

ONENESS

2020 3rd Investor Conference

Corporate Presentation

Science · Integrity · Transparency

2020.11.07

Forward-looking Statement

ONENESS

- This presentation contains forward looking statements. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements.
- Such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward looking statements.
- Such forward looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future.
- Further, certain forward looking statements are based upon assumptions of future events which may not prove to be accurate. The forward looking statements in this document speak only as at the date of this presentation. Oneness Biotech does not undertake any obligation to update or revise forward looking statements in this presentation nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

Financial Report

As of 2020.11.07

2019/2020 2nd Quarter

2020 & 2019 Q2 Financials

Items	2020Q2	2019Q2	Difference
Revenue	31,665	2,186	29,479
R&D Exp.	183,537	37,400	146,137
Net Profit (Loss)	487,683	(68,334)	556,017
Total Assets	10,531,955	2,631,939	7,900,016
Total Liabilities	1,597,275	524,820	1,072,455
Owner's Equity	8,934,680	2,107,119	6,827,561

(Currency in thousand NTD)

2019-2020 Chart (NTD)



Previous Close	Day' s Range	Year' s Range	Market Cap
296.00	293-299	19.4-476.5	111 bn.

(Currency : NTD)

Consolidated Statement of comprehensive income

(Currency in thousand NTD; Expect Earnings (Loss) per share)

Item	2020 Q2	2019 Q2	2020 H1	2019 H1
Operating revenue	31,665	2,186	34,910	6,370
Operating costs	3,259	4,151	6,919	8,527
Unrealized gross profit	7,060	0	7,060	0
Gross profit (loss) from operations	21,346	(1,965)	20,931	(2,157)
Selling expenses	236	195	351	309
Administrative expenses	33,170	13,559	56,876	26,710
Research and development expenses	183,537	37,400	304,322	61,639
Total operating expenses	216,943	51,154	361,549	88,658
Loss from operations	(195,597)	(53,119)	(340,618)	(90,815)
Non-operating income and expenses	683,280	(15,215)	636,704	(7,898)
Net Profit (loss)	487,683	(68,334)	296,086	(98,713)
Earnings (Loss) per share	1.39	(0.32)	0.86	(0.48)

Consolidated Balance Sheets

(Currency in thousand NTD)

Item	2020/6/30	2020/3/31	2019/6/30
Cash, Securities and Cash in banks	3,204,851	1,543,769	559,596
Other current assets	645,045	125,434	96,692
Property, plant and equipment	620,380	630,907	591,739
Investments	2,761,494	1,359,026	705,074
Other Intangible assets	2,548,202	2,452,890	52,340
Other assets	751,983	756,704	626,498
Total assets	10,531,955	6,868,730	2,631,939
Total liabilities	1,597,275	642,878	524,820
Total share capital	3,546,306	3,529,048	1,957,522
Capital surplus	3,814,168	3,761,393	563,291
Accumulated deficit	(115,475)	(611,394)	(94,105)
Other equity interest	1,689,681	(453,195)	(319,589)
Total equity	8,934,680	6,225,852	2,107,119

Summary of Consolidated Financial Statements for the Years Ended June 30, 2020

Summary of Net Profit NTD 487,683 thousand :

1. Research and development expenses 183,537 thousand :

Research and development expenses are used for multiple international clinical trials of new drugs, including phase I, phase II , phase III and production of experimental drugs. Such R&D expenditure contributes to 84.6% of total operating expenses. Accumulative R&D expenditure in 2020 H1 were 304,322 thousand and contributes to 84.2% of total operating expenses

2. Non-operating income and expenses 683,280 thousand :

Net income after tax mainly consists of non-operating income and expenses. For risk diversification purpose, Oneness reinvests in Diamond Biofund Co., Ltd(venture capital). Due to heavy stock market in 2020 Q2, Oneness revenue increased from reinvested company by equity method.

Summary of Consolidated Financial Statements for the Years Ended June 30, 2020

3. Financial situation stable , important financial ratio :

Current ratio	Quick ratio	Debts ratio
2,565.4%	2,502.9%	15.2%

4. Important assets explanation :

(Currency in thousand NTD)

Items	Amounts	Account for total assets ratio	Explanations
Cash, Securities and cash in bank	3,204,851	30.4%	Maximum number of changes is financial asset investment. The increase of valuation financial asset at fair value is because the stock price rose in 2020 Q2.
Other current assets	645,045	6.12%	Maximum number of changes is account receivable which is mainly from the remaining upfront payment by out-licensing of FB825. According to the agreement, the remaining upfront payment shall be made no later than 2021 Q1.
Financial asset, investment-non-current	2,761,494	26.22%	Reinvest in other biotech venture capital companies for diversifying risk, recognized reinvestment benefits from Diamond Biofund Co., Ltd.
Total liability	1,597,275	15.17%	FB825 out-licensing was completed in 2020 Q2, the upfront payment will be recognized upon completion of FB825 AD Ph2 trial according to IFRS, so the upfront will be put as contract liability on the book for now.
Other equity	1,689,681	16.04%	The increase of valuation other equity at fair value, because the invest value of the financial asset thus the stock price has risen in 2020 Q2.

Summary of cash capital increase

The plan of cash capital increase :

Cash capital increase by issuing 19,100 thousand shares, the dilution percentage by issuance of new shares for global depositary shares for the shareholding of existing shareholders is only 5.09%, the fund receipt of certificate of payment is 5,584,649 thousand. Oneness will follow the plan to move the R & D forward.

The influences of financial :

This will enhance the financial and inject sufficient fund in R&D. The company will be able to connect with international research institutes and pharmaceutical companies as well as improve competitiveness in global market .

R & D Progress

As of 2020.11.07

Progress of Important New Drugs

Milestones & Key Factors

FB825	ON101	FB704A
Ph2 Trial Result	NDA & Out-licensing	Ph2 Trial Indication
1	2	3

FB825-AD Progress

Atopic Dermatitis Ph 2a in U.S.

- Completion of site initiation of **10** sites with **22** subjects enrolled
- Aim to complete recruitment of 90 subjects enrolled in **February** 2021
- Aim to unblind data in **August** 2021

FB825-AD Key Factor

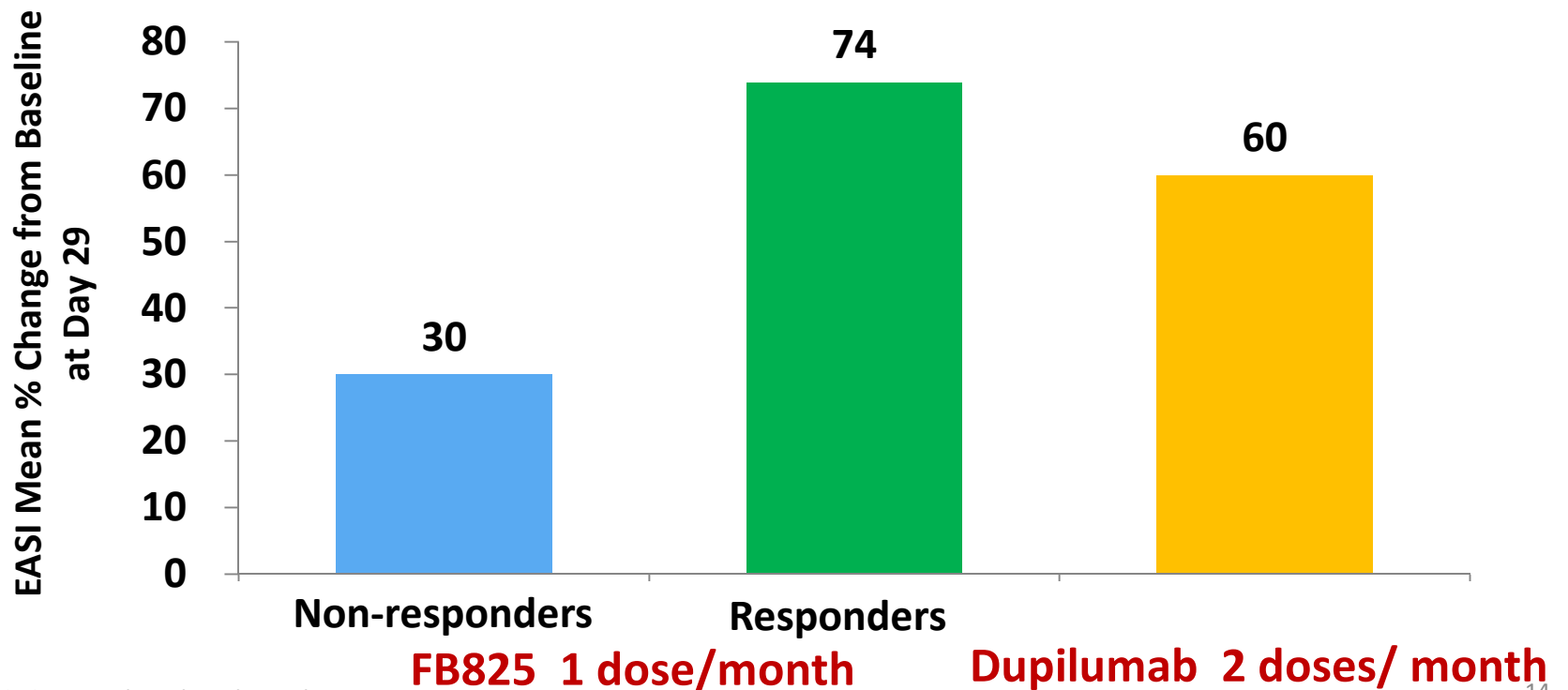
Biomarker for Clinical Response

(FB825 Responder)

- Atopic dermatitis (AD) is heterogeneous and patients are often with mixed types of skin disorders.
- Based on FACS analysis on 60 AD subjects, exploratory study on 12 subjects, biomarker study on 20 subjects (ongoing), FB825 **biomarker for clinical responder** has been observed. It is shown that AD subjects with such biomarker level significantly responded to FB825 treatment without drug-related AE.
- Such biomarker level can be measured by medical examination.
- Completion of **global patent application submission** while the trial is ongoing.
- The biomarker may be a key indicator in Ph2 trial to interpret data.

Biomarker - Clinical Benefits

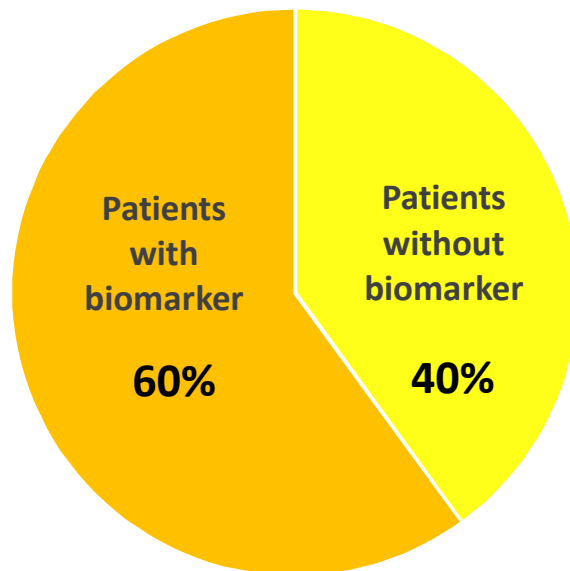
Compared with Dupilumab (Sanofi)



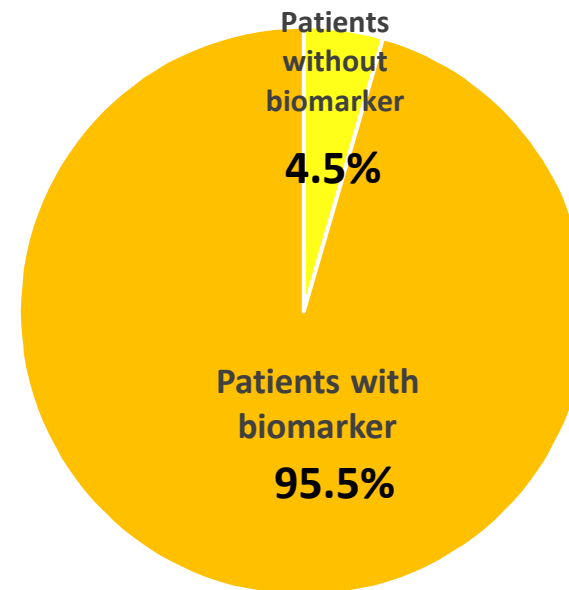
FB825-AD

Patient % with Biomarker

Taiwan



US

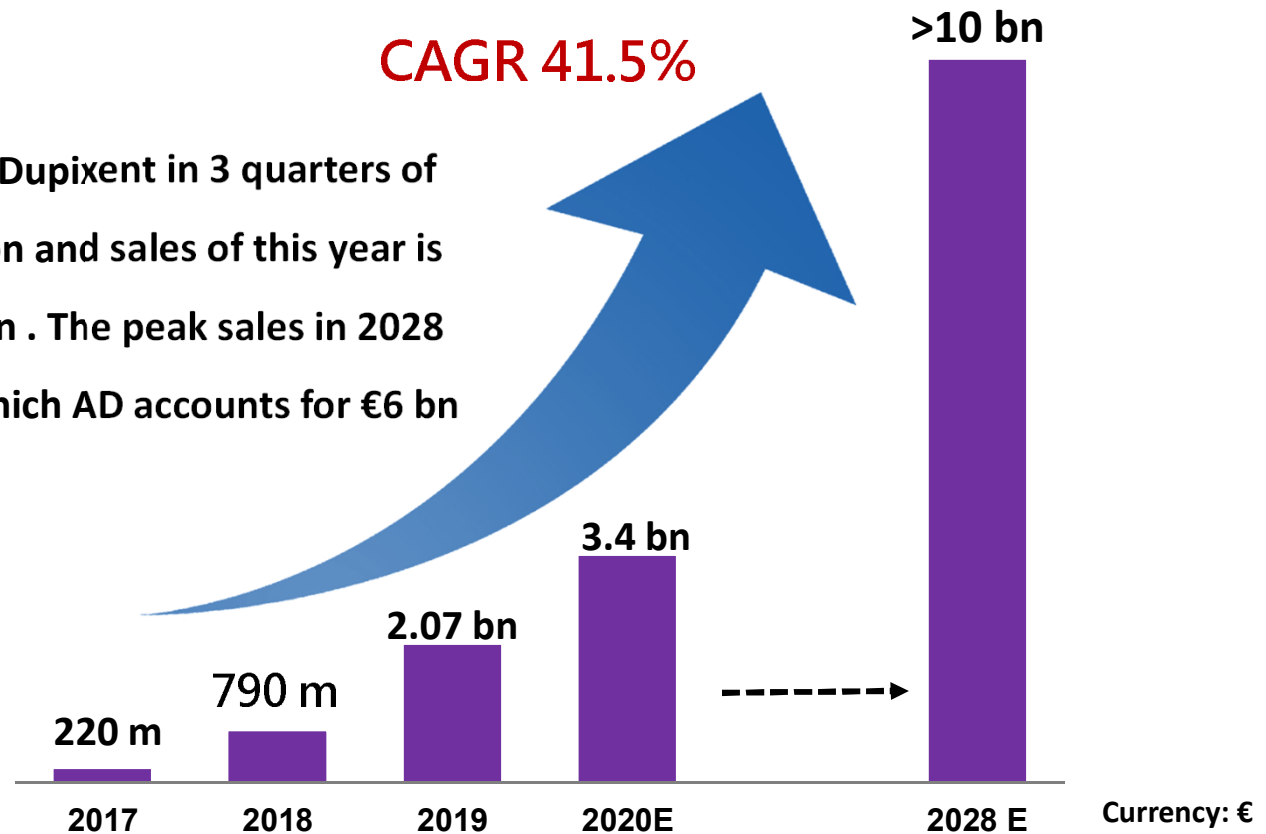


Dupixent (Sanofi)

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CAGR 41.5%

The accumulated sales of Dupixent in 3 quarters of 2020 has exceeded €2.55 bn and sales of this year is projected to exceed €3.4 bn . The peak sales in 2028 will reach over €10 bn of which AD accounts for €6 bn



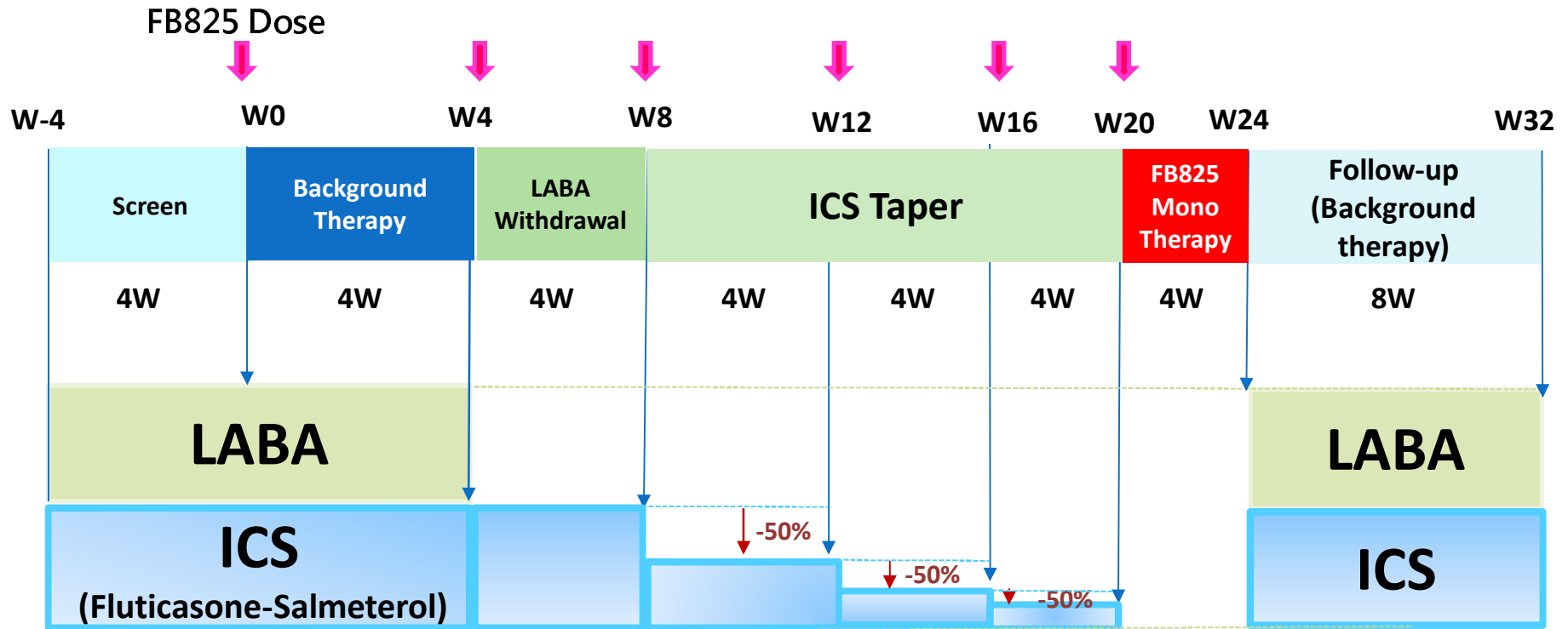
Source: Sanofi's financial reports, Forecast by Jefferies publicly available from Fiercepharma

FB825-AA Progress

Allergic Asthma Ph2 trial in Taiwan (Sponsored by Microbio Shanghai)

- **2020.08 Completion of cGMP Production**
- **2020.08 Protocol approved by TFDA approved**
- **2020.11 Protocol amendment (ICS taper)**
- **Aim to initiate in Dec 2020 and recruit 100 subjects**
- **Aim to unblind in 2022**

FB825-AA ICS Taper Design



*Albuterol/salbutamol given as reliever medication.

FB704A Progress

Indication for Ph2 Trial –Severe Neutrophilic Asthma

- 2020.08 Data read out for Ph1 completed in U.S. : (1) FB704A is well tolerated in both healthy and RA subjects with good safety profile.
(2) FB704A can effectively neutralize serum IL-6 and reduce CRP.
(3) FB704A can reduce counts of neutrophils
- Completion of Ph2 IND submission to TFDA in Nov. 2020
- Aim to complete neutrophilic asthma Ph2a trial in 2021.

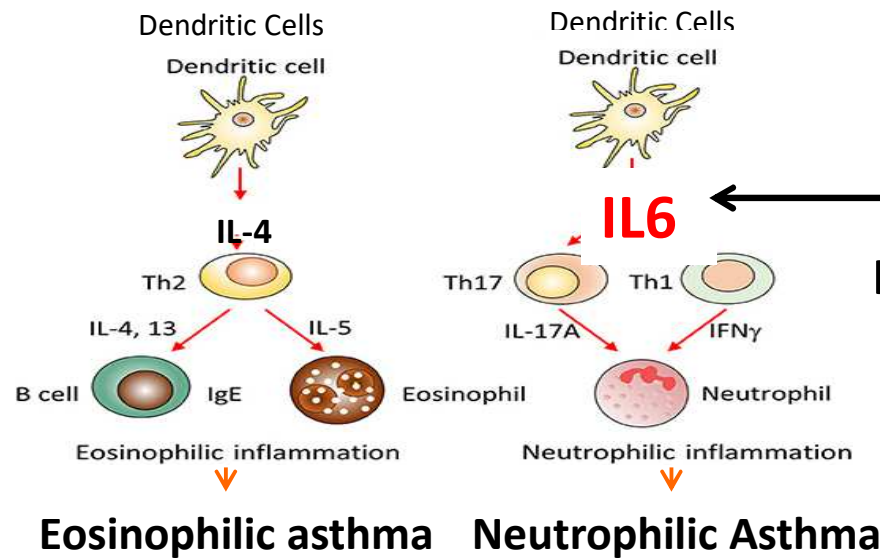
FB704A Key Factor

Indication for Phase 2 Trial

Neutrophilic Asthma (Unmet Medical Need)

Eosinophilic asthma

- Benralizumab (IL5)
- Dupilumab (IL4R)
- Mepolizumab (IL5)
- Omalizumab (IgE)

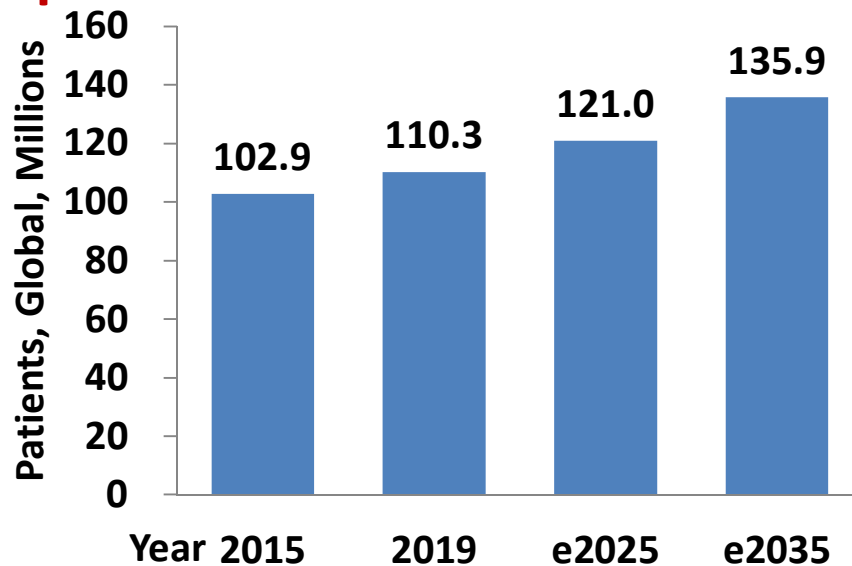


IL6 is a key cytokine to neutrophilic asthma

Modified from Front Immunol. 2018;9:2718

Neutrophilic Asthma Market

Neutrophilic Asthma (NA) patients is about 1.1 million¹



Severe Neutrophilic Asthma Market

- The importance of neutrophilic asthma has been gradually recognized and severe NA are 5%² of total NA patients which is approx. 5.5 million patients (annual treatment costs of biologics is US\$16,425³)
- Remain unmet medically
- The number of severe neutrophilic asthma patients will continue to increase along with the asthma assessment improvement

1. Source: Literature Review, Frost & Sullivan Analysis
 2. European Respiratory Journal 2018 52: PA3918
 3. https://http://www.sonecon.com/docs/studies/0208_GenericBiologicsStudy.pdf

ON101 Progress

- **2020.08 Submission of CSR (212 subjects) for completing supplementation to NDA at Taiwan FDA**
- **2020.10 Completion of Phase 3 trial site GCP inspection.
Aim to complete NDA in Q4 2020**
- **2020.10 Completion of Pre-NDA meeting with NMPA.
Submission of NDA package in Nov. 2020**
- **2020 Q4 Completion of PIC/s GMP certification on API and finished product manufacturing plant**
- **2021.Q1 Completion of MoA clinical trial**
- **2021.H1 Initiation of Phase 3 trial in the U.S.**

ON101 Key Factor -1

Regulatory Approval in Major Markets

- **Market entry into China: NDA submission will be made under natural drug category 1. NDA package will be submitted soon and approval is subject to the review procedure at regulatory authority.**
- **Market entries into U.S. & EU: Data under preparation for reply to Hold Letter under US medical device application. Will initiate 2nd Ph3 trial in the U.S. and apply for rolling review to accelerate NDA**
- **Market entries to Asia: Market entry by collaboration on clinical trials or accelerated regulatory pathway upon receipt of Taiwan or China drug license.**

ON101 Key Factor -2

Global Pricing and Licensing

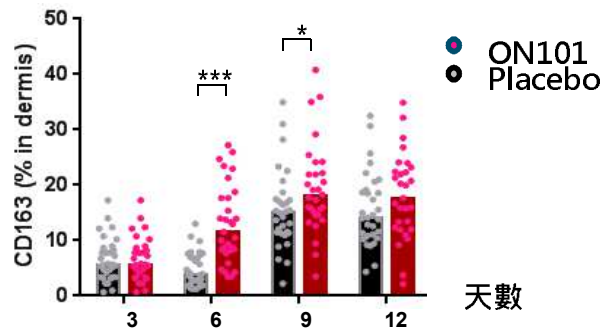
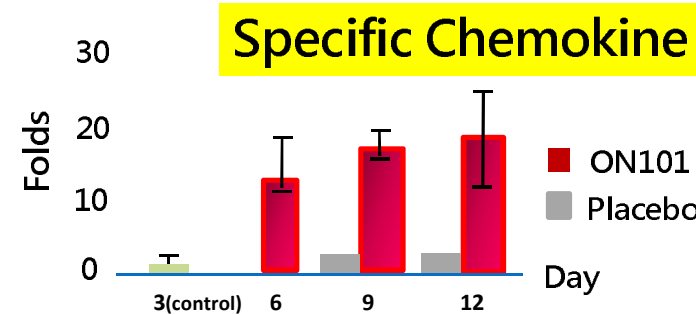
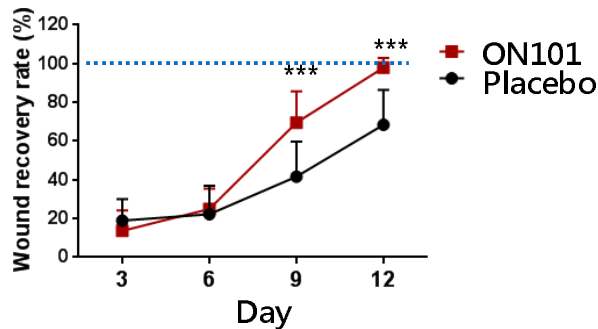
- **DFU is a global disease and DFU new drug pricing shall consider global markets.**
- **Pricing strategy includes pricing analysis of U.S. (largest market) and China (3rd largest market with most DM patients and the 1st major market for market launch) as well as the pricing relations between the markets.**
- **Analysis on self-paid/insurance markets and pricing range with volume trade-off**
- **Global pricing will affect global market share and be the key element in out-licensing negotiation**
- **Currently, there are four global pharms and more than 10 pharms in discussion on licensing or collaboration for regional out-licensing and market value creation.**

ON101 Key Factor -3

Mechanism of Action

ON101 MoA -1

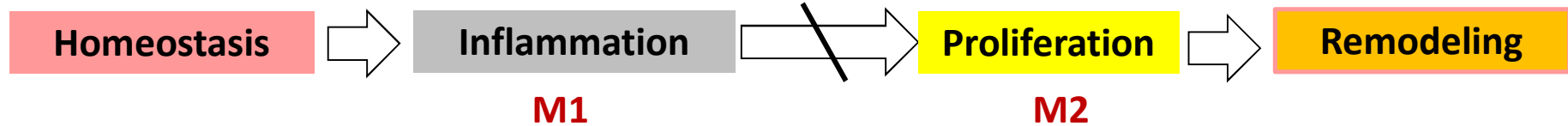
DFU to Normal Wound



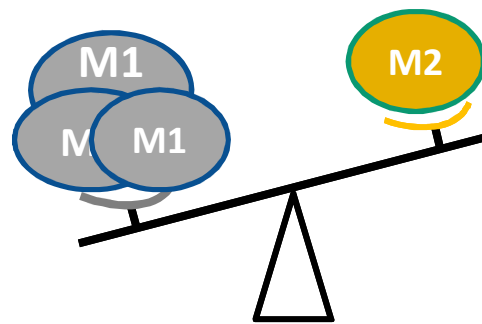
ON101 regulates **specific chemokine** and **growth factor** which guided M ϕ phenotypic switch from M1 to M2 inducing tissue repair.

ON101 MoA - 2

Chronic Ulceration: Imbalance M1/M2



The existence of excessive M1 Φ in DFU prolongs the inflammation and causes chronicity which prevent the inflammation stage from proceeding to proliferation stage and delay the wound healing



The delayed transition between M1/ M2 Φ will reduce angiogenesis, keratinocyte activity, and collagen deposition which delay tissue repair and remodeling.

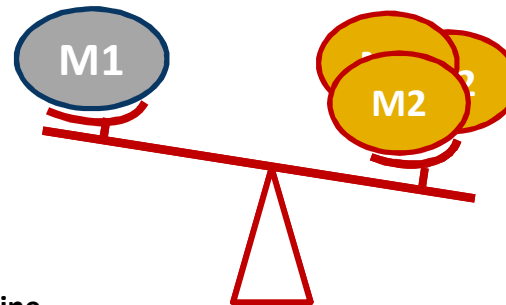
ON101 MoA - 3

Rebalance M1/M2



Regulates Macrophage

- Suppressed M1 polarization, promote M2 recruitment
- Balanced the M1/ M2 ratio
- Suppressed the secretion of pro-inflammatory cytokines
- Inhibited the NLRP3- mediated inflammasome activity
- Promote the secretion of specific chemokine and growth factors.



Regulates the surrounding cells

- Suppressed inflammation state
- Promote keratinocyte proliferation & migration
- Promote collagen deposition
- Promote the recruitment of CD71⁺ progenitor cells
- Promote wound healing

ON101 Phase 3

**DFU Healing Factor &
Hard-to-heal Ulcers Analysis**

ON101/Aquacel

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Equally-distributed Baseline Characteristics

Ulcer Location

Ulcer Etiology

Ulcer Duration

Ulcer Severity

Ulcer Size(cm²)

Diabetes Type

DM Duration

DM Complication

Amputation History

Cardio-vascular Disease

Diabetic Neuropathy

Diabetic Kidney Disease

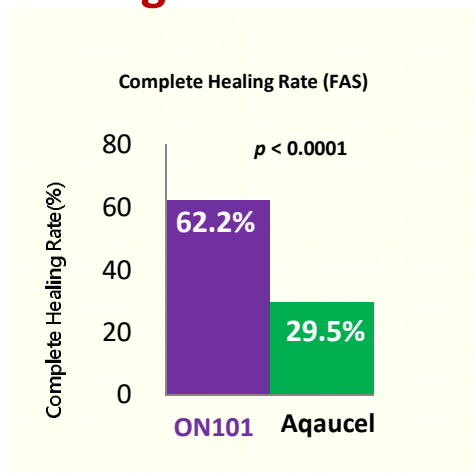
Diabetic Retinopathy

Peripheral Vascular Disease

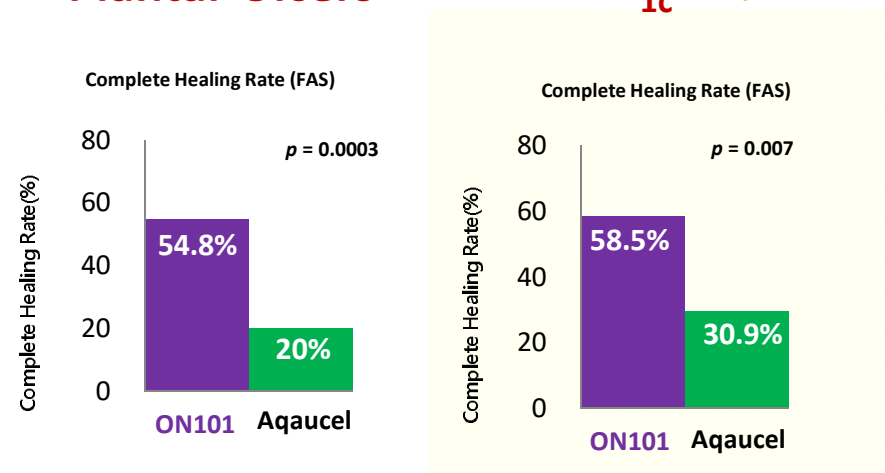
Other

Healing Factor Analysis -1

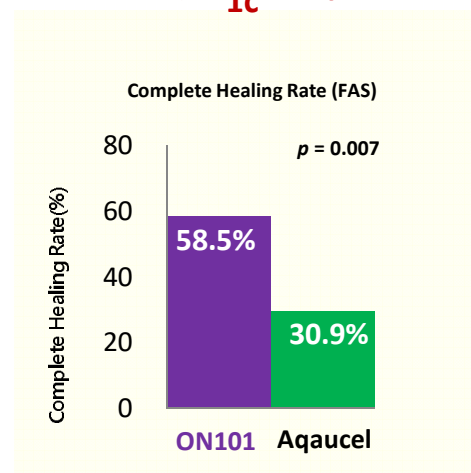
Wagner Grade 2



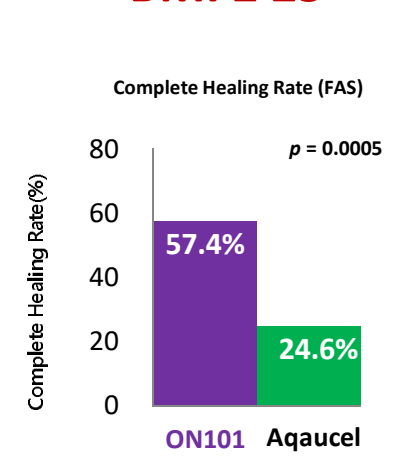
Plantar Ulcers



HbA_{1c} >7%

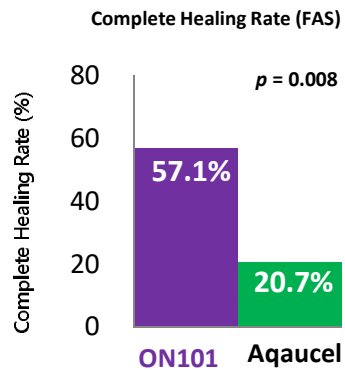


BMI ≥ 25

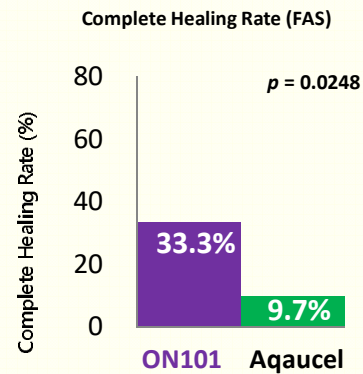


Healing Factor Analysis -2

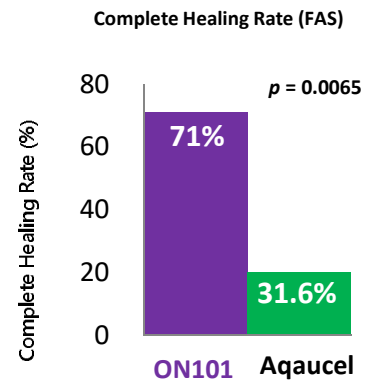
Ulcer > 5 cm²



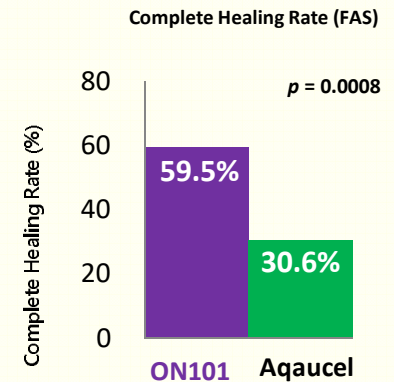
Ulcers ≥ 6 mons



Smokers

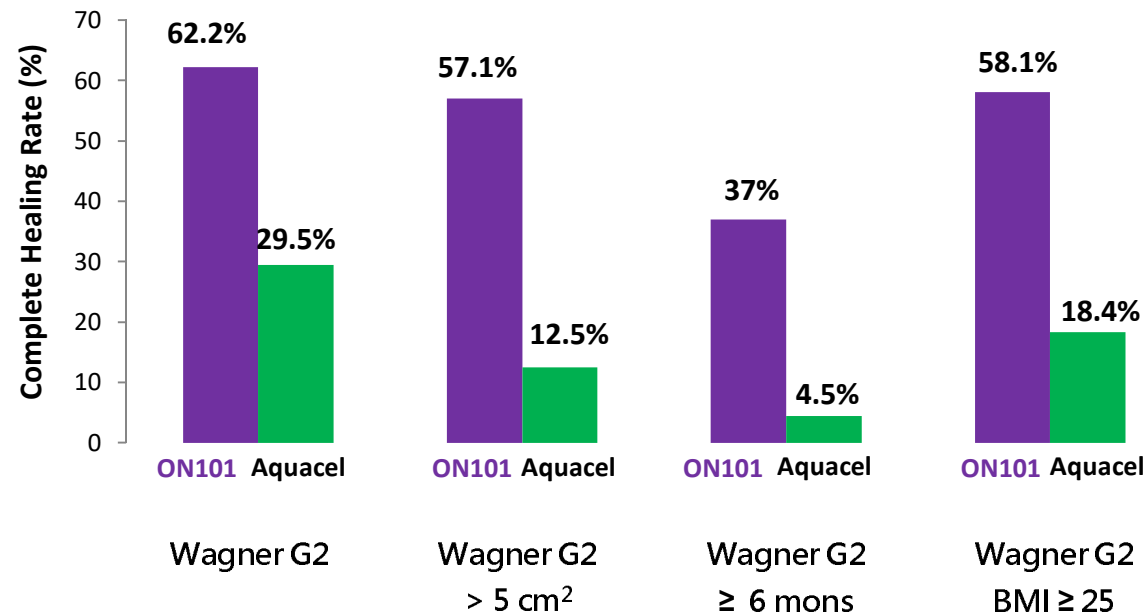


Neuropathy



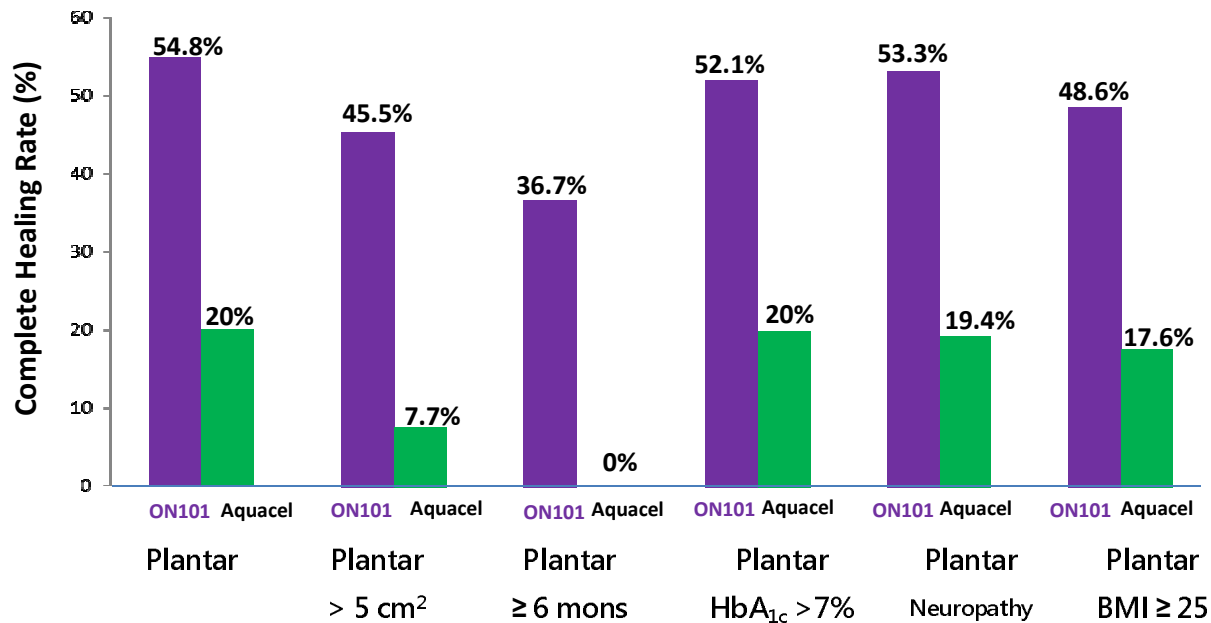
Hard-to-heal Ulcers Analysis – 1

Wagner Grade 2 Ulcer



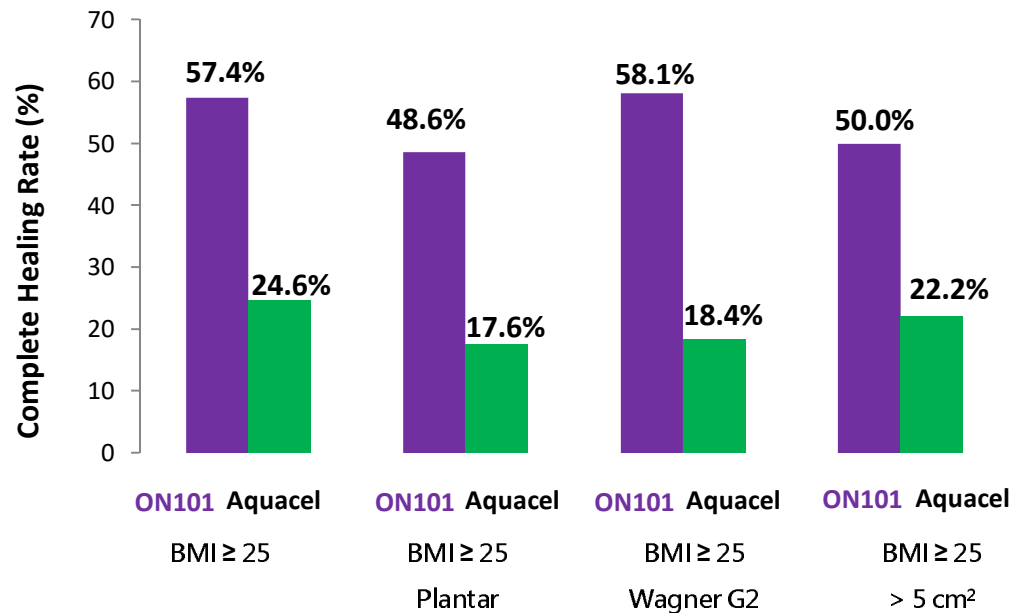
Hard-to-heal Ulcers Analysis – 2

Plantar Ulcer

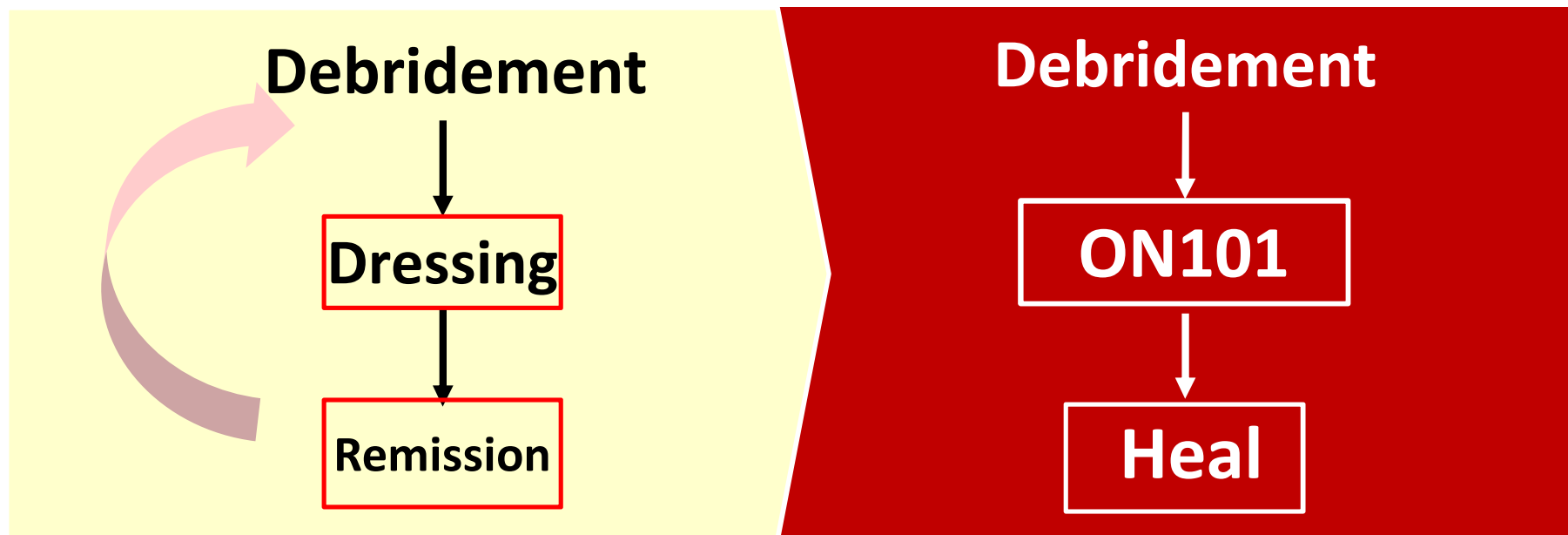


Hard-to-heal Ulcers Analysis– 3

BMI ≥ 25



ON101 as a Revolution for DFU Treatment



Change of DFU Treatment Guidance will Start from 2021!

Innovation =
Value + Risk

Final Note on Investment Risk

Investment in R&D biotech companies is with huge risk and can't guarantee returns or dividends within a short period of time. Investors shall understand the nature and operation of the companies before making investment.

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Q & A

Thank you

4th Investor Conference will be held in Dec 2020

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