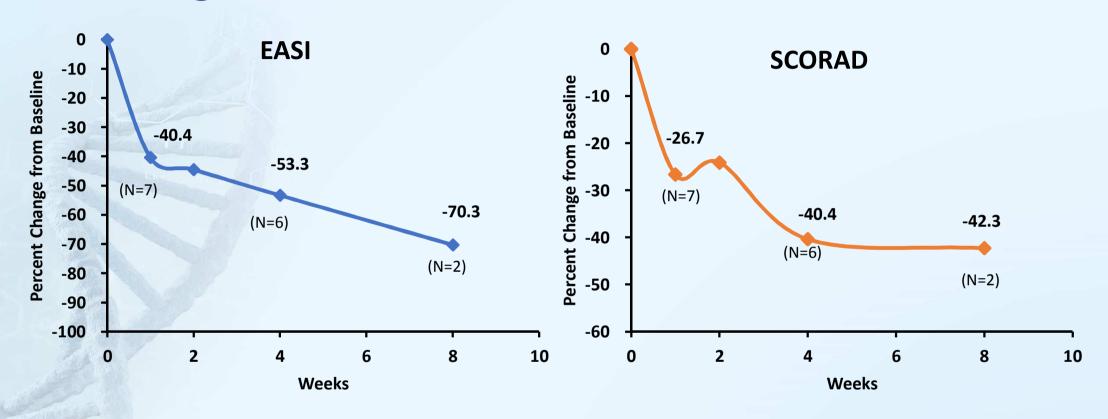
		EASI Score Change from Baseline						Dose Interval
	W1	W2	W4	W8	W12	W13	W16	
FB825	-40%	-45%	-53%	-70%				12W per dose
Dupilumab*	-15%	-35%	-55%	-66%	-70%	NA	-70%	2W per dose

<sup>\*</sup>Phase III Trial Results, Dupilumab is currently the only approved biologics for atopic dermatitis.

260% Improvement over Dupilumab at Week 1
One dose/8w of FB825 is equal to 4 doses/8w of Dupilumab

#### **FB825** Significant Reduction





1 dose / 8 Weeks

70% Reduction in EASI42% Reduction in SCORAD

#### FB825



## **Breakthrough Findings in Atopic Dermatitis**

- Earlier Onset
  - EASI score reduced by 40% in the first week after dosing
- Longer Effect
  - Be effective up to 2 months by single dose
  - 1 dose of FB825 are comparable to 4 doses of dupilumab (based on current data)
- Minor Side Effect
  - No local reaction observed

#### FB825



## **Looking for Strategic Partnership**

- In-licensing
- Co-development







**Thank You Very Much**