



Futura Medical
Advanced Transdermal Technology

**Preliminary
Results
and R&D
Summary**

**Year Ending
31st December 2018**

April 2019

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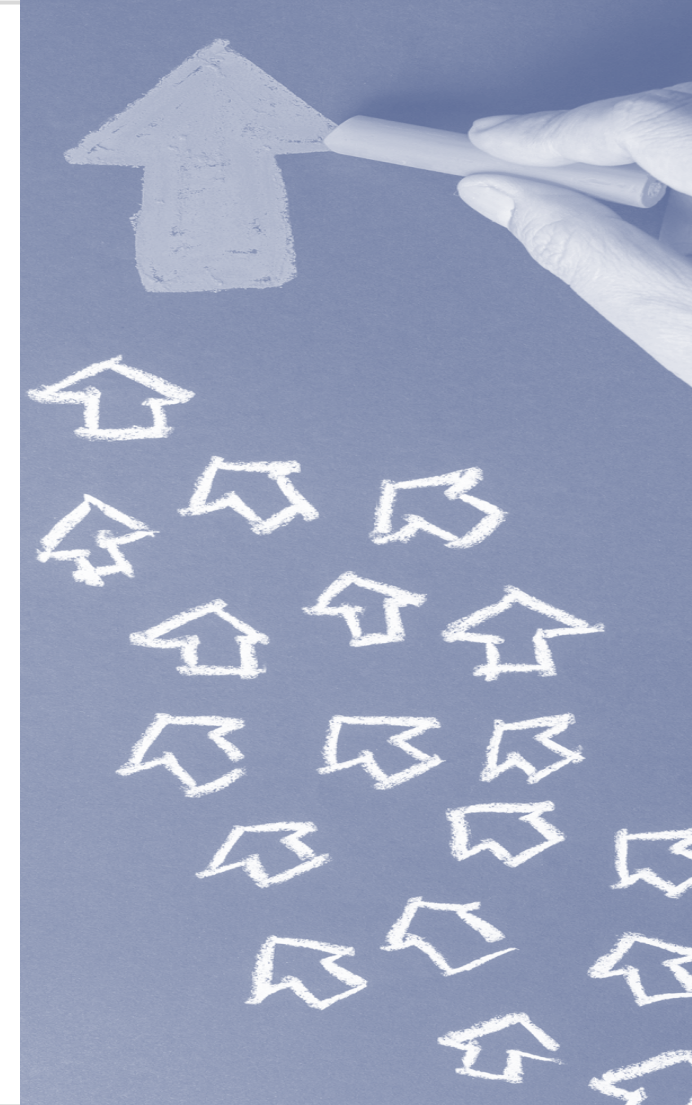
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Futura Medical – a corporate overview



About Futura – a corporate overview

Fundamentals

Futura listed on AIM market and located at the Research Park, Guildford

- 'Virtual' organisation with 15 staff and low overheads
- Significant outsourced infrastructure with over 30 consultants

DermaSys®

Clinically proven transdermal science

- Drug delivery through the skin of existing pharmaceutical drugs for improved or new indications
- Excellent safety profile - no harsh permeation enhancers

Track Record

Clinically proven innovation using existing pharmaceutical compounds

- Sexual health and pain relief focus
- Late stage products with experienced Management Team

Key Portfolio Products

MED2005 – Topical gel for the treatment of erectile dysfunction (ED)

- Highly differentiated treatment including potential 5-minute speed of onset
- Positive Phase 2 data, excellent PK results in H1 2018 & Phase 3 programme underway

TPR100 – Topical gel for the treatment of pain relief

- UK regulatory dossier submitted in July 2018 – 1st round of questions received
- Further out-licensee interest pending UK regulatory approval

Year End Highlights – Products, Organisation & Financial



Strategic decision to focus resources on maximising R&D pipeline value
Priorities are MED2005 Phase 3 trial completion and further realisation of value from pain portfolio
Increased awareness of MED2005 within scientific and pharmaceutical communities

MED
2005

Positive Phase 2 “FM53” data published in peer reviewed Journal of Sexual Medicine¹
First Phase 3 “FM57” commenced and remains on track for headline data in December 2019
Positive PK study “FM58” showing dose related absorption & acceptable safety profile

TPR
100

UK dossier submitted in July 2018 by Thornton & Ross to MHRA
Initial feedback received, Futura providing support to Thornton & Ross on its responses
Interest from other EU licensing partners post MHRA approval

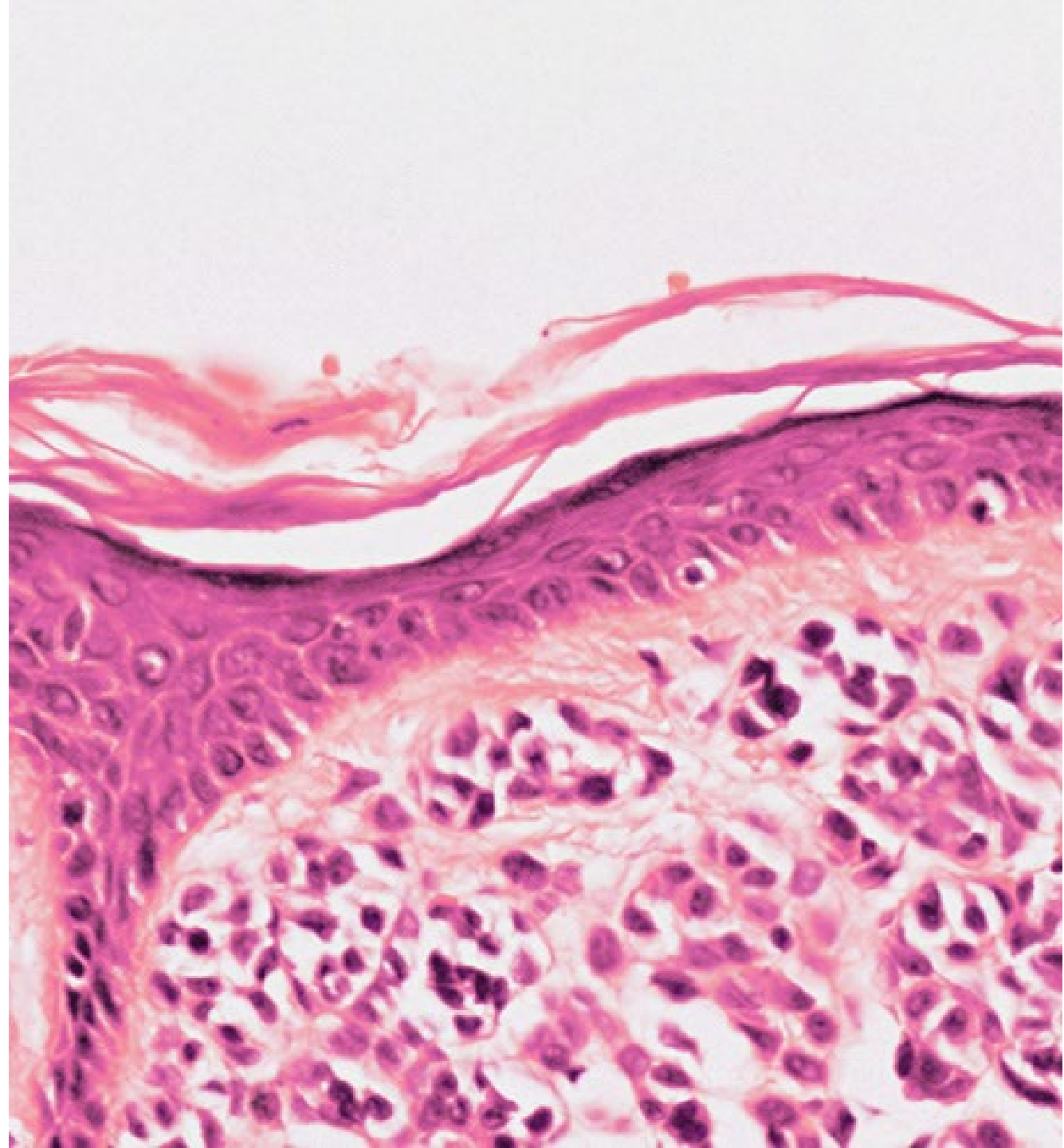


Strengthened resources with Angela Hildreth appointed as Chief Operating Officer
Net loss for year ending 31 Dec 2018: £5.89 million (Net loss 31 Dec 2017: £3.90 million)
Cash resource at end of year: £9.16 million (with tax credit of £1.36 million expected)



MED2005 – AN INNOVATION IN THE TREATMENT OF ED

LEAD PRODUCT



Erectile Dysfunction – Quality of Life & size of the problem

1 Sexual activity is beneficial¹

2 Low self esteem and confidence

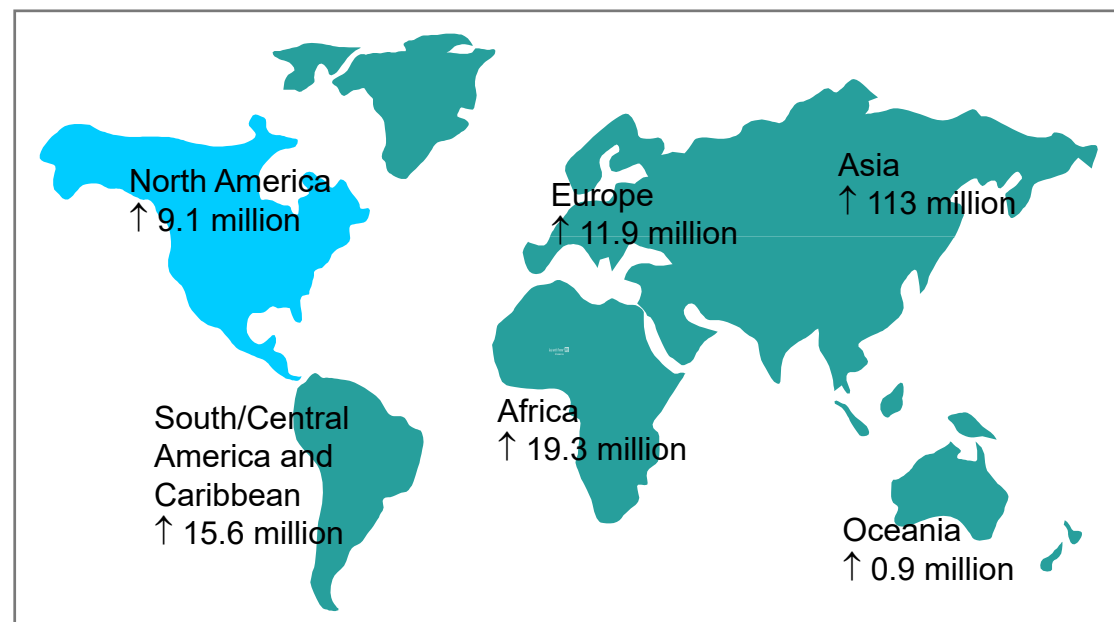
3 Partner concerns – affair, less attractive

4 Loss of intimacy

5 Affects work and family

6 Depression

The number of men with ED will increase from 152 million men in 1995 to 322 million men by 2025



- Growing population
- Ageing population
- Growth in obesity
- Increased awareness/acceptance

Further information regarding the ED market is contained in the Annual Report

8 1. Early cessation of sex associated with premature death – Swedish study 1981; 50% reduction in cardiac death with more than two orgasms per week – Caerphilly Cohort Study BMJ 1997
2. Adapted from McKinlay JB. *Int J Impot Res.* 2000;12(suppl 4):S6-S11

ED market size and treatment options

Erectile Dysfunction prescription (Rx) market worth over US\$ 5.6 billion in 2016¹

But no real innovation for 10+ years

PDE5 inhibitors

Viagra
US\$ 1.8 billion¹

Levitra
US\$ 0.3 billion¹

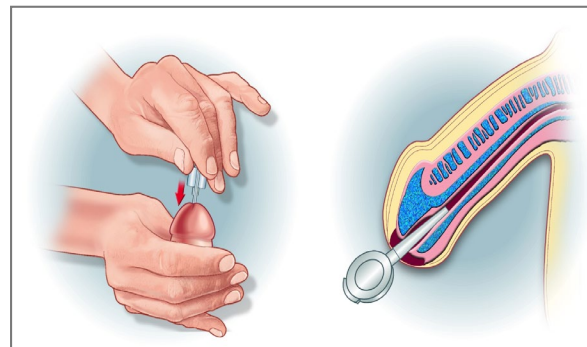
Cialis
US\$ 2.5 billion¹



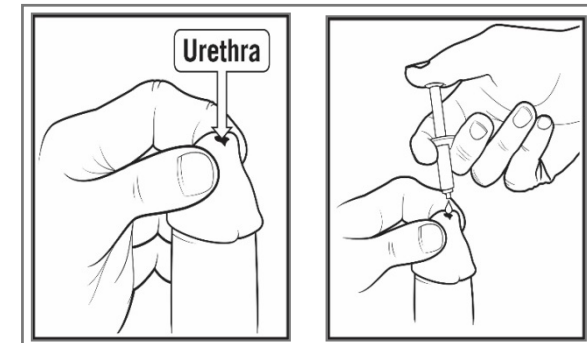
Caverject®



Muse®

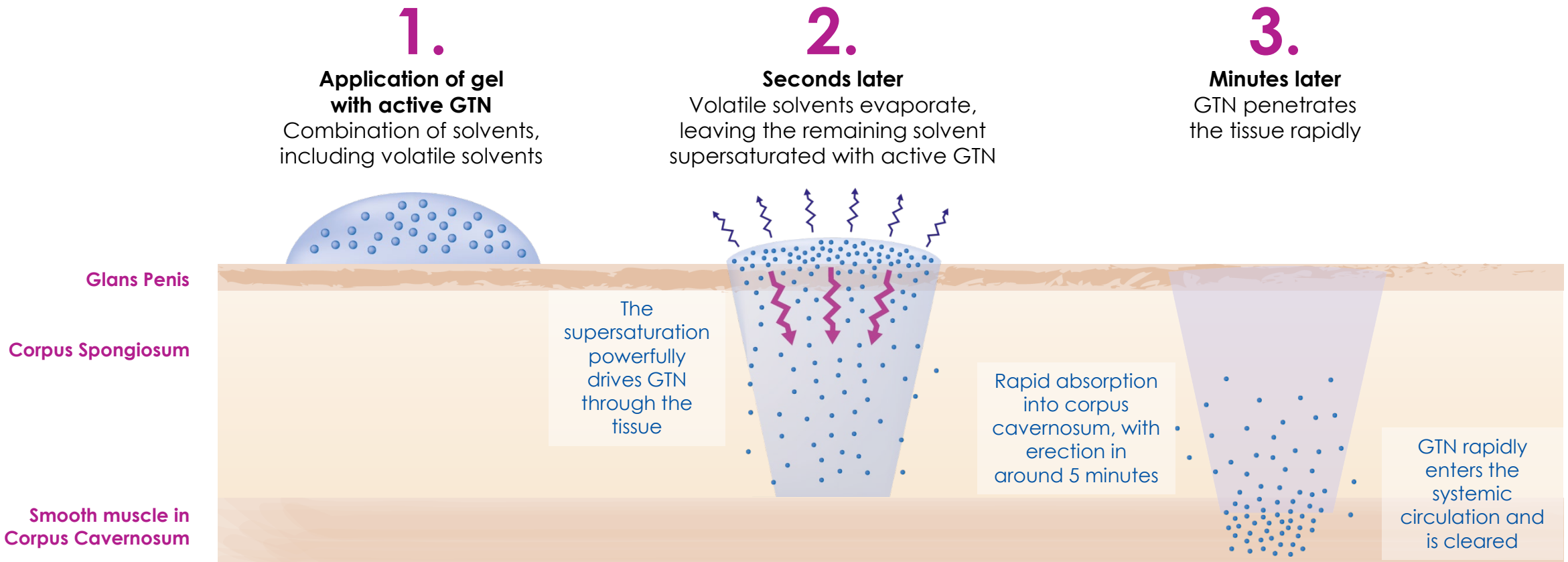


Vitaros®



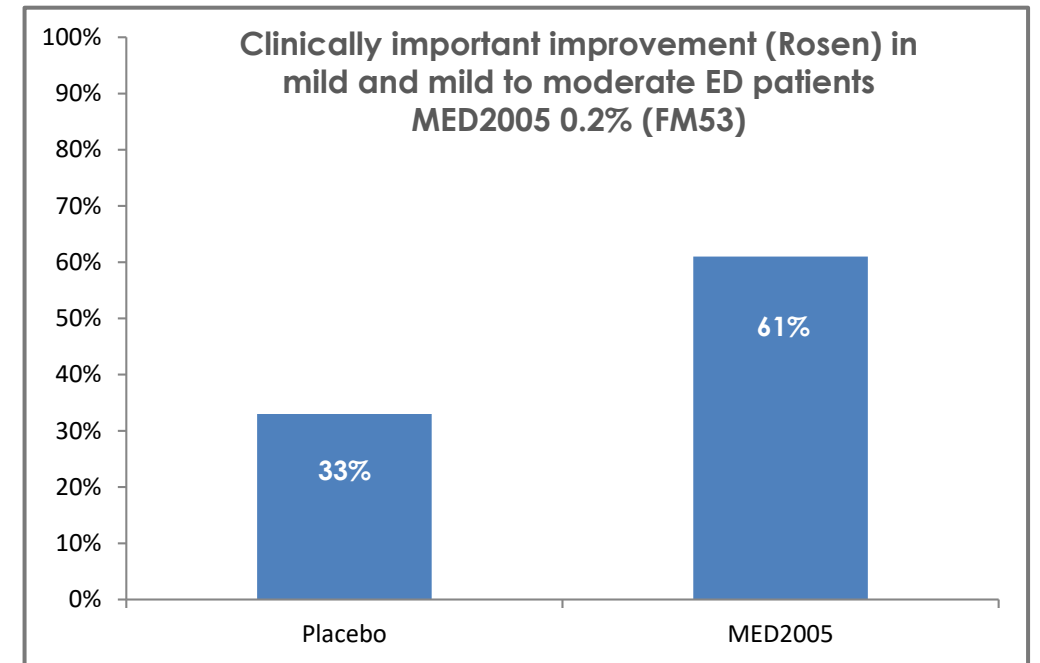
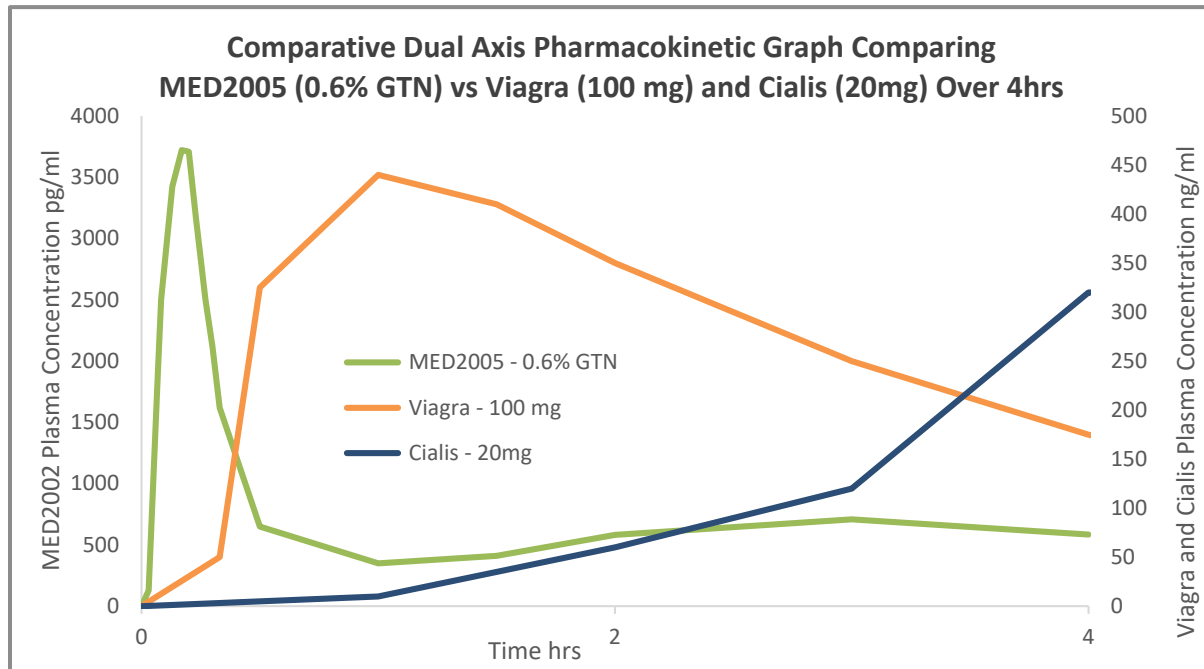
MED2005 & the DermaSys[®] transdermal technology

MED2005 uses **unique DermaSys[®] technology**, which enables **targeted and rapid delivery** of GTN through the tissue to achieve and maintain an erection



MED2005 – First topical gel to treat ED with key differentiators

- MED2005 is a **topical gel** containing from 0.2% up to 0.6% w/w of **glyceryl trinitrate (GTN)**
- Utilises Futura's proprietary **drug delivery technology** DermaSys®
- Is applied directly to the exterior of the glans penis **by the male or sexual partner**
- Has a rapid onset of action **5-10 minutes**



MED2005 value proposition

MED2005's unique proposition could become a **preferred treatment option** for many men with ED and their partners. It will also present a **new treatment option** for those for whom PDE5is are unsatisfactory or unsuitable

Alternative first line treatment

MED2005 is an **effective alternative first line** treatment for couples looking for a **spontaneous and more intimate solution** to erectile dysfunction

50% of physicians consider MED2005 a significant treatment improvement¹

Unable to use PDE5is

MED2005 represents a **treatment option** for those patients on nitrates therefore **contra-indicated to PDE5is**

At least 10% of ED patients are contraindicated from using oral PDE5is¹

Dissatisfied PDE5i users

MED2005 represents a **new treatment option** for patients who have discontinued treatment and for those who find **PDE5i side effects unacceptable**

Up to 50% of ED patients discontinue current ED treatments within a year¹

Dr. Wayne J.G. Hellstrom is Professor of Urology and Chief of Andrology at Tulane University School of Medicine in New Orleans and member of the Futura Medical Advisory Panel, said:

"The treatment of ED has not seen any new clinical products for nearly two decades...."

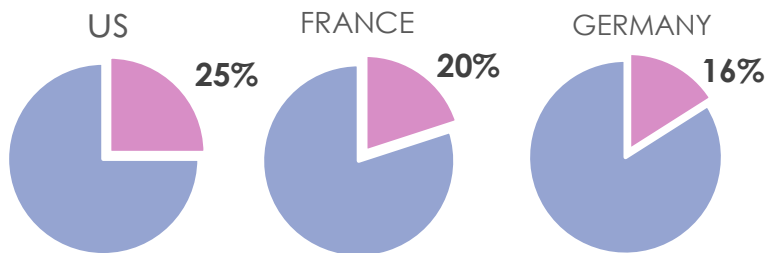


MED2005 represents a potential US\$1 billion opportunity¹



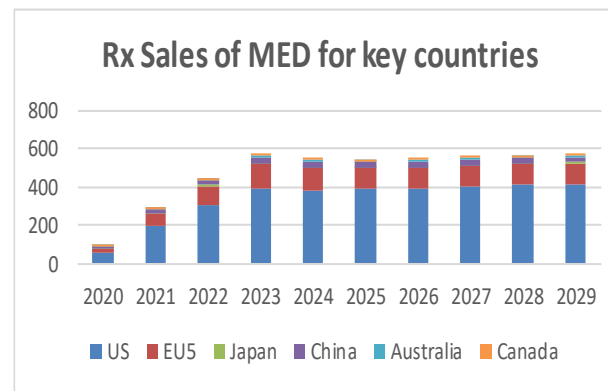
- 01 ED prescription (Rx) market worth over **US\$5.6 billion** in 2016² (up 6% vs. 2015)
Research by Cello suggests a **> 20% patient share** for MED2005 (Branded Eroxon®)
- 02 **\$560 million potential prescription peak sales** at \$5 per dose
Research by Cello and model provided by Decision Resources for Futura
- 03 **\$660 million potential 'Over the Counter' sales** at \$5 per dose with 70% incremental to prescription sales
Research and forecast provided by Ipsos Mori for Futura
- 04 **Strong commercial out-licensing interest** in particular with Phase 3 headline data expected
December 2019

CELLO HEALTHCARE RESEARCH



SWITCH FROM CURRENT ED TREATMENT

DECISION RESOURCES RESEARCH



IPSOS MORI RESEARCH

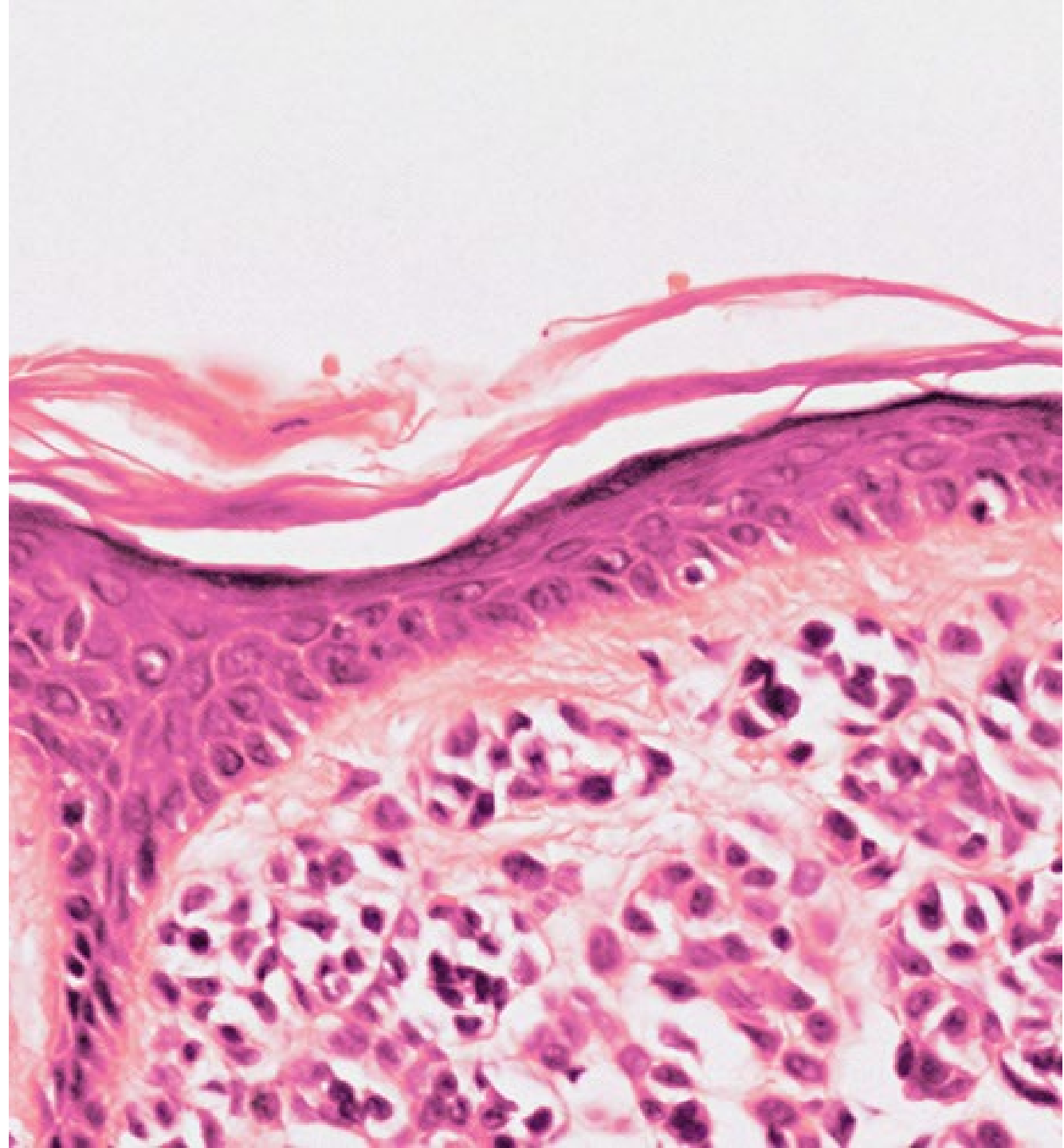
RSP (\$m)	Ipsos scenario		
	Year 3	Year 5	Year 10
	500	584	661

1 - Directors' belief based on market research conducted on Company's behalf by Ipsos, Cello Health Consulting and Decision Resources Group
2 - Market size with sales based on Manufacturers' Selling Prices 2016: 15 Key ED markets, IMS Health



MED2005 – CLINICAL DEVELOPMENT PROGRAM

LEAD PRODUCT



Clinical study programme

Study Code	Study Phase	Number of Subjects	Test Article	Study status
FM33	Phase I – PK.	16	0.025%, 0.033% , 0.083% & 0.166% MED2003, 0.25% MED2004 and 0.4% MED2005	✓ Complete
FM35	Phase I – PD.	15	0.0033% , 0.025% & 0.083% MED2003 and 0.2% MED2005	✓ Complete
FM53	Phase 2a – headline data Sep 2016 & peer-reviewed journal publication early 2018	231	0.2% MED2005 vs PLO	✓ Complete
FM58	Phase I – PK.	40	0.2%, 0.4%, 0.6% & 0.8% MED2005 and Nitrostat	✓ Complete
FM57	Phase 3 – Safety and efficacy dose ranging. Top-line results Dec 2019	1,000	0.2%, 0.4% & 0.6% MED2005 and PLO MED2005	Ongoing
FM59	Phase 3 – Safety and efficacy Confirmatory study. Top-line results Q4 2020	690	0.2%, 0.4% & 0.6% MED2005 and PLO MED2005 (likely choosing two of three doses from FM57)	H2 2019 start ¹

Studies FM02 to FM07, FM22, FM23, and FM27 were early phase exploratory studies using previous MED formulations and are not presented here

FM53 (Phase 2a efficacy study) – completed Sep 2016

FM53	A randomized double blind, placebo-controlled, home use, cross-over clinical trial of topically-applied glyceryl trinitrate, MED2005, 0.2% for the treatment of erectile dysfunction in 231 patients
Objectives	Primary endpoint: Evaluate efficacy of MED2005 using the International Index for Erectile Function (IIEF) questionnaire Secondary endpoints: <ul style="list-style-type: none">• Evaluate efficacy of MED2005 using the other domains of the IIEF, the Sexual Event Profile (SEP) and the Global Assessment Questionnaire (GAQ), mild/moderate, moderate & severe ED patient groups• Assessment of speed of onset• Assess safety and acceptability of MED2005
Duration	8-week treatment period (4 weeks active + 4 weeks placebo)
Results	Primary end point and number of secondary endpoints were met Efficacy in mild and mild/moderate patients; minimum effective dose Extremely favorable side-effect profile in patients and female partners Patients experienced erections in 5-10 minutes Product used for spontaneous intercourse; in 33% of couples, the female applied to the male

Phase I PK study (FM58) – successfully completed April 2018

(Part 1 30 Subjects; Part 2 10 Subjects)

Dose-related absorption

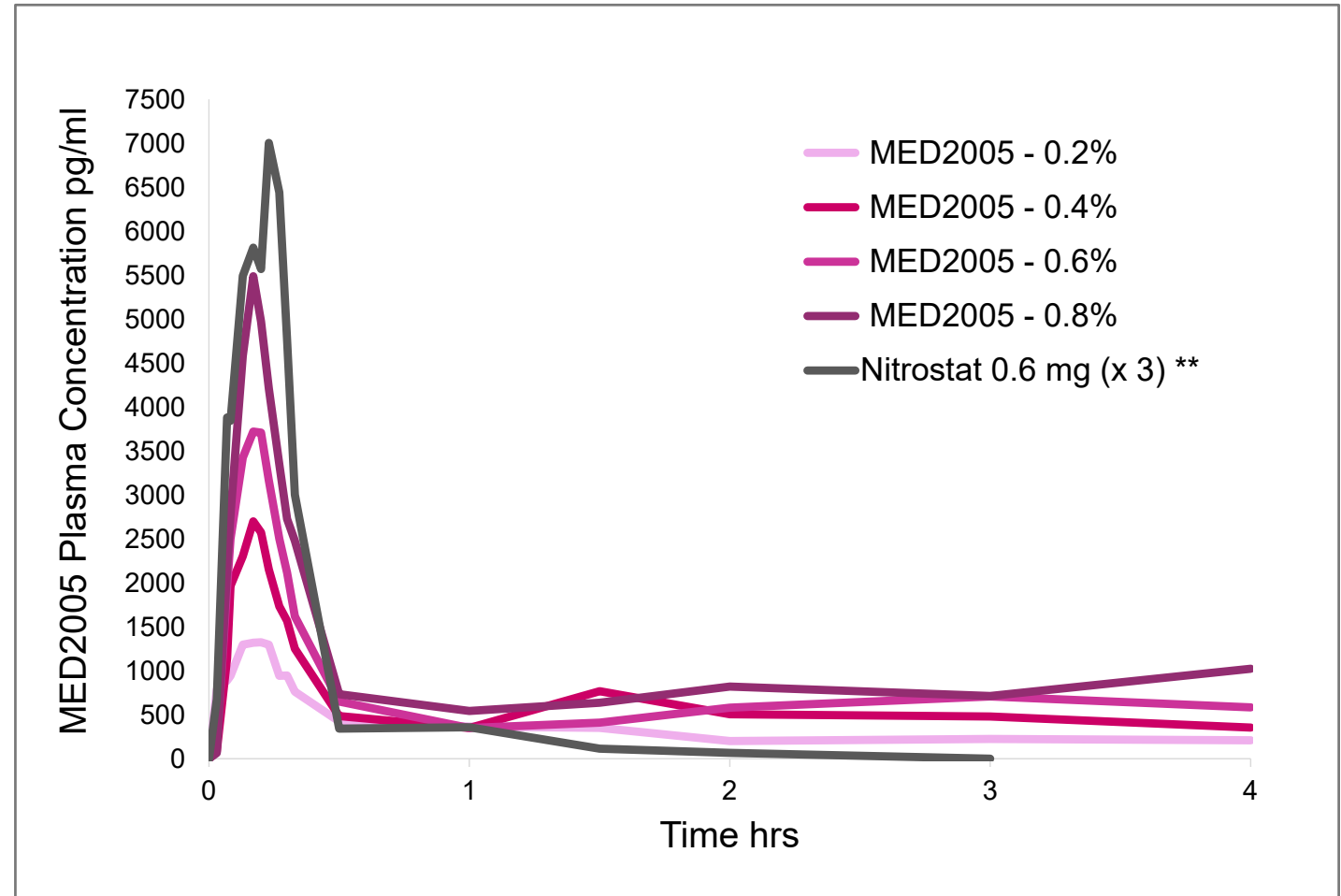
- C_{max} achieved with MED2005 GTN doses of 0.4%, 0.6% and 0.8% was approximately 170%, 260% and 320% respectively of that achieved at 0.2%
- Excellent dose proportionality for a topical product

Rapid onset for all doses

- All doses were first detected in bloodstream within 4-5 minutes
- T_{max} of 10-12 minutes for all doses
- Similar systemic side effect profile across all doses – mild transient headaches
- 75% of GTN absorbed through penis after 5 minutes

Bioavailability of MED

- Topically applied MED2005 doses of 0.2% to 0.6% achieved equivalent or lower plasma concentrations than Nitrostat thereby confirming systemic safety and 505(b)2 regulatory pathway in USA.
- GTN levels within plasma of topically applied MED2005 versus intra-venous GTN infusions confirmed MED2005 is efficiently absorbed thus supporting potential efficacy.



Phase 3 studies – risk mitigation

01

- ✓ Strong evidence of efficacy from Phase 2a study (FM53)
- ✓ Regulators acknowledged 'Minimally effective dose' probably established

02

- ✓ Broad regulatory consensus¹ on remaining clinical program (Phase 3)
- ✓ Regulatory recommendations included into Phase 3 study design and analysis

03

- ✓ FM58 PK study data suggests higher doses will increase efficacy whilst maintaining adverse events at an acceptable level for patients & their partners

04

- ✓ Design of Phase 3 studies enhanced by seeking world expert opinion
- ✓ Potential commercial partner feedback also incorporated into the Phase 3 design

05

- ✓ FDA confirmed US Regulatory Pathway – US 505(b)2 using Nitrostat[®] as reference drug²
- ✓ MEB confirmed EU Regulatory Pathway – Article 8(3) of Directive 2001/83/EC³

All Regulatory Agencies open to OTC after period of Rx marketing

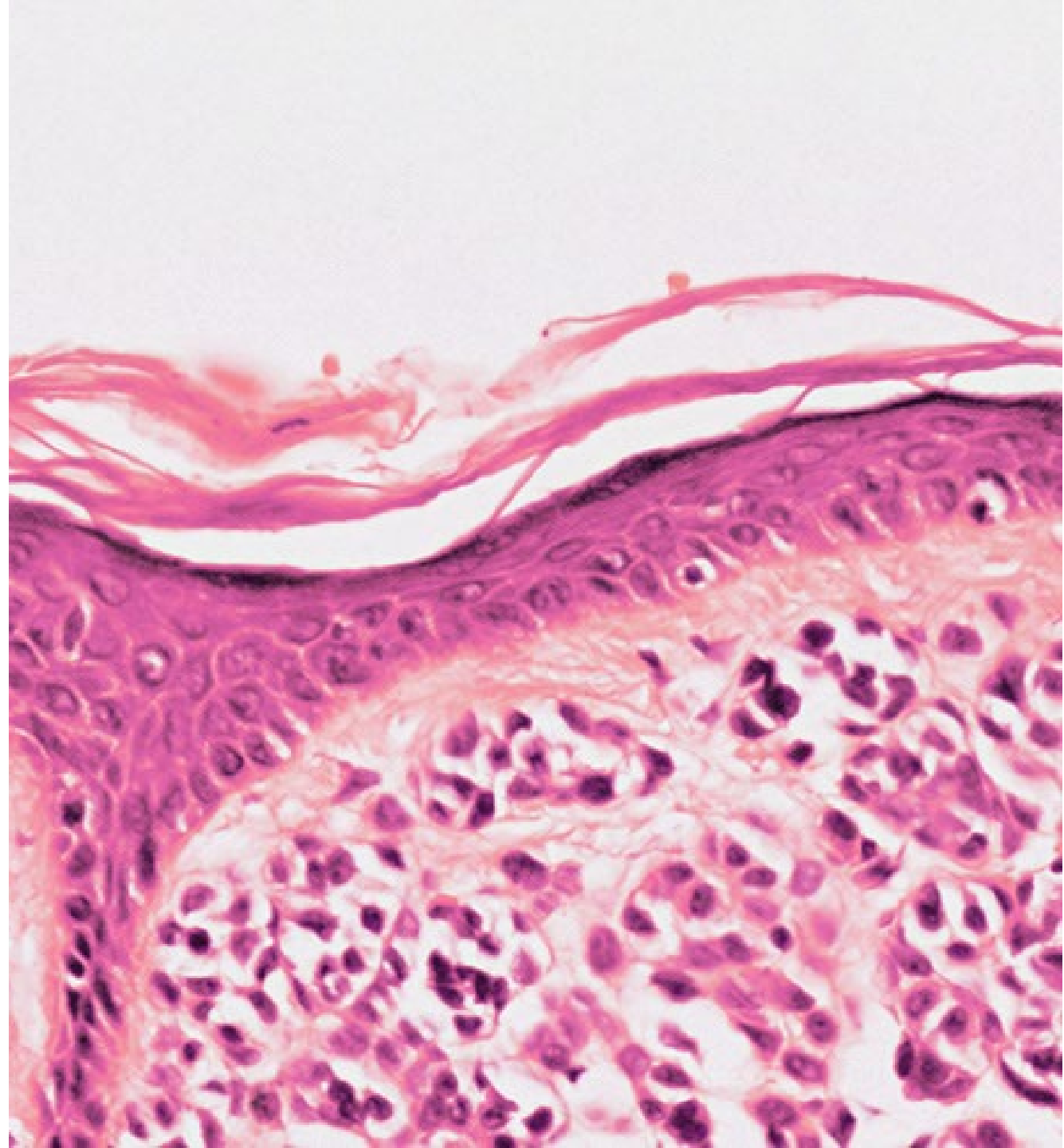
Phase 3 study design - FM57

FM57	A Phase 3, dose-ranging, multi-centre, randomized, double-blind, placebo-controlled, home use, parallel group clinical trial of topically applied GTN for the treatment of ED
Objectives	<p>Primary objective:</p> <ul style="list-style-type: none">To demonstrate the efficacy of MED2005 versus placebo in male subjects self-diagnosed with ED using the erectile function domain of the International Index for Erectile Function (IIEF), the Sexual Encounter Profile (SEP) Question 2 & 3. <p>Secondary objectives:</p> <ul style="list-style-type: none">To evaluate the efficacy of MED2005 in male subjects using Self-Esteem And Relationship Questionnaire (SEAR) for men and women, the Global Assessment Questionnaire (GAQ), the additional domains of the IIEF as well as subjective measures of the time of onset and duration of action (erection) and additional questions on usage and application of MED2005.To evaluate the safety of MED2005 using Adverse Events (AEs) and standard assessmentsAssess safety and acceptability of MED2005 in nitrate contraindicated patients
Study sites	Central and Eastern Europe
Study size	1,000 male subjects with ED, and their female partners.
Open label extension	Approximately 300 subjects will also participate in a 6-month open label extension long-term safety study (100 of these for a further 6 months – totalling 12 months) to confirm safety of MED2005.
Products Tested*	MED2005 0.2% GTN , 300 mg gel = 0.6mg GTN; MED2005 0.4% GTN , 300 mg gel = 1.2mg GTN; MED2005 0.6% GTN , 300 mg gel = 1.8mg GTN; and Placebo vehicle;



**MED2005 –
COMMERCIAL
OPPORTUNITY &
INTELLECTUAL PROPERTY**

LEAD PRODUCT



Commercial opportunity

- 1 Futura has a **proven track record** in delivery of Research & Development ('R&D')
- 2 First Phase 3 (FM57) **Fully Funded**
First patient **enrolled October 2018** – Headline data expected by end of **December 2019**
- 3 Futura monetises its assets via 3rd parties. **Strong interest** from a number of companies. Futura expects this **interest to grow once Phase 3 completes** and remaining R&D further de-risked
- 4 **\$1 billion potential sales opportunity** compared to current Futura market cap of c £30 million
- 5 **Share** of Innovator NPV likely to **increase by 50%*** from Phase 2 to Phase 3 success

*Assumptions

- Innovator NPV based on Futura's out-licensing advisor deal experience and on-going assessment of pharma deals
- \$560 million potential prescription peak sales at \$5 per dose – Research by Cello and Decision Resources for Futura; \$660 million potential 'Over the Counter' sales at \$5 per dose with 70% incremental to prescription sales – Research and forecast provided by Ipsos Mori for Futura

Robust IP protection

Patent protection

- **Patents are formulation specific**
 - GTN has narrow therapeutic range for ED
- **First generation patent covers all MED2002-5 formulations**
- **Patents are granted/submitted in key territories**
 - US until 2028
 - EU / RoW until 2025
- **New patent filed in February 2017 specific to final product**

EU Data exclusivity protection

EU rules grant 10-year protection

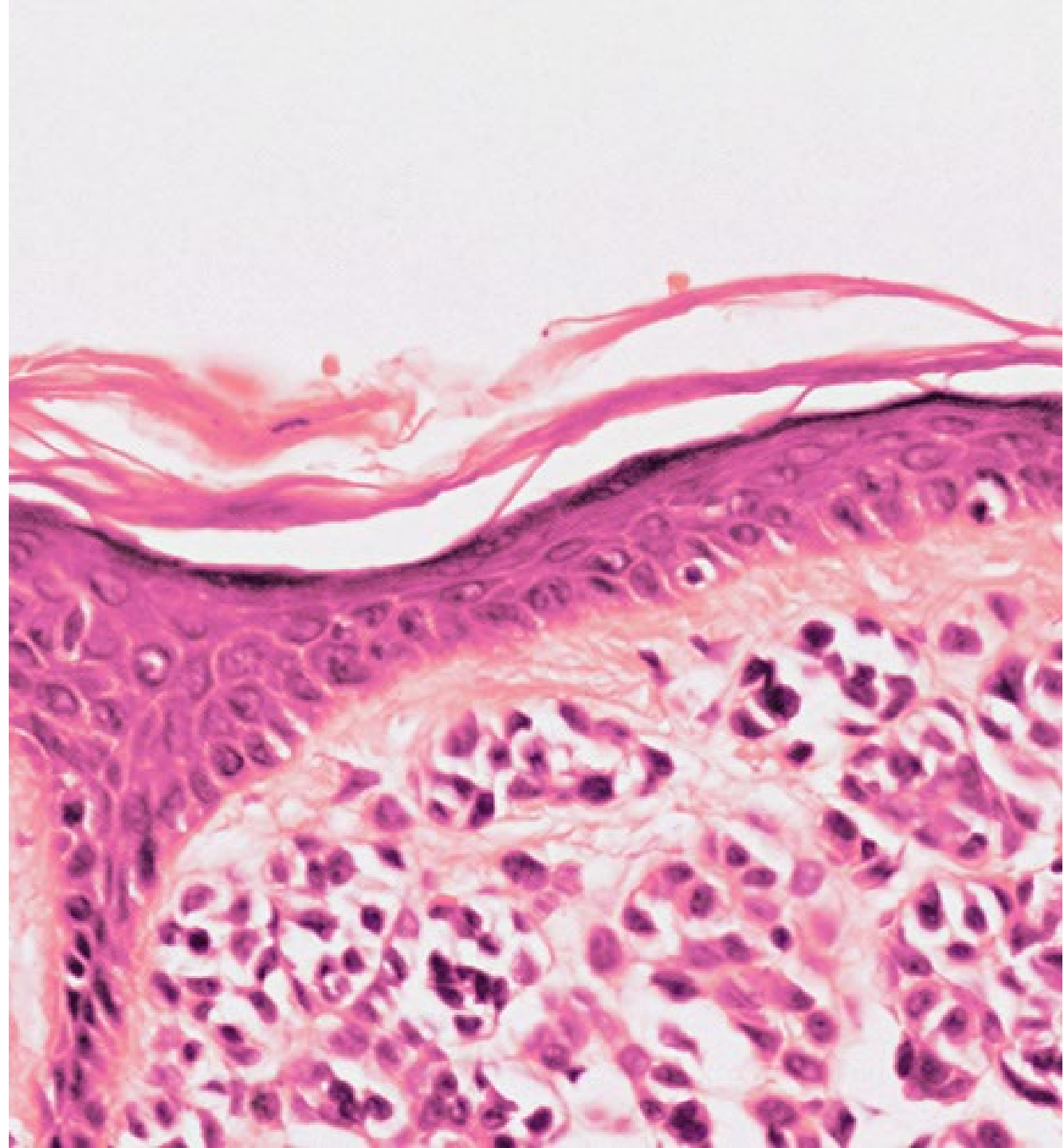
- **8-year exclusivity period**
Data generated by Futura cannot be used for an MAA to support their application
- **10-year protection**
No generic version of the product may be marketed for 10 years after the first approval

Generic regulatory protection

- Current US regulations for generic topical pharmaceutical products typically require a clinical trial programme to show equivalence unlike generic oral drugs which typically only require to show bioequivalence



TOPICAL PAIN RELIEF



Futura's DermaSys[®] transdermal technology

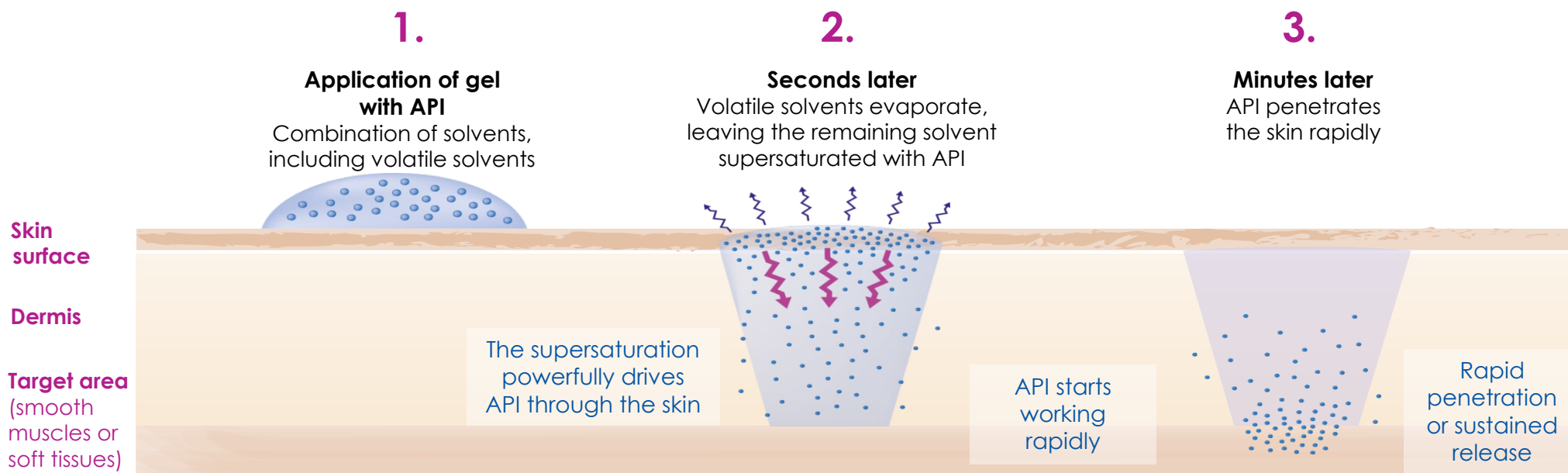
TPR100 uses **unique DermaSys[®] technology**, which enables **targeted and rapid delivery** of Diclofenac through the skin to achieve rapid pain relief

TPR100
Pain relief gel

Applying Futura's advanced transdermal science to diclofenac

- Increased permeation of active compound through the skin - DermaSys[®]
- Sustained pain relief for up to twelve hours

Futura's **unique DermaSys[®] technology** enables **targeted and rapid delivery** of active pharmaceutical ingredients (API) through the skin to the required site of action



Topical Pain Relief

01

Global sales of topical over the counter non steroidal anti-inflammatory drugs (“NSAIDs”) > US\$2.9 billion¹

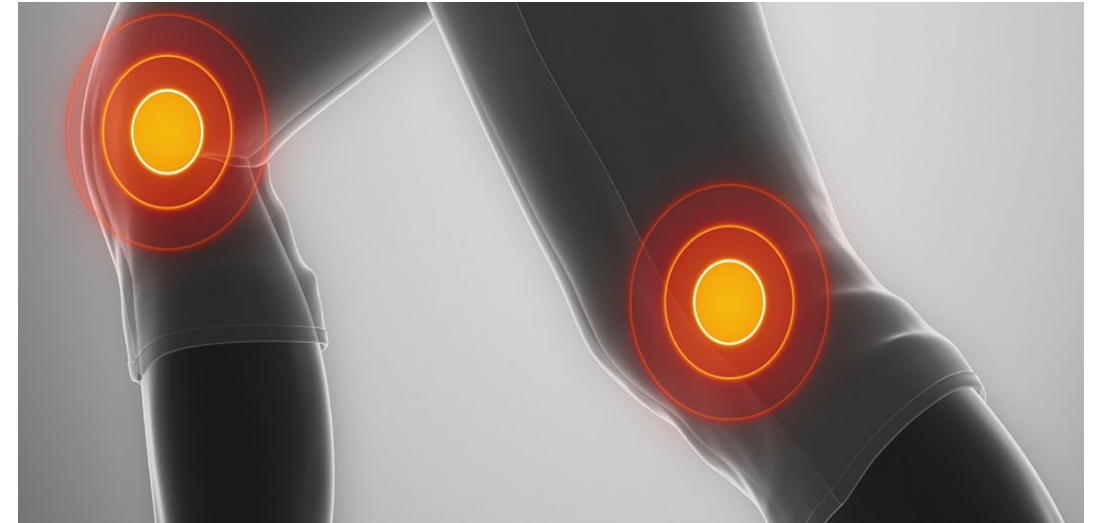
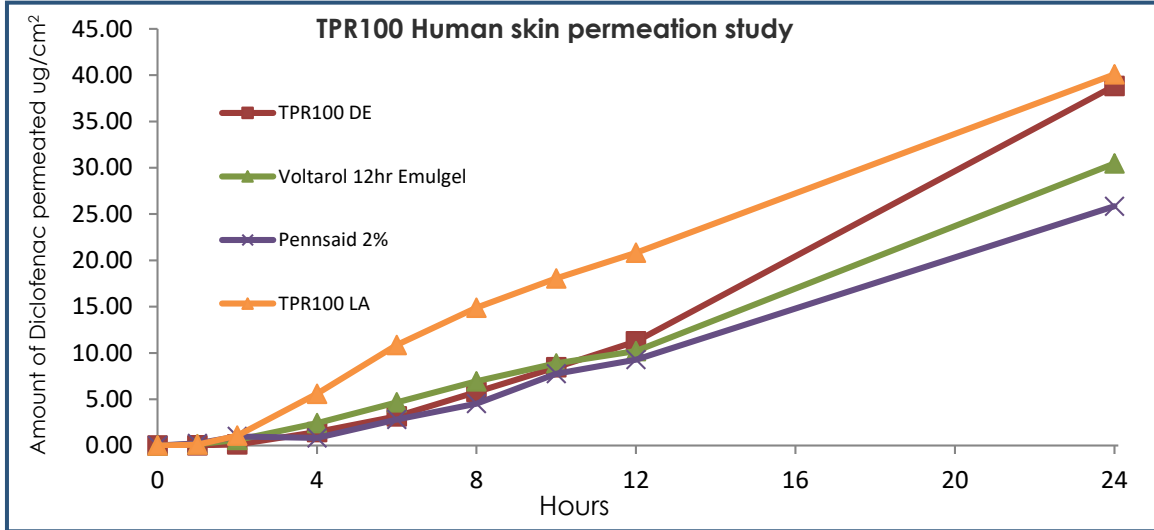
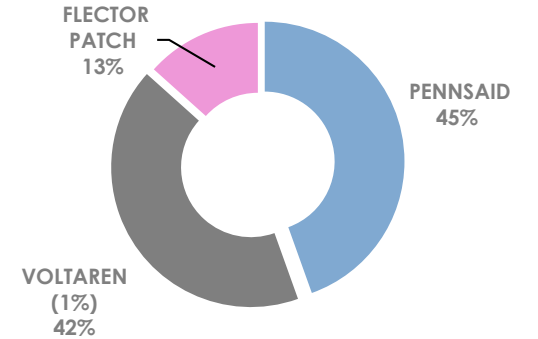
02

Demand for safe, effective and long lasting topical pain relief
 DermaSys[®] provides **faster drug permeation**, a key point of difference

03

TPR100 is a Diclofenac gel that utilises Futura’s DermaSys[®] technology
Improved permeation compared to market leaders at same dosage

US market - \$1 billion²



Topical Pain Relief

01

2017 agreement with Thornton & Ross (part of STADA) for UK rights to TPR100
UK regulatory submission filed in July 2018 – 1st round of questions received from MHRA in March 2019

02

Commercial discussions ongoing with other potential distributors
TPR100 - USA will require further clinical data to support regulatory submission



TPR100 – USA strategy

- **FDA Pre-IND response given**
 - Simplified new drug application 505(b)(2) filing route
 - 700 patient, placebo controlled 12-week efficacy study required
- **Ongoing discussions with potential US licensees**
 - Futura require partner commitment before (progressing) additional clinical expenditure

Illustrative positioning only

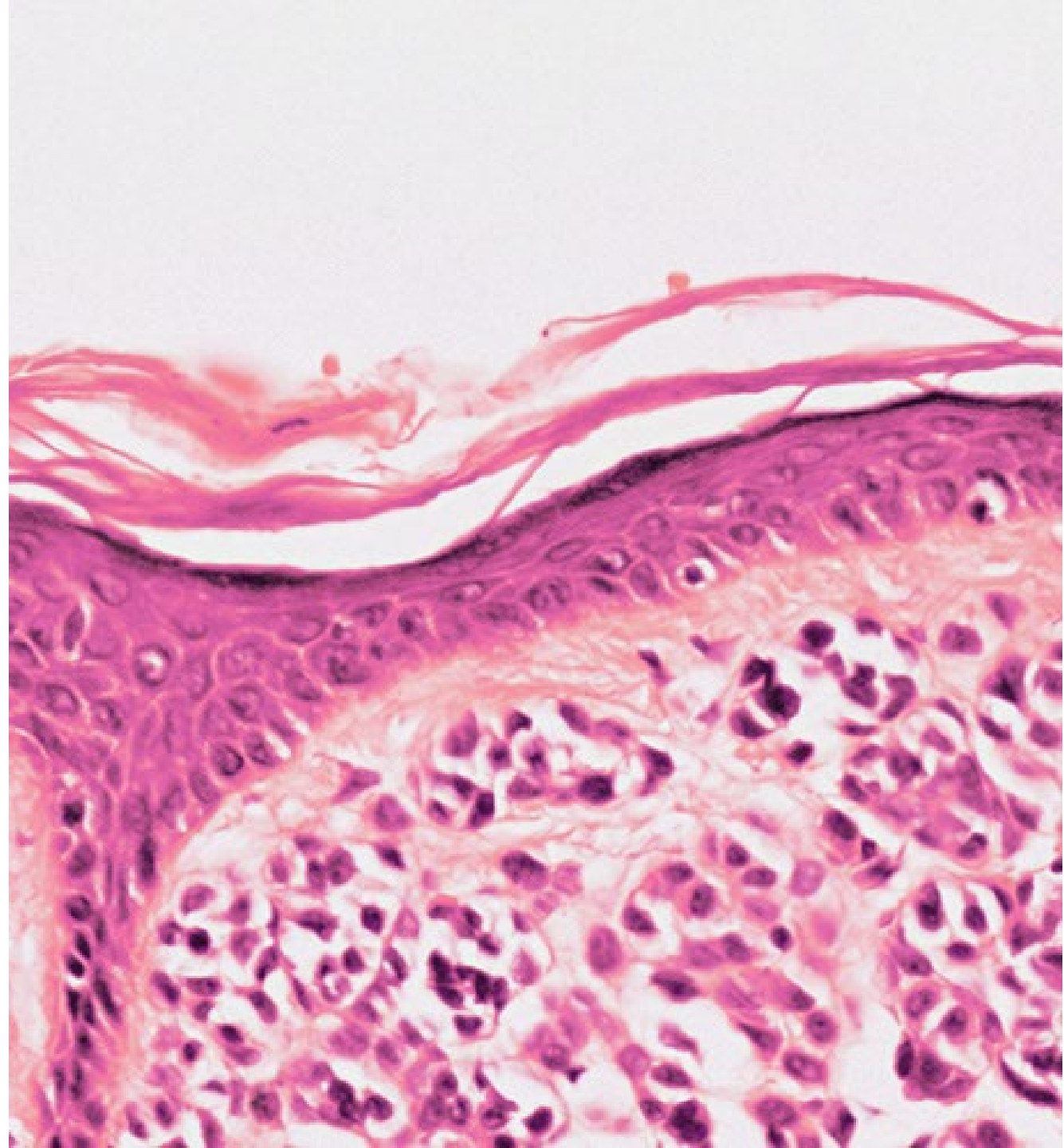


TIB200 – 10% ibuprofen gel

- Opportunity to move from current 3-4 times to twice a day dosing
- Placebo controlled efficacy study required prior to EU regulatory filing
- Futura require partner commitment before progressing clinical expenditure



**FINANCIAL
RESULTS
&
OUTLOOK**



Year End Highlights – Organisation & Financials

- ➔ Net loss of £5.89 million in period
 - (2017: net loss of £3.90 million)
- ➔ Cash resources of £9.16 million (at 31 December 2018)
 - Plus tax credit of £1.36 million expected Q2-3 2019
 - (At 31 December 2018: cash resources excluding potential tax credit due H2 2019)

➔ Outlook

Headline data of first Phase 3 for MED2005 by end of December 2019
Commencement of second Phase 3 in H2 2019 with headline data by end of 2020

Increasing awareness of MED2005 through scientific advisory meetings involving high profile US and EU key opinion leaders ('KOLs') in addition to increasing scientific and general publicity

Progress/approval on TPR100 MHRA regulatory submission with further out-licensing discussions

Further ongoing out-licensing discussions on MED2005 with Rx and OTC companies