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合一生技股份有限公司

Corporate Presentation (TPEx 4743)

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Dec 2019

Forward Looking Statement

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.

Outline

- Overview of New Oneness
- Specialties of New Oneness
- Introduction of Core Assets
- Milestones in the next five years
- Concluding Remarks

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The NEW Oneness

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

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Market Value & Financials

2017-2019 Q3 Financials

Currency in thousand NtD	2019.Q3	2018	2017
Revenue	11,100	18,856	2,587
R&D Exp.	124,157	94,436	65,432
Net Profit	(152,898)	(244,941)	(155,923)
Total Assets	7,225,806	2,335,421	2,521,393
Liabilities	576,204	169,643	26,464
Owner's Equity	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	10,346Mn

(20 Dec, 2019) (Currency in NTD)

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Consolidated Balance Sheets

(Currency in thousand NTD)

Item	2019/09/30	2018/12/31	2017/12/31
Current assets	1,737,780	745,176	1,237,325
Property, plant and equipment	627,199	561,012	455,714
Intangible assets	2,278,502	51,925	23,106
Other assets	2,582,325	977,308	805,248
Total assets	7,225,806	2,335,421	2,521,393
Total liabilities	576,204	169,643	26,464
Share capital	3,524,908	1,957,522	1,957,522
Capital surplus	3,751,668	799,295	764,582
Retained earnings	(232,523)	(254,379)	(155,446)
Other equity	(394,451)	(336,660)	(71,729)
Total equity	6,649,602	2,165,778	2,494,929

The NEW Oneness

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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					

Global Supply Advantage

From cultivation to production

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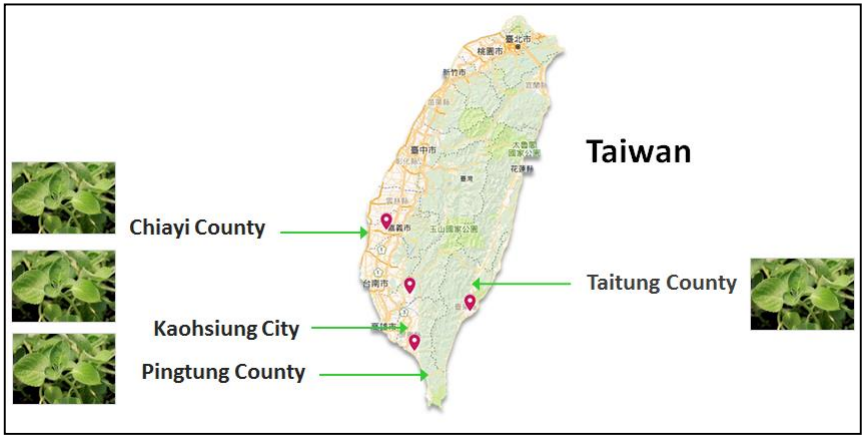
Global Supply

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

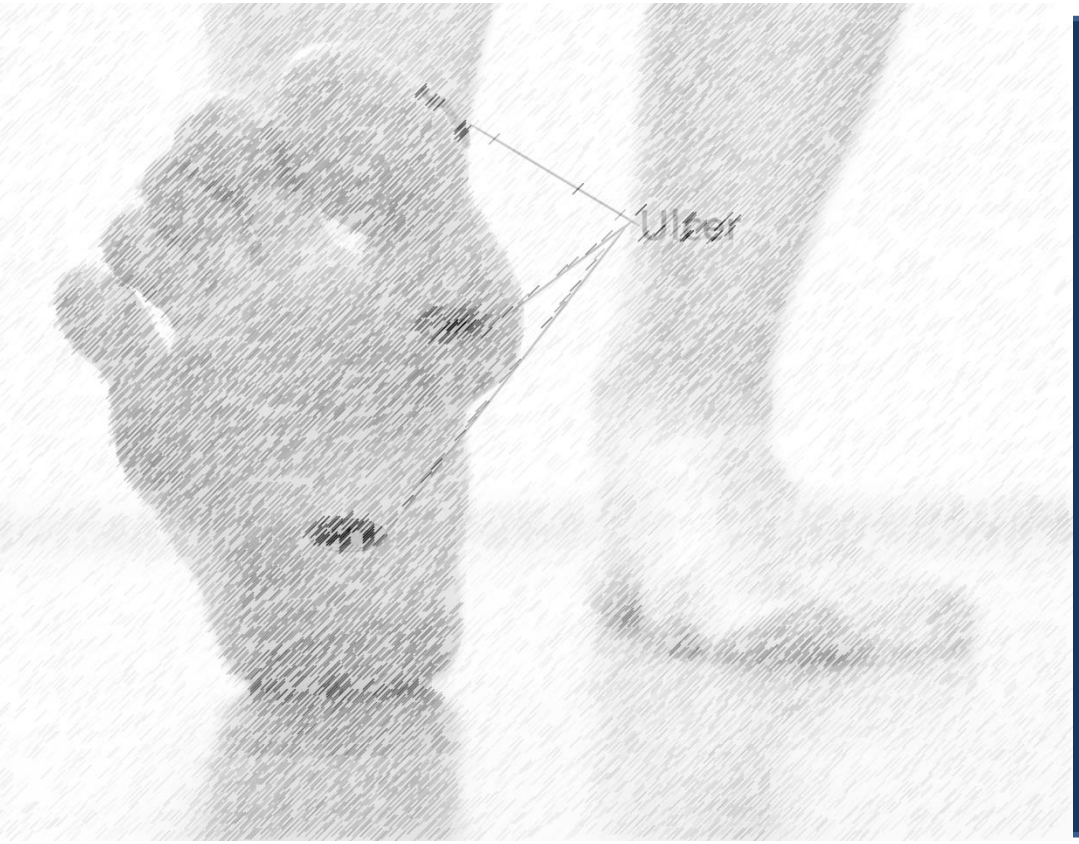
- **PIC/s GMP生產廠(第一階段可供應2,500萬條)**

44-acre GACP 種植基地



PIC/s GMP 生產廠

Core Asset-ON101



Global Unmet Medical Needs

The Best-in-class for DFU

(Diabetic Foot Ulcerations)

DFU(Diabetic Foot Ulcers)

1. Global Unmet Medical Needs

2. Global Medical Expenditures exceed US$60Bn

3. Failed phase III studies of many new DFU drugs in the past 20 years

4. 50-60% 5-year survival rate after amputation

ON101 Clinical Healing Consistency (1)

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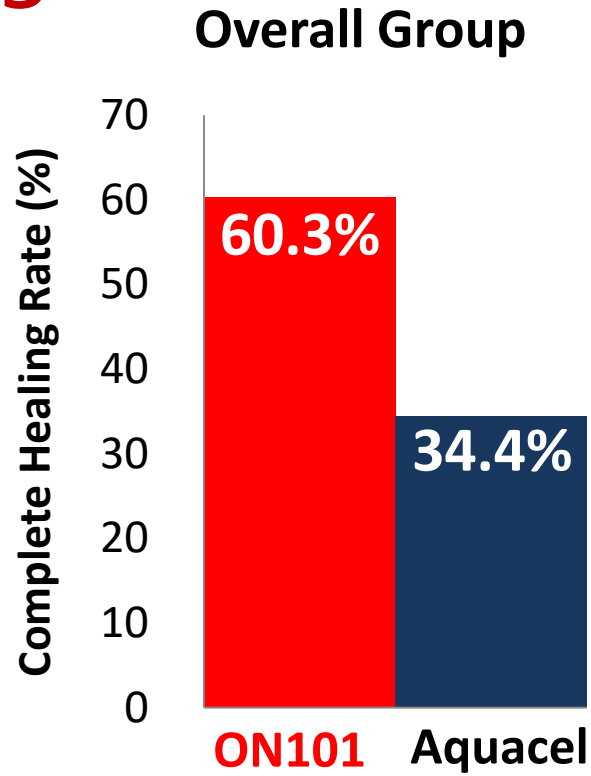
Main Therapeutic Indicator: Complete Healing Rate of Ulcers (FAS)



Complete Healing Rate :

ON101組 60.3%

Aquacel組 34.4%

The only phase III DFU study achieve 60% complete healing rate

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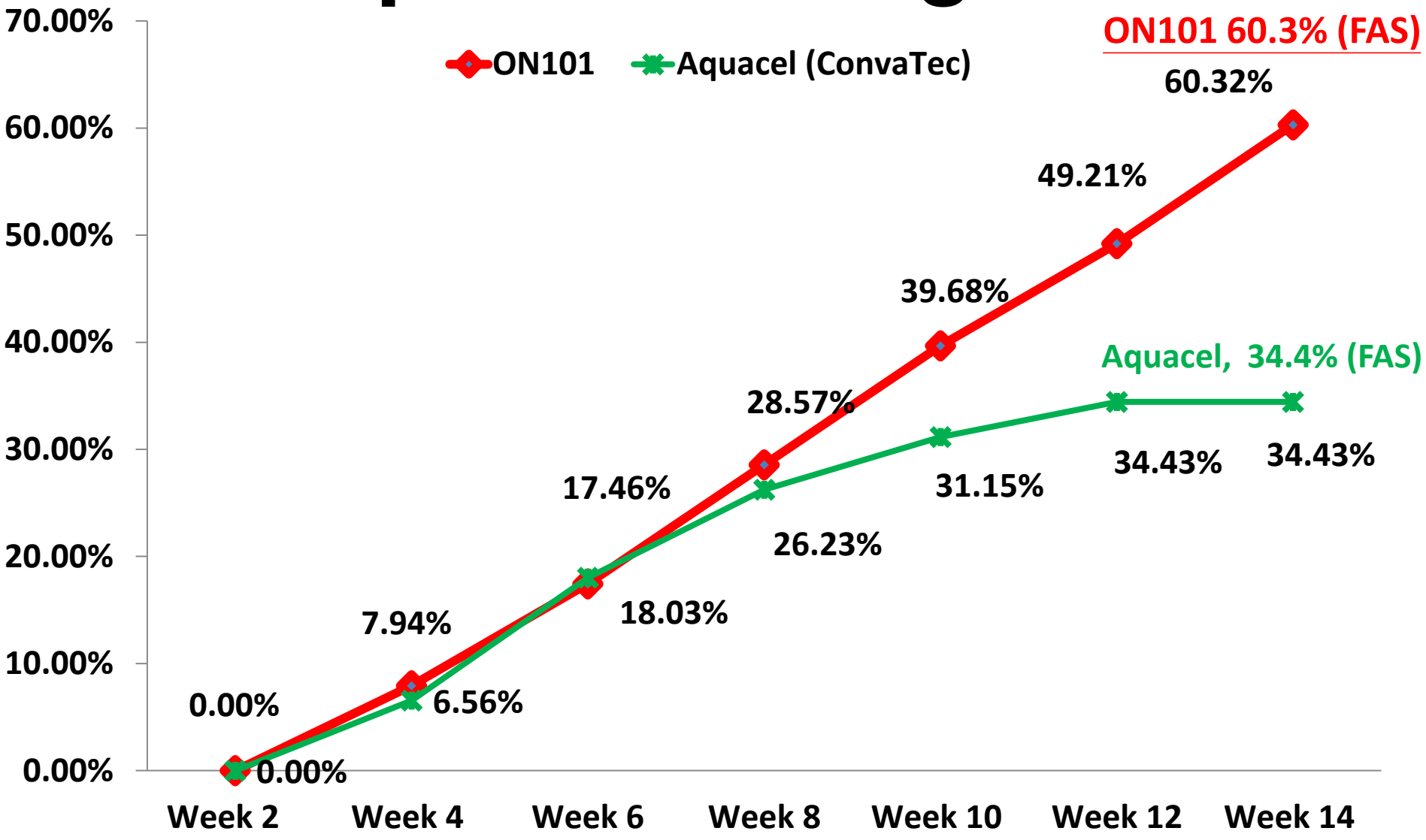
Complete Healing Rate



ON101 Clinical Healing Consistency (2)

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Subgroup Analysis of Complete Healing Rate on Hard to heal Ulcers

	ON101 : Aquacel
• Plantar Wound	60.0% : 26.7%
• Wounds >5 cm^2	53.3% : 5.9%
• Wagner Grade 2	63.0% : 32.7%
• HbA1c > 7%	50.0% : 30.0%

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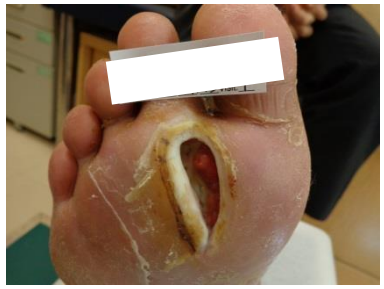
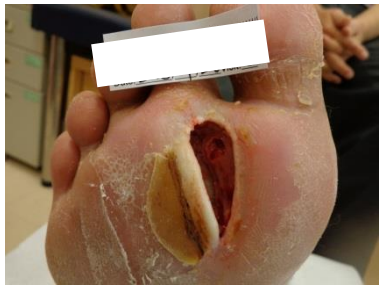
Phase III Interim Analysis

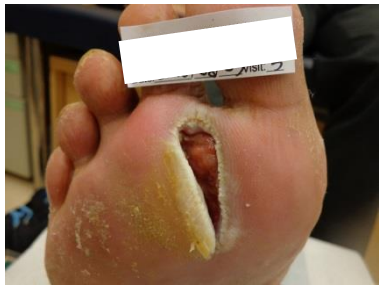
Ulcer duration 1.2 month; Plantar wound size 3.23 cm^2;
Completely healed in 10 weeks



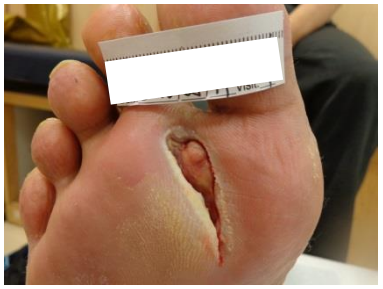
V1 2016/07/13
G2 Area: 2.85 cm^2



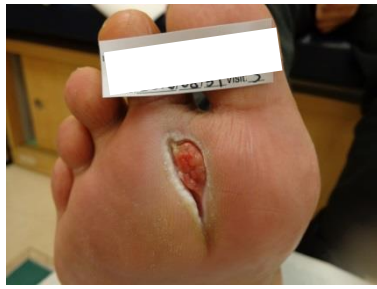
V2 2016/07/20
G2 Area: 3.23 cm^2



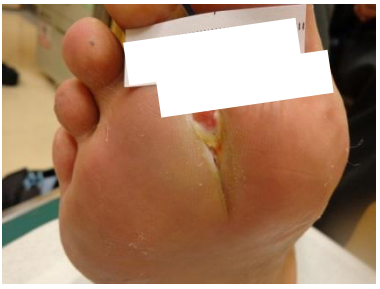
V3 2016/08/03
G2/G1 Area: 2.30 cm^2



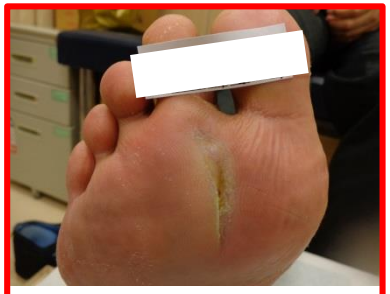
V4 2016/08/17
G1 Area: 1.77 cm^2



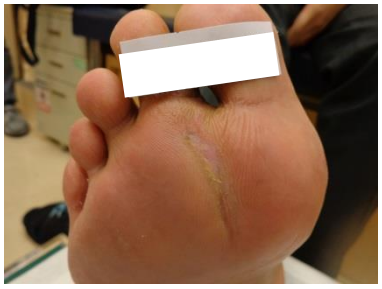
V5 2016/08/31
G1 Area: 1.49 cm^2



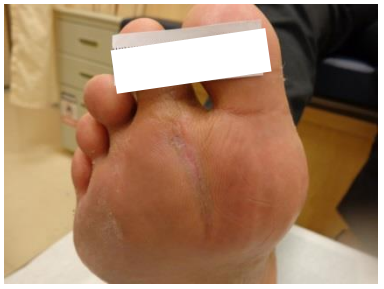
V6 2016/09/14
G1 Area: 0.48 cm^2



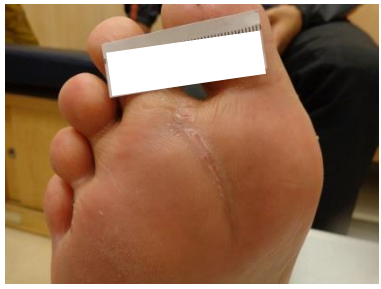
V7 2016/09/28
Healing
G0 Area: 0.00 cm^2



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 Development Plan

Manufacturing

- Mass production trial run at PIC/S GMP factory in Taiwan
- Obtained the API drug certificate of PA-F4

Clinical Development

- NDA drug registration review in Taiwan
- Phase III clinical trial in China
- Second Phase III clinical trial in the US

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Core Asset-FB825

With Revolutionary Mechanism in Atopic Dermatitis

The First-in-class for AD

(Atopic Dermatitis)

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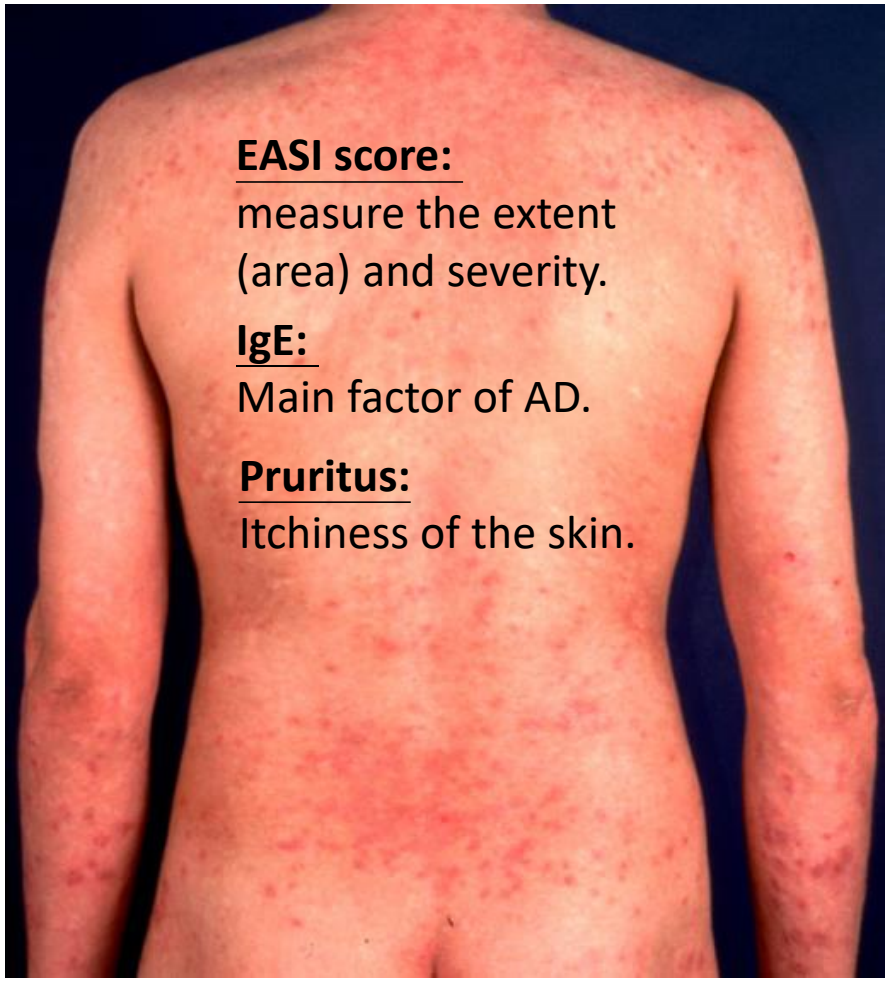
Atopic Dermatitis (AD)



>28 million

Global patients number with Severe AD

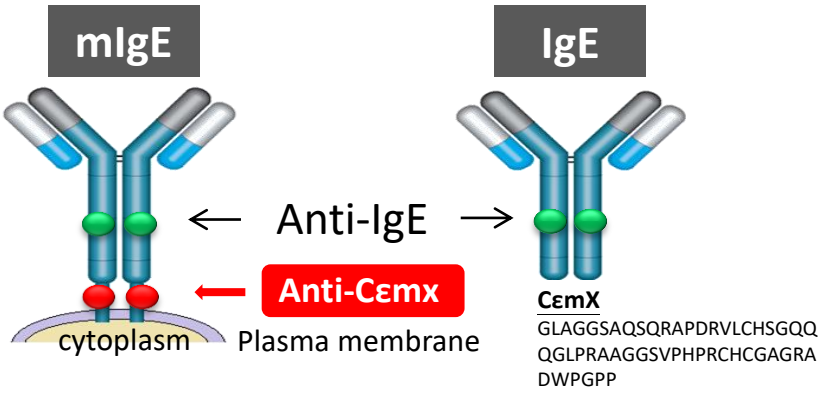
>15.7 million

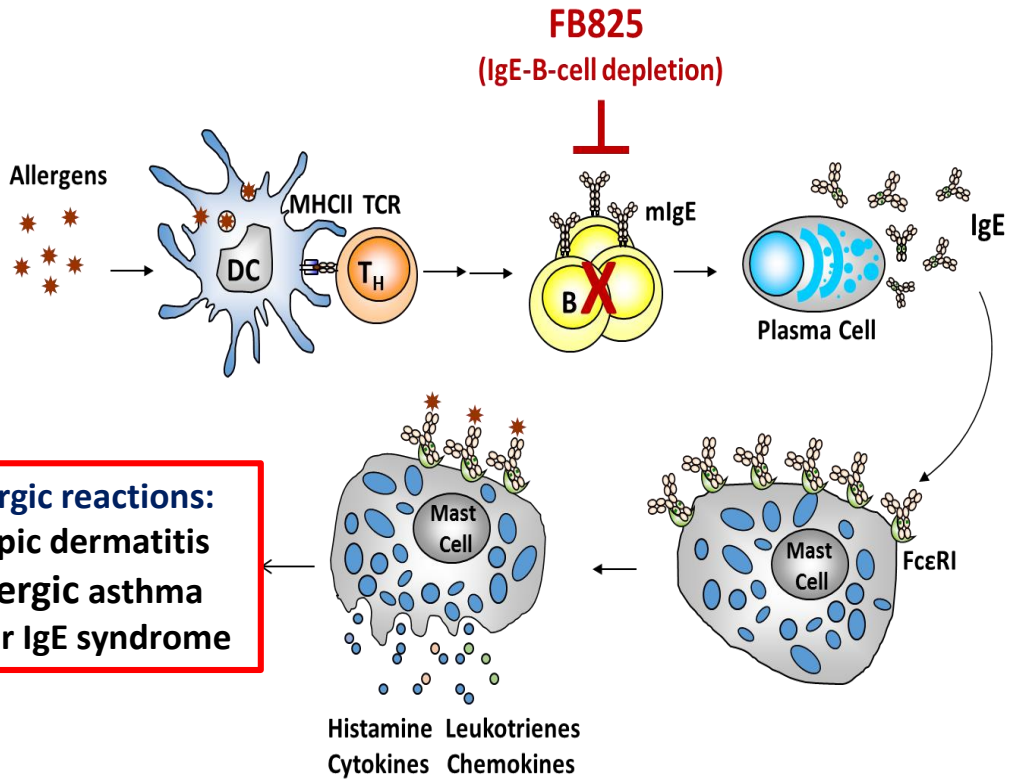
Inadequately Controlled Patients Numbers

>18 billion

Five-year market forecasts

FB825 Mechanism





- **CεmX is expressed on mIgE B cell**
- **IgE is related to many types of allergic diseases**

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FB825 Clinical Outcomes (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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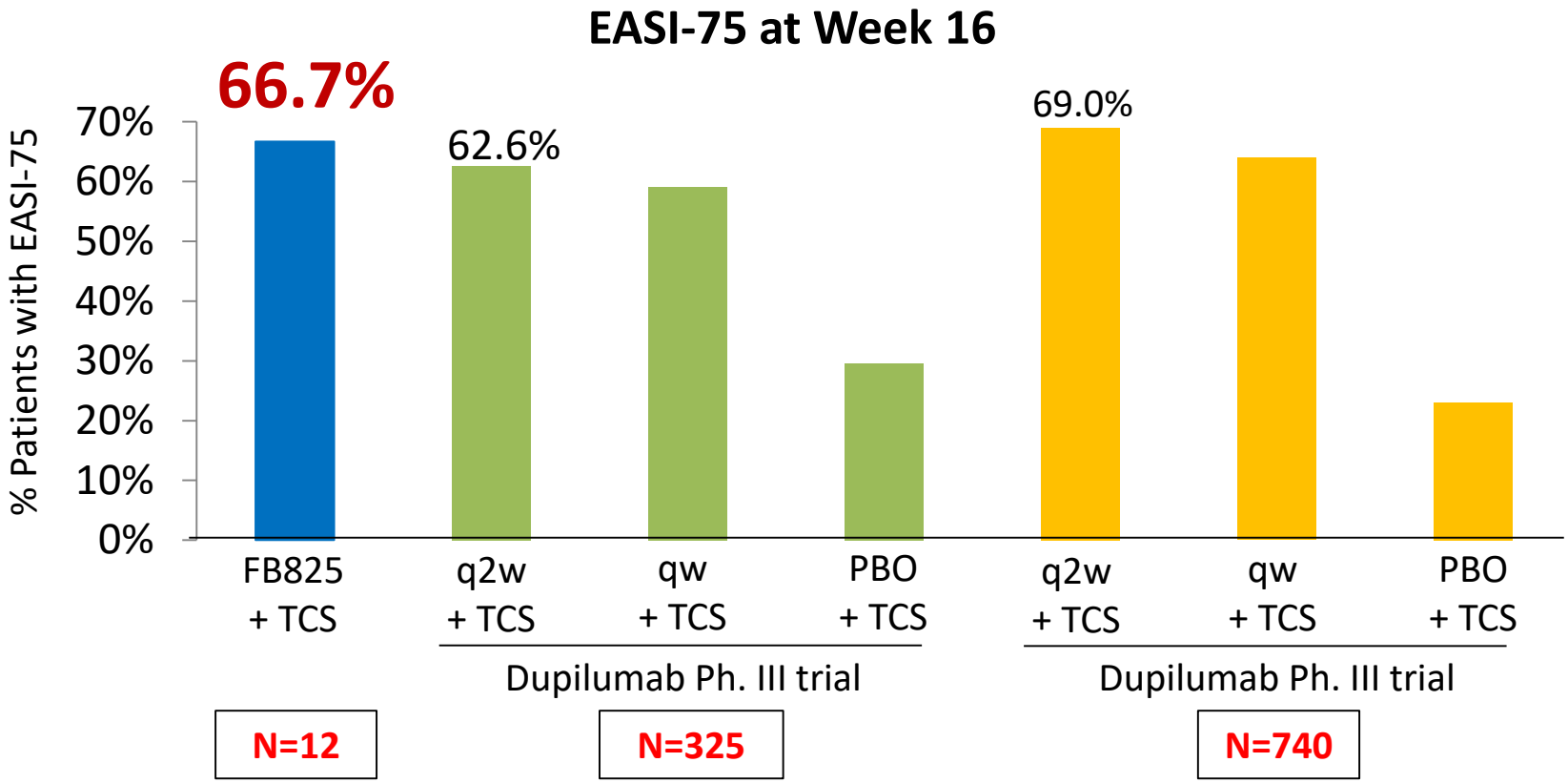
FB825 vs. Dupilumab

Dupilumab (Sanofi) is currently the only approved new AD antibody drug, which was launched in the second quarter of 2017, and the sales of 2019 Q3 has reached US $ 1.5 bn.



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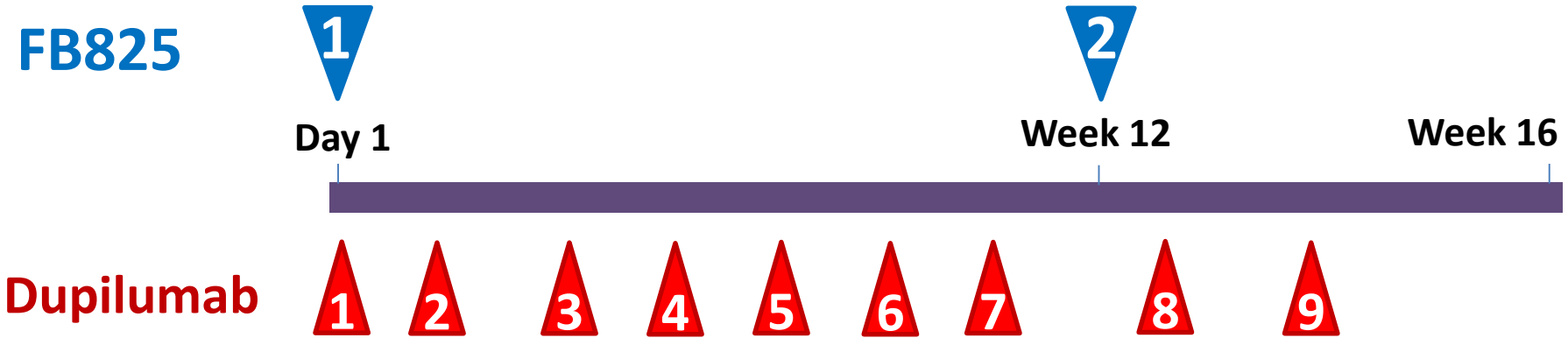
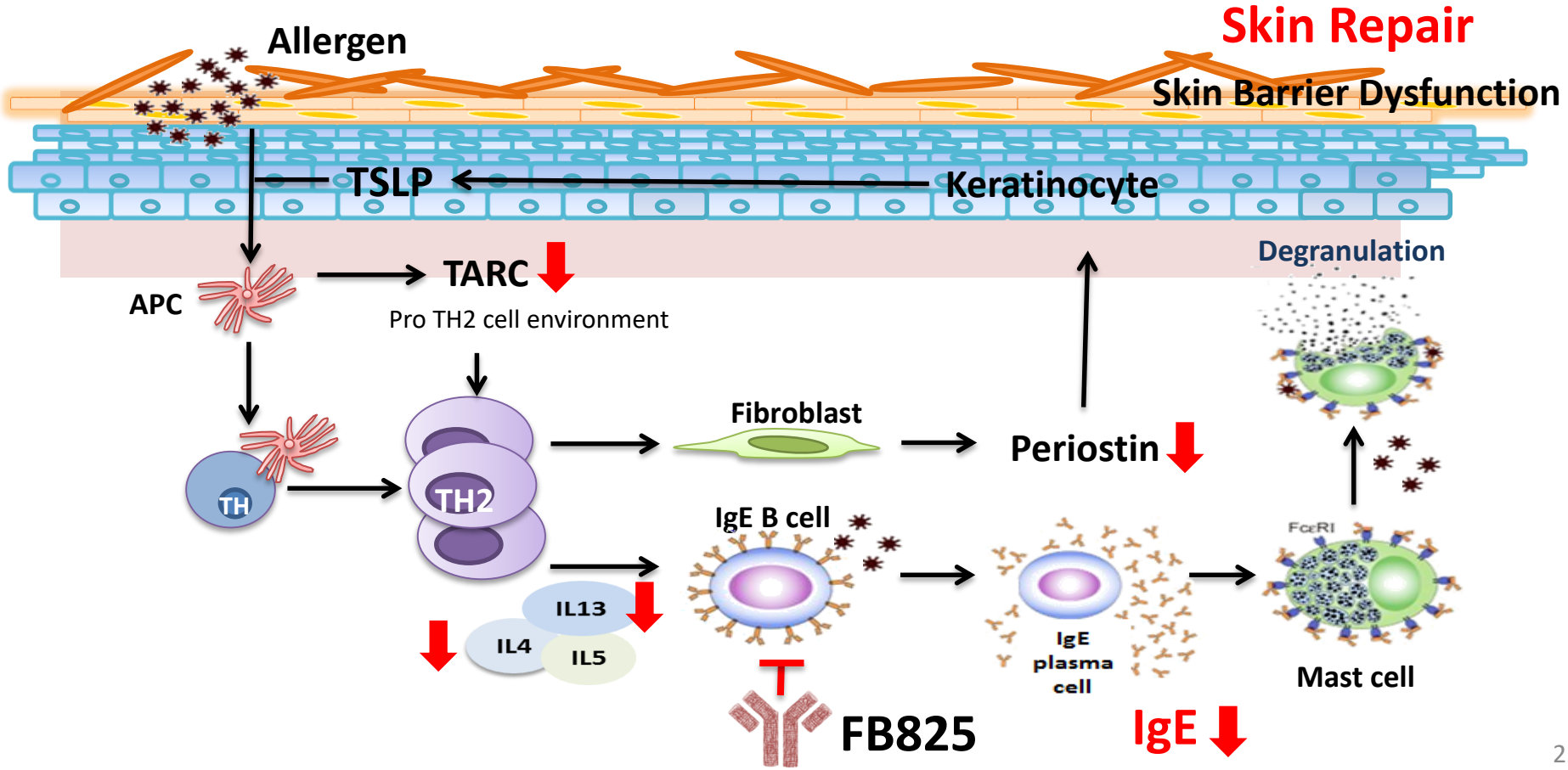
FB825 Clinical Advantage

The efficacy of 2 injection of FB825 is comparable with 9 injections of Dupilumab (Sanofi)



Brand New Mechanism of Drug Action



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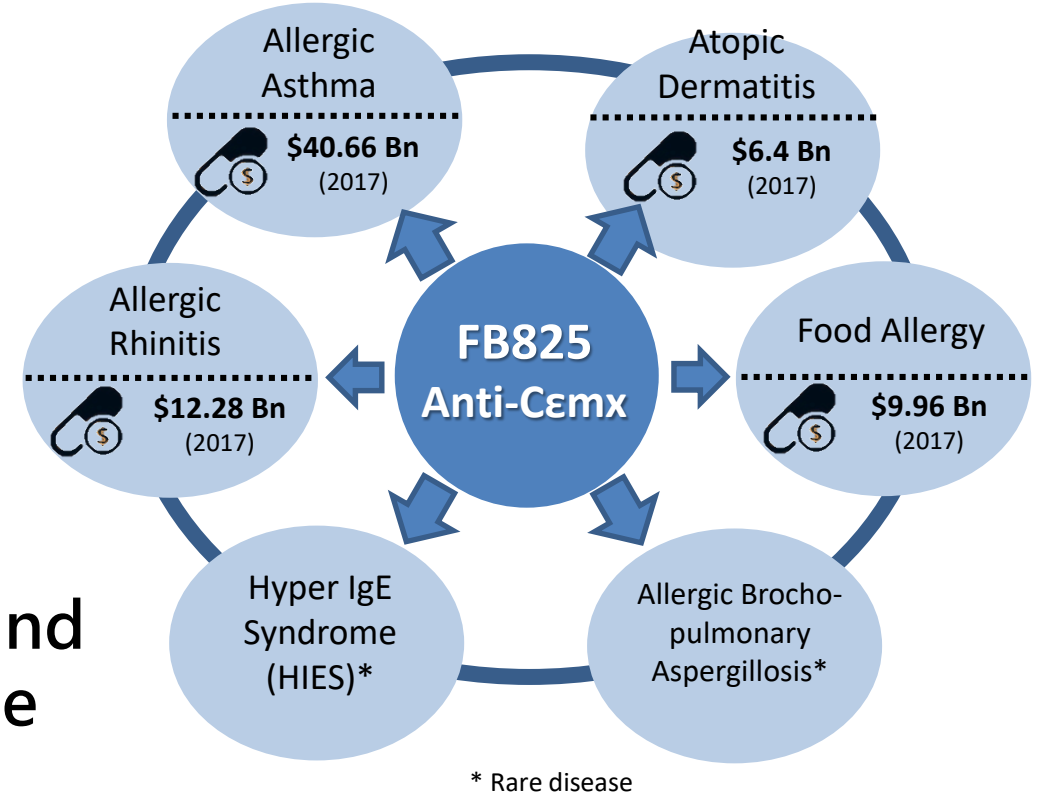
The world's only new drug to treat high IgE diseases

- Currently the only potential treatment for high IgE (>1,500 IU/mL) disease
- Long-acting antibodies against various allergic diseases with no significant side effects and good patient compliance
- Market value of US$8 reached by 3% of AD patient treated with FB825



* Rare disease

FB825 Development Plan

Manufacturing

- Completion of 3 cGMP batches of drug production at an US-based CMO

Clinical Development

- Start Phase II study for atopic dermatitis in the US
- Start Phase II study for allergic asthma in China

International Commercialization Strategy

- **FB825 has been demonstrated with proven efficacy and dosing advantage with the exploratory study**
- **Licensing Discussions with Global Pharma are ongoing**

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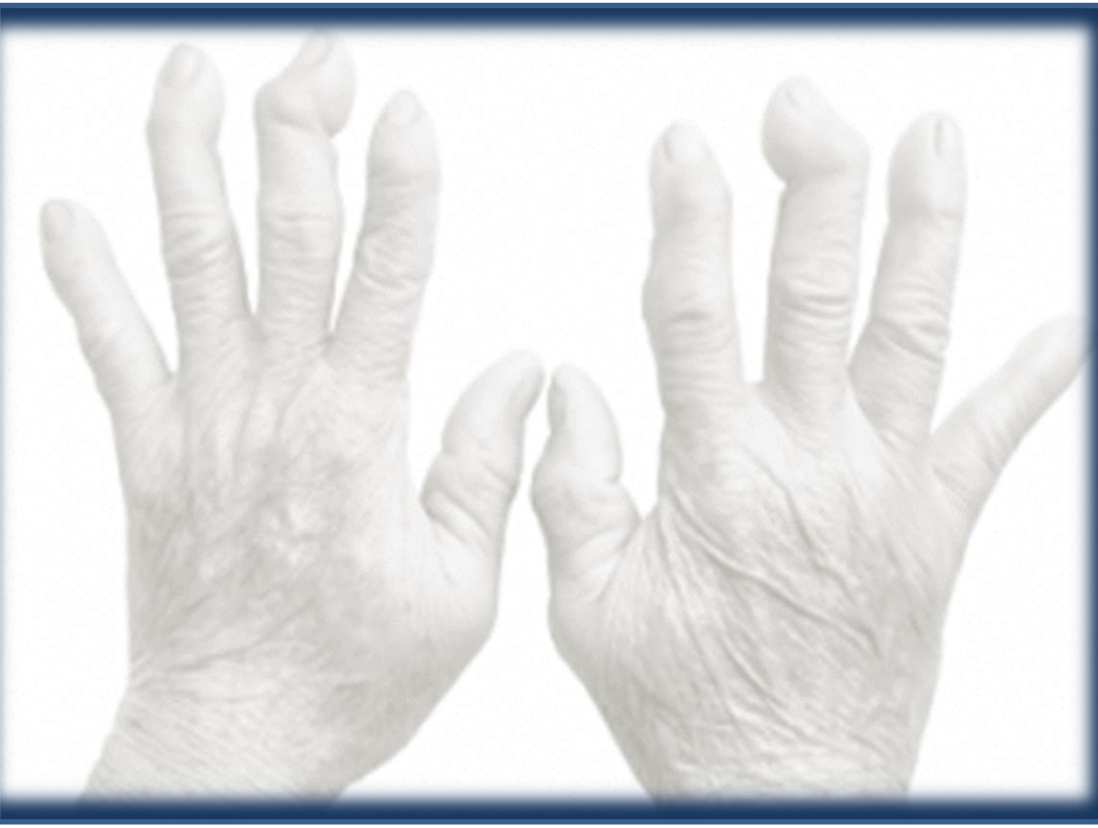
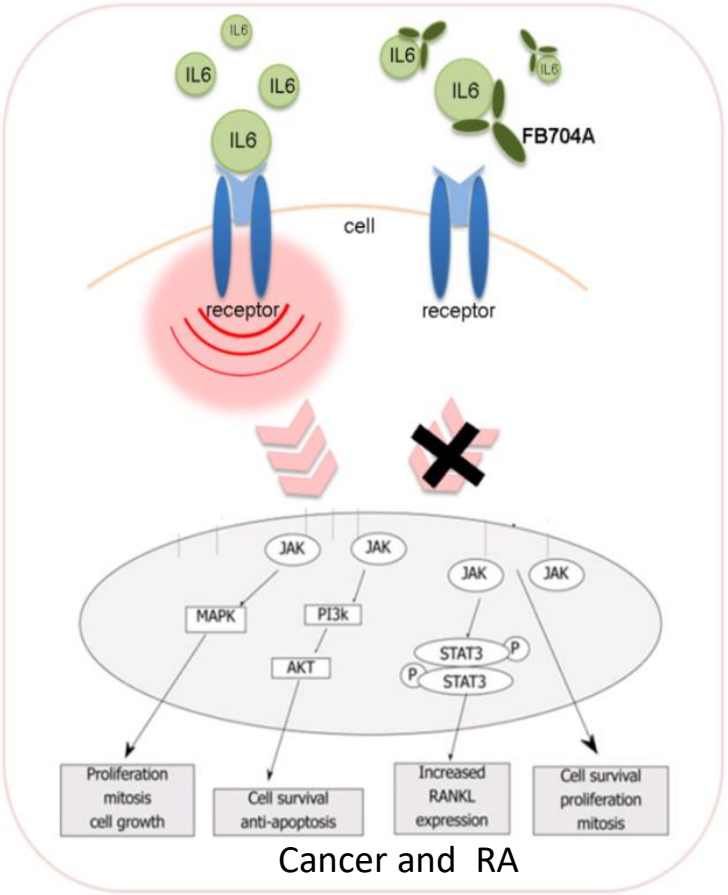
Core Asset-FB704A



Anti-IL6 humanized monoclonal antibody new drug

The Best-in-class for RA
(Rheumatoid Arthritis)

FB704A
Target IL6 related applications

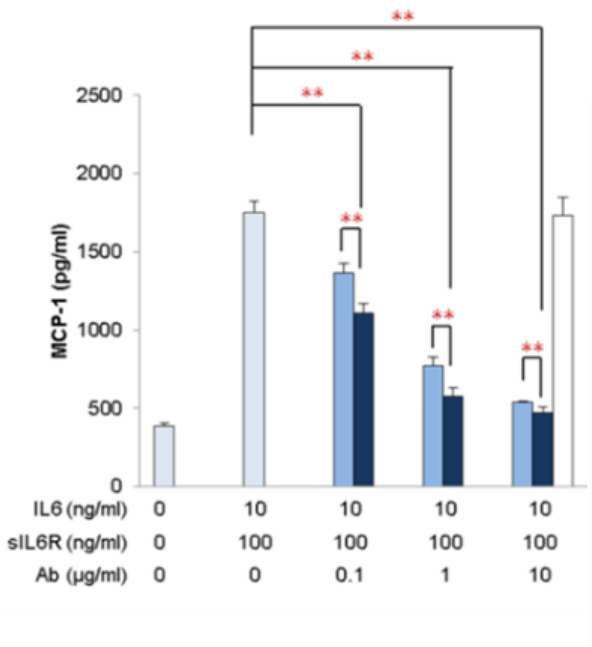


Cancer and RA

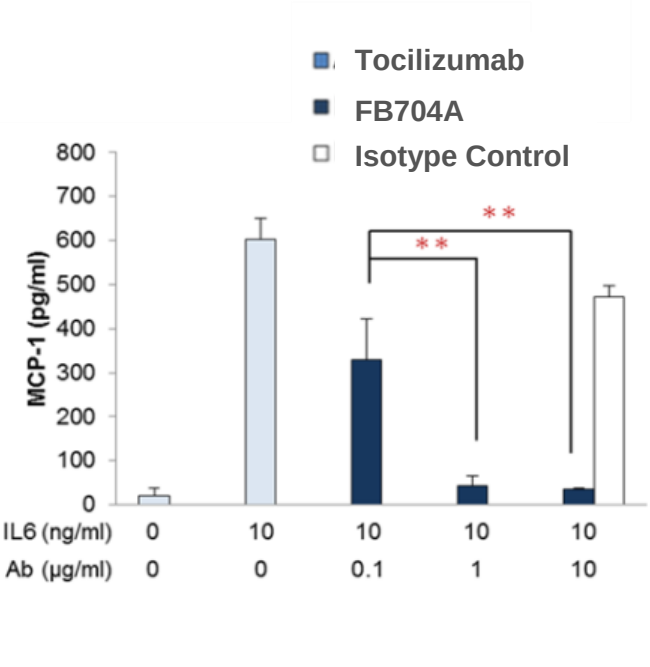
Name	Disease	Targets	Company
Tocilizumab (Approved)	Rheumatoid arthritis Castleman disease Giant cell arteritis	IL-6R	Roche
Siltuximab (Approved)	Castleman disease	IL-6	Janssen
Sarilumab (Approved)	Rheumatoid arthritis	IL-6R	Sanofi
FB704A	**Rheumatoid arthritis Inflammatory Bowel Disease (IBD) (unmet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

FB704A vs. Tocilizumab (Roche)

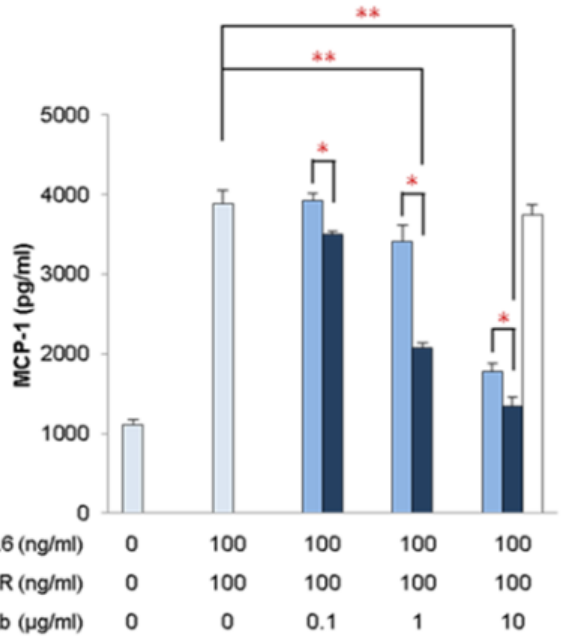
HUVEC cells



Human PBMC



Fibroblast-like synoviocytes (RA-FLS)



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FB704A Development Plan

Manufacturing

- Completed pilot run of cGMP drug production at a US-based CMO

Clinical Development

- Completed Phase I study in healthy volunteers in the US
- Start Phase I clinical study for Rheumatoid Arthritis in the US

International Commercialization Strategy

- **Completed Trial of proven clinical efficacy and treatment advantages**
- **Initiate out-licensing or co-development approaches**

Core Asset-OB318

Global Urgent Medical Needs

Liver Cancer

OB318 Mechanism of Drug Action

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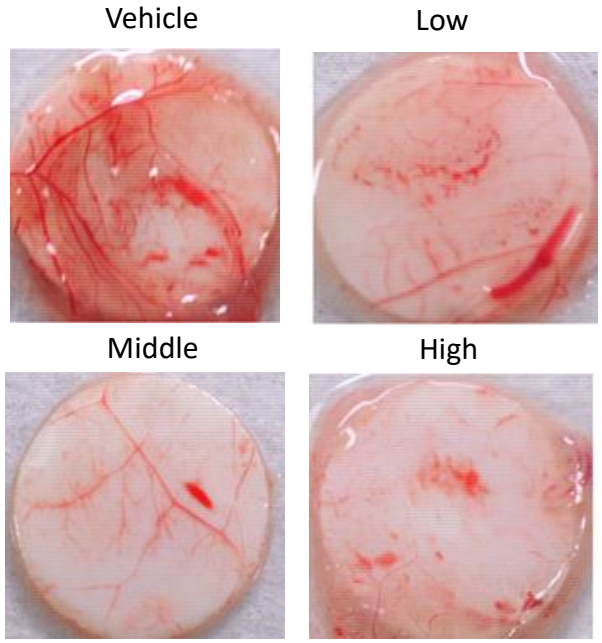
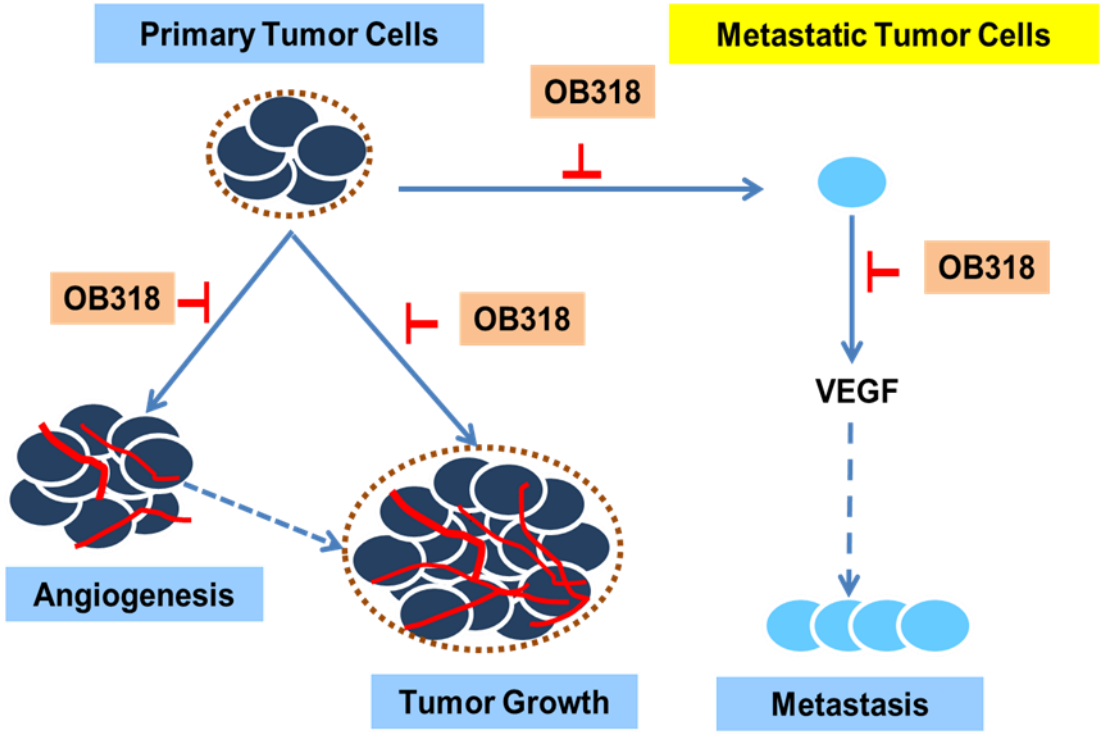
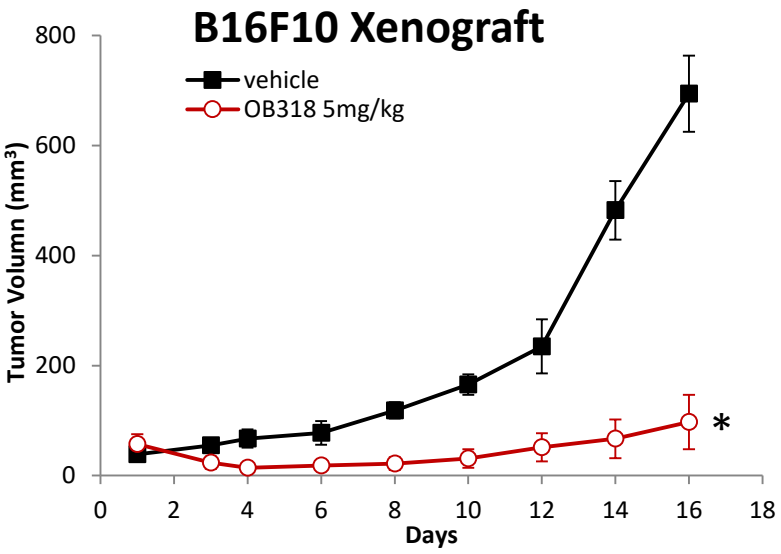
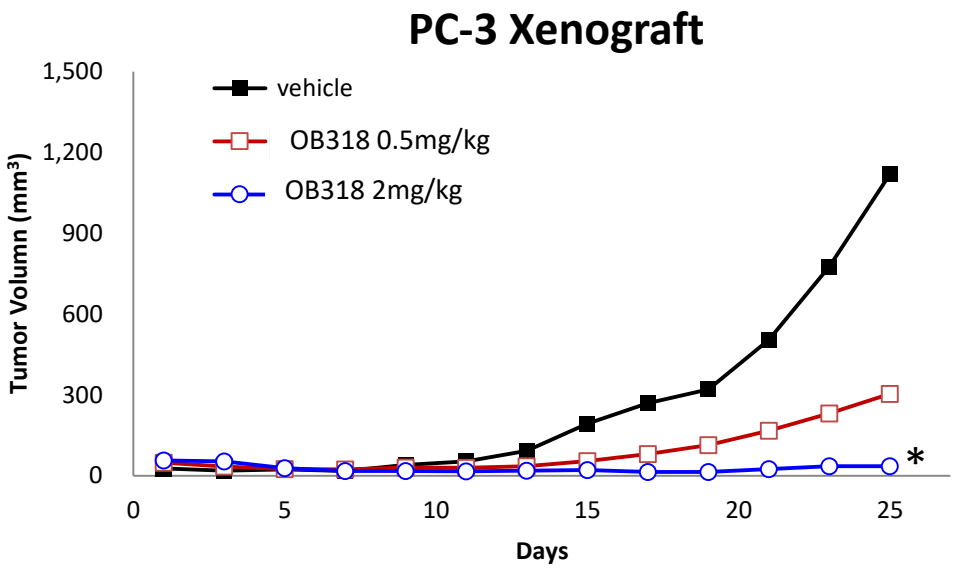
Angiogenesis of the Chick Embryo Chorioallantoic Membrane





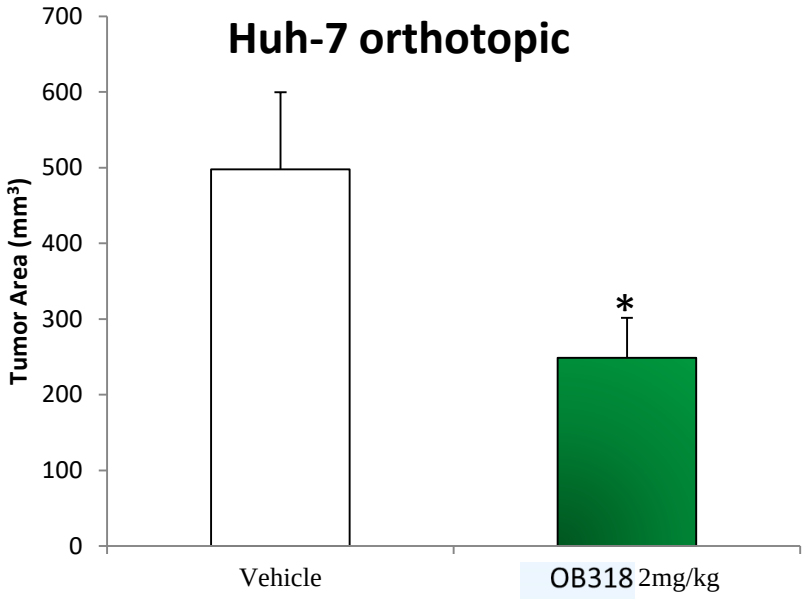
OB318 Pre-Clinical Studies

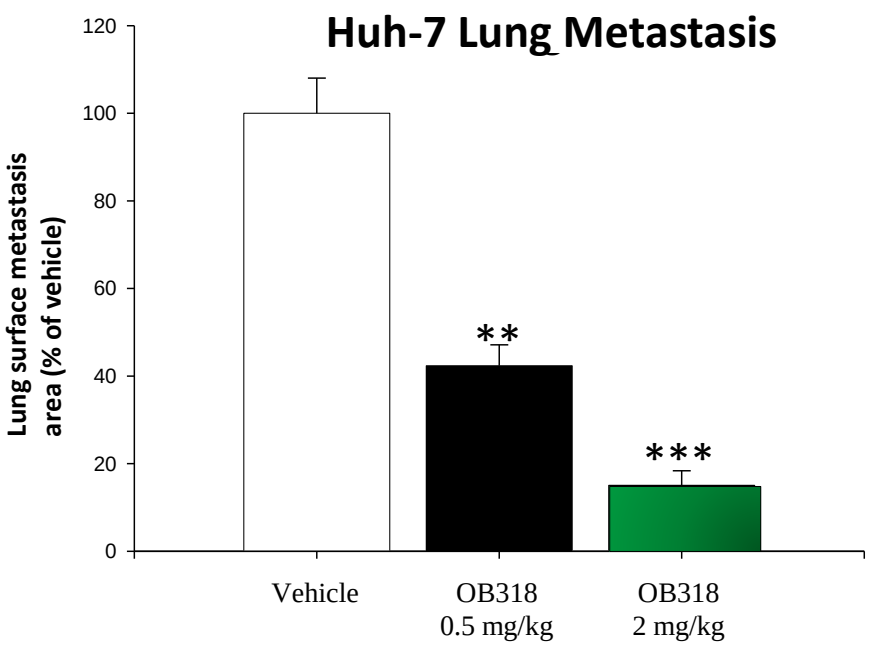




OB318 dramatically inhibits the *in vivo* tumor growth of various kind of cancers.

OB318 Pre-Clinical Studies





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

OB318 Development Plan

Clinical Development

- Obtained IND Permission of TFDA and USFDA
- Completed fermentation yield optimization and process control
- Phase I clinical Study in the US in 2020Q1
- Initiate out-licensing approaches after the completion of trial with proven clinical efficacy in 2021

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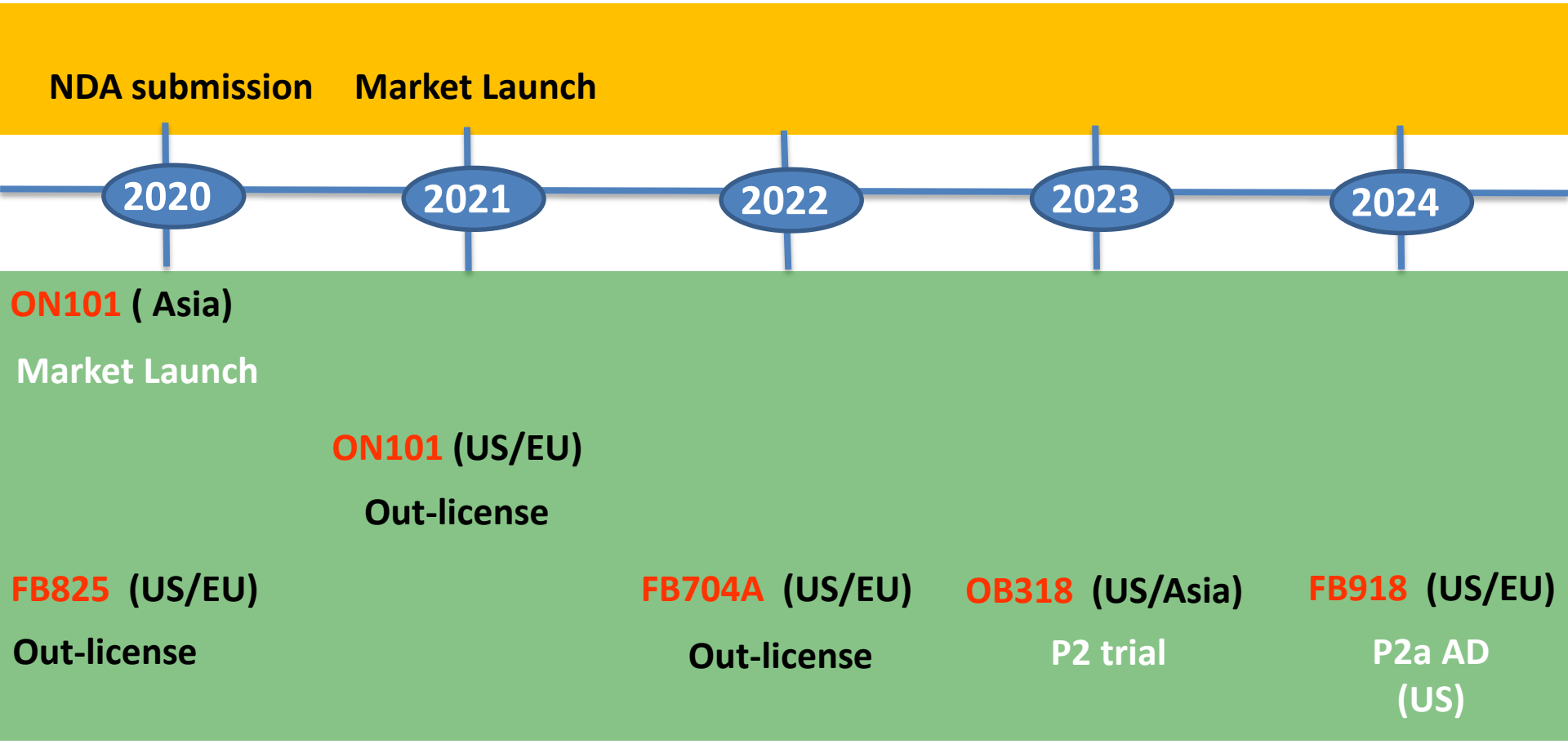
Milestones in the Next Five Years



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Transformation from Innovation

蛻變的鳳凰

Globalization by Innovation