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合一ON101新藥

以全球唯一DFU新藥為核心的
營運與獲利模式

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2017.12.6

DFU新藥 - 未被滿足的醫療需求

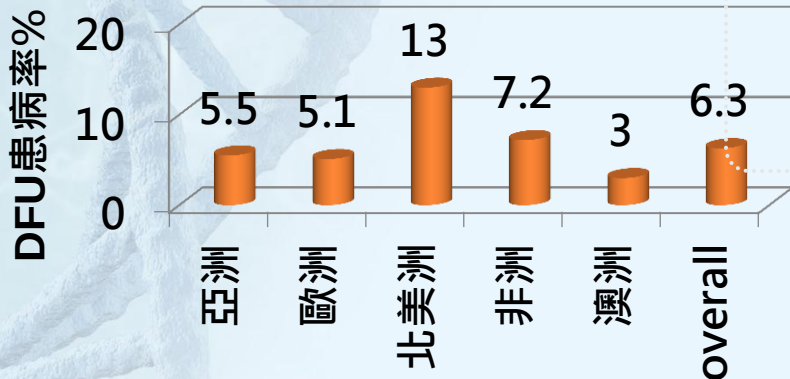


Unmet Medical Need

- 糖尿病常見併發症

糖尿病患者中足部潰瘍患病率約 4%-10%
終其一生**15%-20%**發生DFU
33%發生截肢，截肢後5年死亡率超過70%

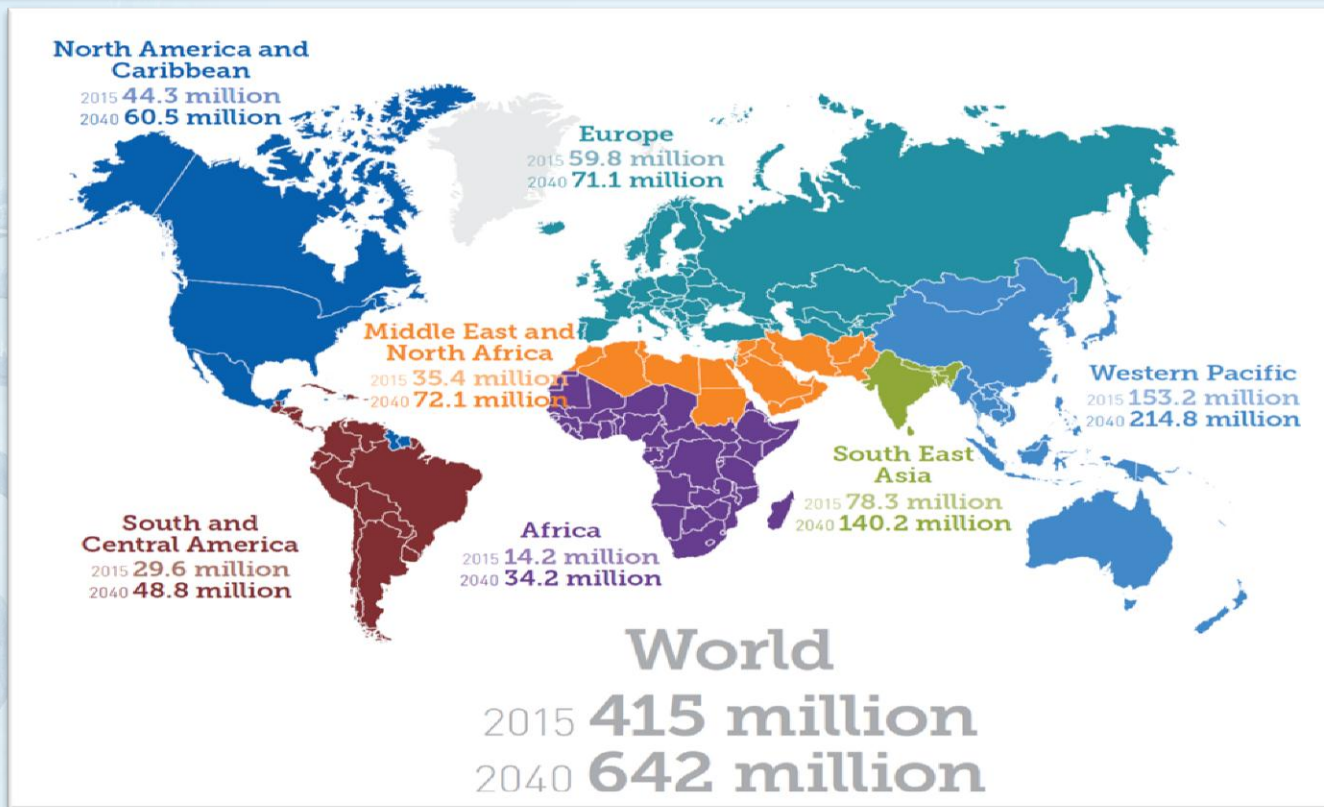
中國糖尿病足診治指南 (2017年) –
大陸糖尿病患者1年新發潰瘍發生率為**8.1%**，
DFU患者1年內新發潰瘍發生率為**31.6%**



大陸糖尿病足患者總數約
750萬人，接受治療者約100萬人

DFU (Diabetic Foot Ulcer · 糖尿病足部傷口潰瘍)

全球糖尿病患者統計



Reference : IDF 全球糖尿病概覽 (第7版)

大陸成人糖尿病患病率

新診斷糖尿病 6.9%

男性：7.7%

女性：6.1%

10.9%

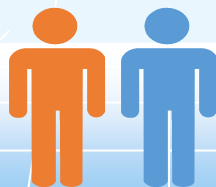
男性：11.7%

女性：10.2%

已知糖尿病 4.0%

男性：3.9%

女性：4.1%



糖尿病未診斷率 63.3%

發病年輕化：40歲以下患病率達 5.9%

全國抽樣170,287例，採用2010年美國糖尿病協會 (ADA) 診斷標準

Reference: Limin Wang; Pei Gao ; Mei Zhang, JAMA. 2017;317(24):2515-2523

DFU 治療費用

2004 Europe

每年DFU治療成本

平均 **5,658** 美元

2014 China

2004年糖尿病足住院費用

1,850美元/人

2012年住院費用上升為

2,685美元/人

2014年糖尿病足引起截肢

平均醫療費用5,932美元

2014 USA

糖尿病足患者的總

醫療費用

(不包括DM治療) 達

90 ~ 130億美元



Regranex (J&J, USD600/條)

全球唯一核准治療DFU的藥品 (1997 approved)



U.S. Food and Drug Administration



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FDA News

FOR IMMEDIATE RELEASE

June 6, 2008

Media Inquiries:

Rita Chappelle, (301) 827-6242

Consumer Inquiries: 888-INFO-FDA

FDA Announces New Labeling Changes for Regranex

Product to carry boxed warning

The U.S. Food and Drug Administration today announced the addition of a boxed warning to the label of Regranex Gel 0.01% (becaplermin) to address the increased risk of cancer mortality in patients who use 3 or more tubes of the product. Regranex is a topical cream indicated for the treatment of leg and foot ulcers that are not healing in diabetic patients.

The WARNINGS section of the product has been updated to include a BOXED WARNING and a description of the epidemiologic data that is the basis for the revised label. These data come from a retrospective study that compared cancer incidence and cancer mortality among 1,622 patients exposed to Regranex to 2,809 otherwise similar patients who were not exposed. The results were consistent with no overall increase in cancer incidence among the patients exposed to Regranex. However, there was a five-fold increased risk of cancer mortality in the group exposed to three or more tubes of Regranex.

美國FDA於2008年6月發佈 - Regranex對癌症患者會增加 **五倍** 致死風險

2015/2016 **Failed** Phase III Clinical Trials in DFU

Company	Derma Sciences	MacroCure	CytoTools	ADOCIA
Drug Product	DSC-127	CureXcell	DermaPro	BioChaperone PDGF
Drug Category	Peptide Drug	Cell-derived Products	Small Molecules	Recombinant Protein
Date	November 2015	October 2015	November 2015	August 2016

Unmet Medical Need for Decades (since 1997)

Ongoing DFU Phase III Clinical Trials

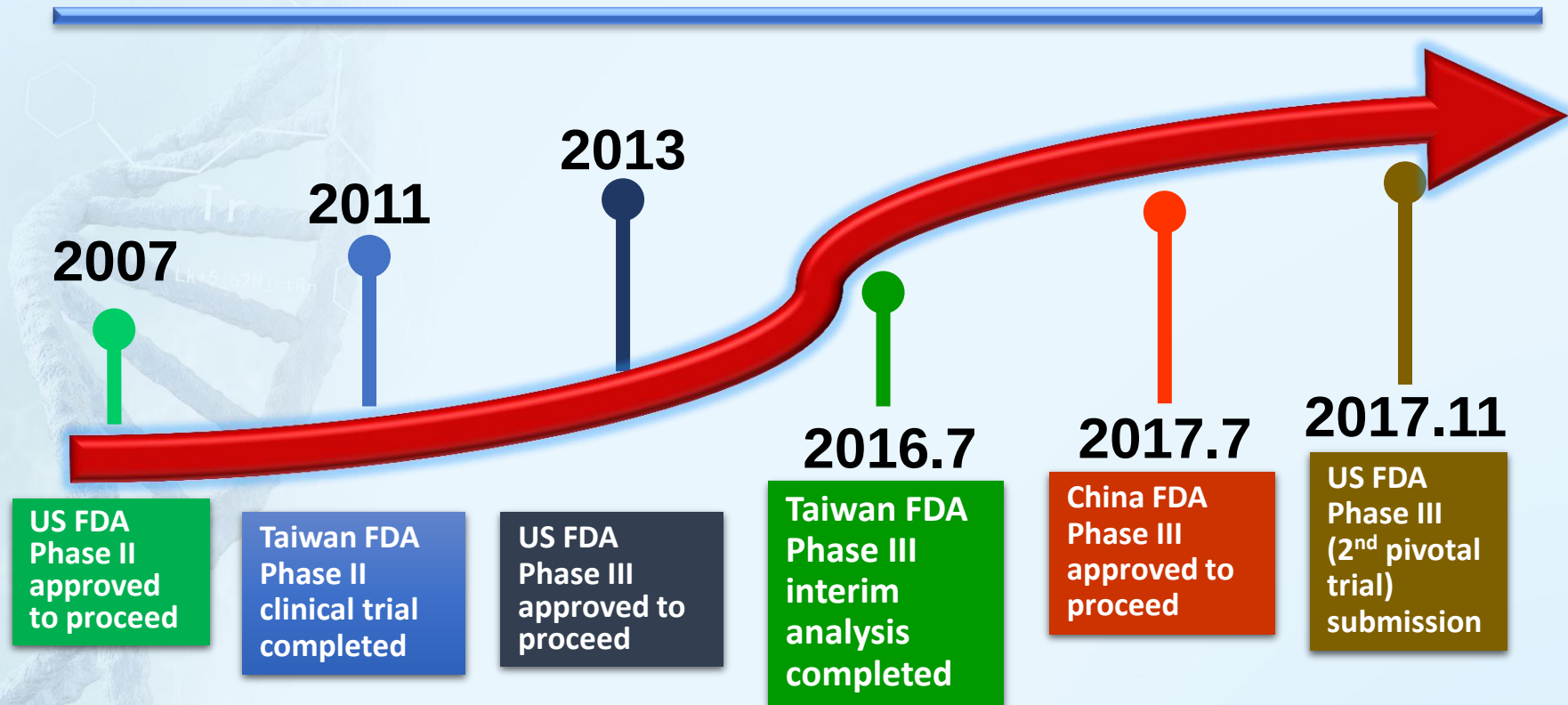


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Drug	Pharma	Status	Drug Classes
ON101 cream	Oneness Biotech	Phase III	Botanical drug
Trafermin 0.01% spray (rh-bFGF)	Olympus Biotech Corporation	Phase III (completed)	Growth factor
Ofloxacin (Oral)	MacroChem Corporation	Phase III (completed)	Antibiotic
Granexin gel	FirstString Research, Inc	Phase III	ACT1 peptide
Gentamicin Collagen sponge	Innocoll	Phase III	Antibiotic

DFU is absolutely a global **UNMET MEDICAL NEEDS** which require urgent medical care.

ON101 R&D Status

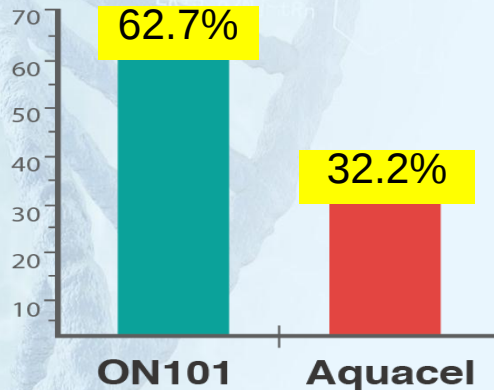


Wound Complete Healing Rates



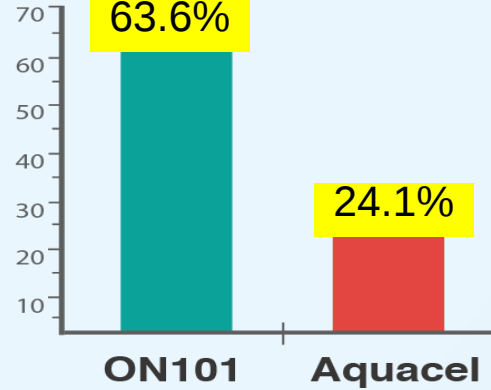
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► mITT Group



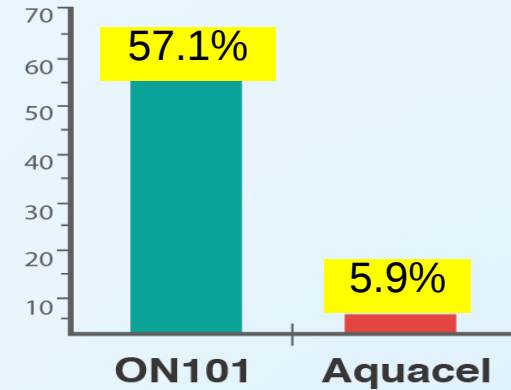
Difference = 30.5% ($p < 0.001$)

► Plantar Ulcers Group



Difference = 39.5% ($p = 0.002$)

► Large Wound Size
($> 5 \text{ cm}^2$) Group



Difference = 51.2% ($p = 0.002$)

Only Solution Over 60% Complete Healing Rates

Patent Title	Status
Plant extracts for treating skin disorders and enhancing healing of wounds for diabetic patients	Granted : 5 countries US, EU (DP, GB, FR), TW
Process for the preparation of plant extracts for treating skin disorders and enhancing healing of wounds	Granted: 11 countries US, EU (DP, GB, FR), RU, JP, CN, KR, TW, MY, IN
Use of flavonoid compound in preparation of composition for healing wound	OA: 5 counties US, EU, CN, TW, HK
Topical Formulation for Promoting Wound Healing	PCT, US and TW

ON101 is under Strong Global Patent Protection



營運與獲利模式

ON101

糖尿病足部傷口潰瘍新藥

60% 受試者



16 weeks

傷口完全癒合

Item	Manufacturing Practice	Quality Control Guideline
Raw Material – <i>Plectranthus amboinicus</i>	GACP	USFDA “Botanical Drug Development Guidance for Industry”
Drug Substance	GMP & PICs/GMP	
Drug Product	PICs/GMP	

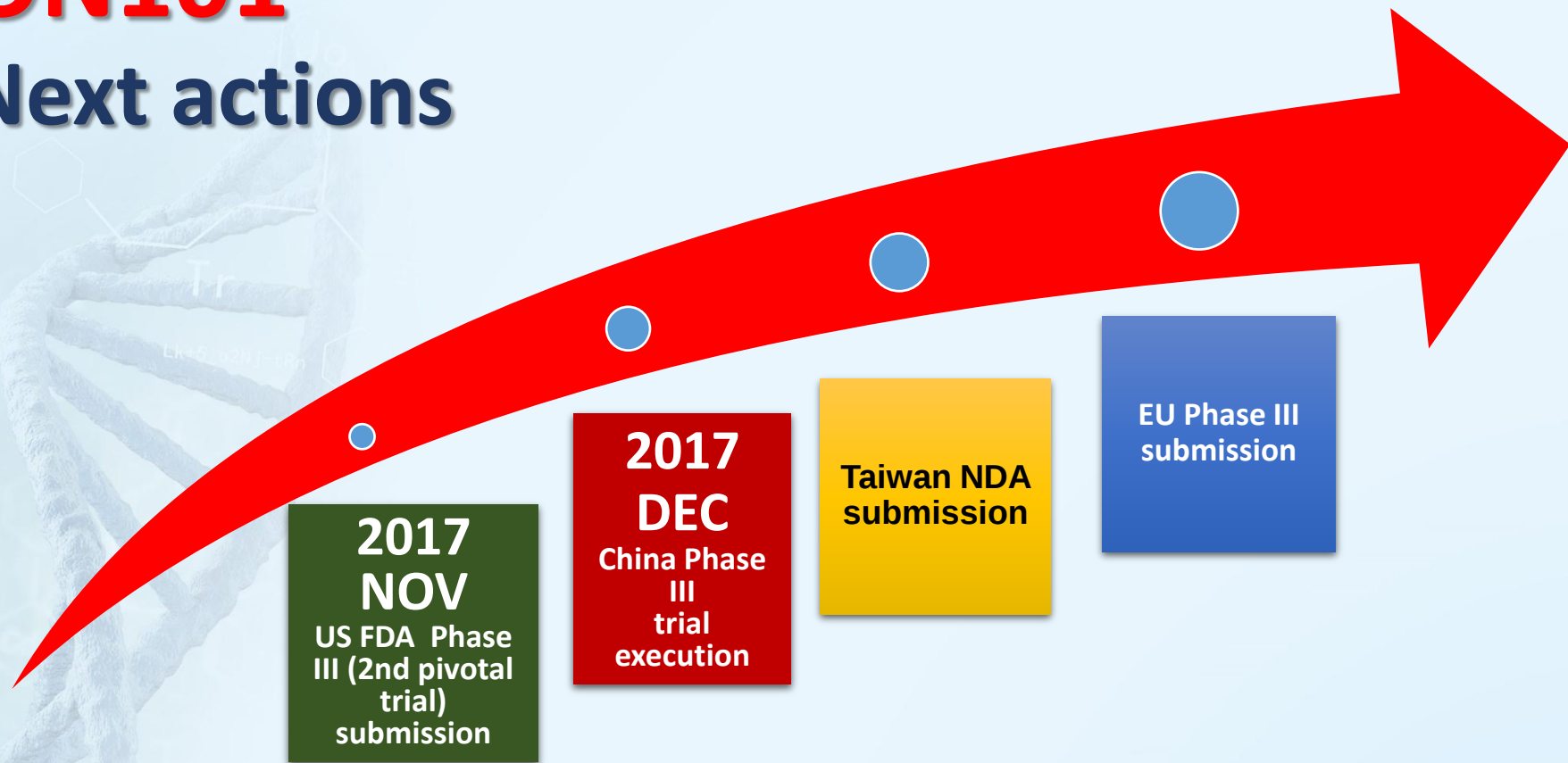


年產能可達5000萬條

PIC/S GMP南州藥廠

ON101

Next actions



以DFU全球最佳新藥為核心的 營運與獲利模式

- 一、以最佳臨床療效及成本優勢，獨佔全球龐大DFU市場
- 二、關鍵藥材之大規模 **GAP**種植、萃取、層析、製劑、量產，完全自主掌控
- 三、台灣首先提出原產國**DFU**新藥藥證申請
- 四、大陸、美國、歐盟申請執行三期臨床，並展開全球授權
- 五、取得全球新藥藥證後，由合一**PIC/S GMP**南州藥廠獨家供應全球市場
- 六、結合新藥研發、藥材種植、新藥生產、國際授權到全球商業化的獲利模式



New Drug for Unmet Medical Need