

ASX/Media Release

20 June 2019

## Updated investor presentation with new BTX 1801 data

### Key highlights

- Botanix releases an updated presentation focusing on the new BTX 1801 antimicrobial data and the recently released BTX 1308 mechanism of action data
- New studies show cannabidiol containing BTX 1801 rapidly kills Gram-Positive *Staphylococcus aureus* (“staph”) and *methicillin resistant Staphylococcus aureus* (“MRSA”)
- Data shows that despite extensive exposure to cannabidiol, MRSA superbugs do not develop resistance
- The data supports the anti-inflammatory, immune cell modulating and antimicrobial nature of cannabidiol, highlighting the potential of Botanix development products to successfully address a range of skin diseases
- Botanix’s ongoing Phase 2 programs (acne and atopic dermatitis) remain on track

**Philadelphia PA and Sydney Australia, 20 June 2019:** Medical dermatology company Botanix Pharmaceuticals (“Botanix” or “the Company”) is pleased to release an updated investor presentation to update shareholders, investors and strategic partners on the key findings of the BTX 1801 antimicrobial study, which shows the potential for BTX 1801 to treat serious skin infections (***further information and additional data provided in pages 15-19***). The presentation also outlines key findings from the recently released successful Phase 1b BTX 1308 psoriasis study.

**Matt Callahan, Founder and Executive Director of Botanix said:** “Botanix is proud to be showcasing one of the most mature clinical pipelines of any cannabinoid company in the world and the recently released mechanism of action data and new antimicrobial data, represent groundbreaking and novel applications of CBD.

Not only do we now have a strong understanding of how CBD impacts inflammatory and immune response pathways, we have generated new data supporting our potential to produce the world’s first non-resistance forming antibiotic against superbugs. With data from the Phase 2 programs (acne and atopic dermatitis) anticipated in the coming months, Botanix is rapidly progressing towards a number of further value inflection points.”

### About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage cannabinoid company based in Perth (Australia) and Philadelphia (USA) committed to the development of pharmaceutical products that are underpinned by science and supported by well-controlled randomised clinical trials. The Company’s focus is the development of safe and effective topical treatments for acne, psoriasis, atopic dermatitis

and other skin conditions. The active ingredient contained in Botanix products is a synthetic form of cannabidiol. Treatment targets include inflammation, deterioration of the of the skin barrier, skin cell proliferation, pruritus (itch), excess sebum production and bacterial infection.

Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases. Botanix is working with multiple parties to test the application of Permetrex™ on both a fee-for-service and traditional license basis. Botanix pursues a rapid clinical development strategy aimed at accelerating product commercialisation.

The Company completed its first acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 clinical study in June 2018 with study completion expected in 3Q CY2019. The BTX 1204 atopic dermatitis Phase 2 patient study is also underway with study completion expected on 4Q CY2019. Finally, Phase 1b BTX 1308 psoriasis mechanism of action study has recently completed, with positive interim data announced in June 2019. Pipeline developments that leverage the antimicrobial properties of cannabidiol are also moving forward and are planned to enter the clinic in 2H CY2019.

To learn more please visit: <https://www.botanixpharma.com/>

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RESTORING HEALTHY SKIN

# Botanix Overview

*Investor Presentation*

*June 2019*



# Botanix overview

Clinical stage cannabinoid company, with one of the world's most advanced pipelines, studying cannabidiol (CBD) in a range of inflammatory and anti-microbial applications



Achieving milestones

**First 2019 clinical milestone (psoriasis) achieved** – awaiting near term milestones for Phase 2 acne and atopic dermatitis studies in **3Q and 4Q**



Driven by science

**Multiple Phase 1b studies show clinical efficacy and safety of CBD** and mechanism of action studies provide **support for other diseases**



Validation of pharma focus

Investment in the sector is moving beyond plants – **Botanix is one of the world's most advanced pharma focused synthetic cannabinoid companies**



Technology driven

Novel skin delivery technology, Permetrex™ is **proven to enhance delivery of CBD** and provides a **novel IP position**



World class team

**World class US and Australian based team** is preparing for Phase 2 study results and rapid commercialisation

# Corporate overview

Multiple near term data read-outs in 2H 2019

## Trading information

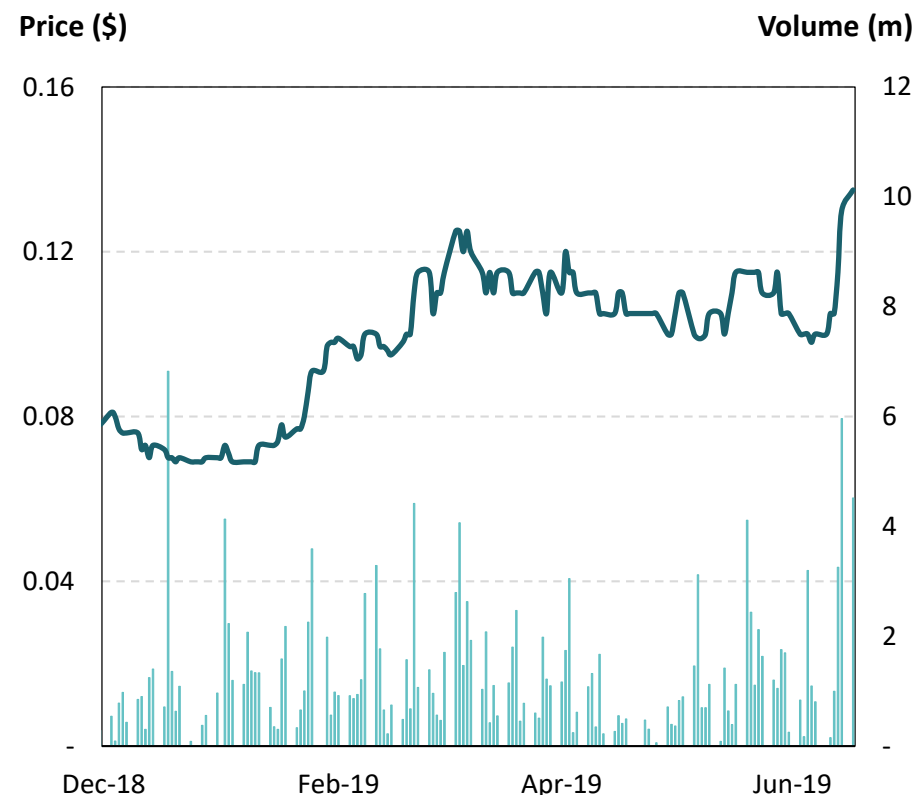
Share price (as at 17-Jun-2019)	A\$0.135
52 week low / high	A\$0.135 / A\$0.069
Shares outstanding <sup>1</sup>	773m
<b>Market capitalisation<sup>1</sup></b>	<b>A\$104.4m</b>
Cash (as at 31-Mar-2019)	A\$9.3m
Debt (as at 31-Mar-2019)	-

## Top shareholders (May 2019)

Shareholder	%
Matthew Callahan – Founder and Executive Director	9.2
Caperi Pty Ltd – Co-founder	9.2
Board and management (excl. shareholders above)	2.6

*Excludes 48.4m options*

## Share price performance



# Phase 1b clinical and MOA studies provide solid foundation

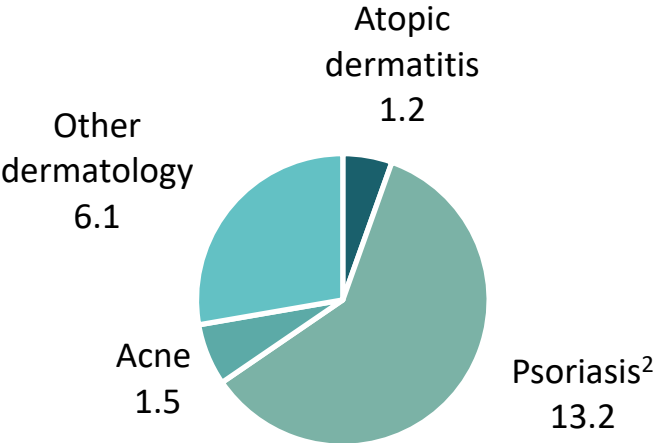
Clinical and safety data, as well as new mechanism of action (MOA) data from Botanix studies provide support to near term completion of Phase 2 studies in acne and atopic dermatitis

Product candidate	Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Status
Synthetic CBD with Permetrex™ technology	<b>BTX 1503</b>	Moderate to severe acne	✓	✓	✓	Completion pending 3Q 2019
	<b>BTX 1204</b>	Moderate atopic dermatitis	✓	✓	✓	Completion pending 4Q 2019
	<b>BTX 1308</b>	Psoriasis	✓	✓	✓	Successful data 2Q 2019
	<b>BTX 1801</b>	Antimicrobial skin infections	✓			Successful data 2Q 2019
Permetrex™ programs	External	Various				Ongoing collaborations with partners

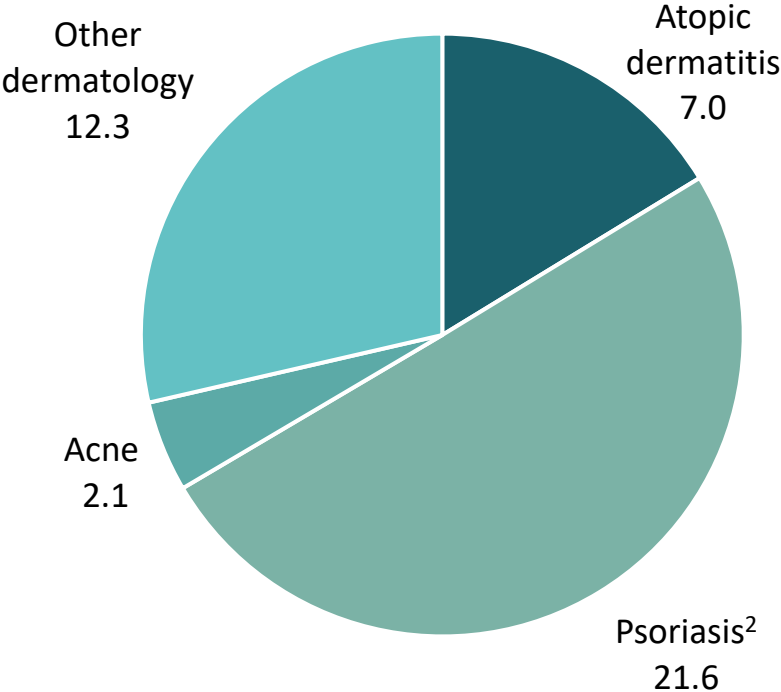
# Our focus is on large markets that are poised for growth

Global medical dermatology market is expected to grow to US\$43bn by 2024<sup>1</sup>

2017 global dermatology market<sup>1</sup>  
US\$22bn sales



2024 global dermatology market<sup>1</sup>  
US\$43bn sales



1. Evaluate Pharma  
2. Growth driven by Biologics



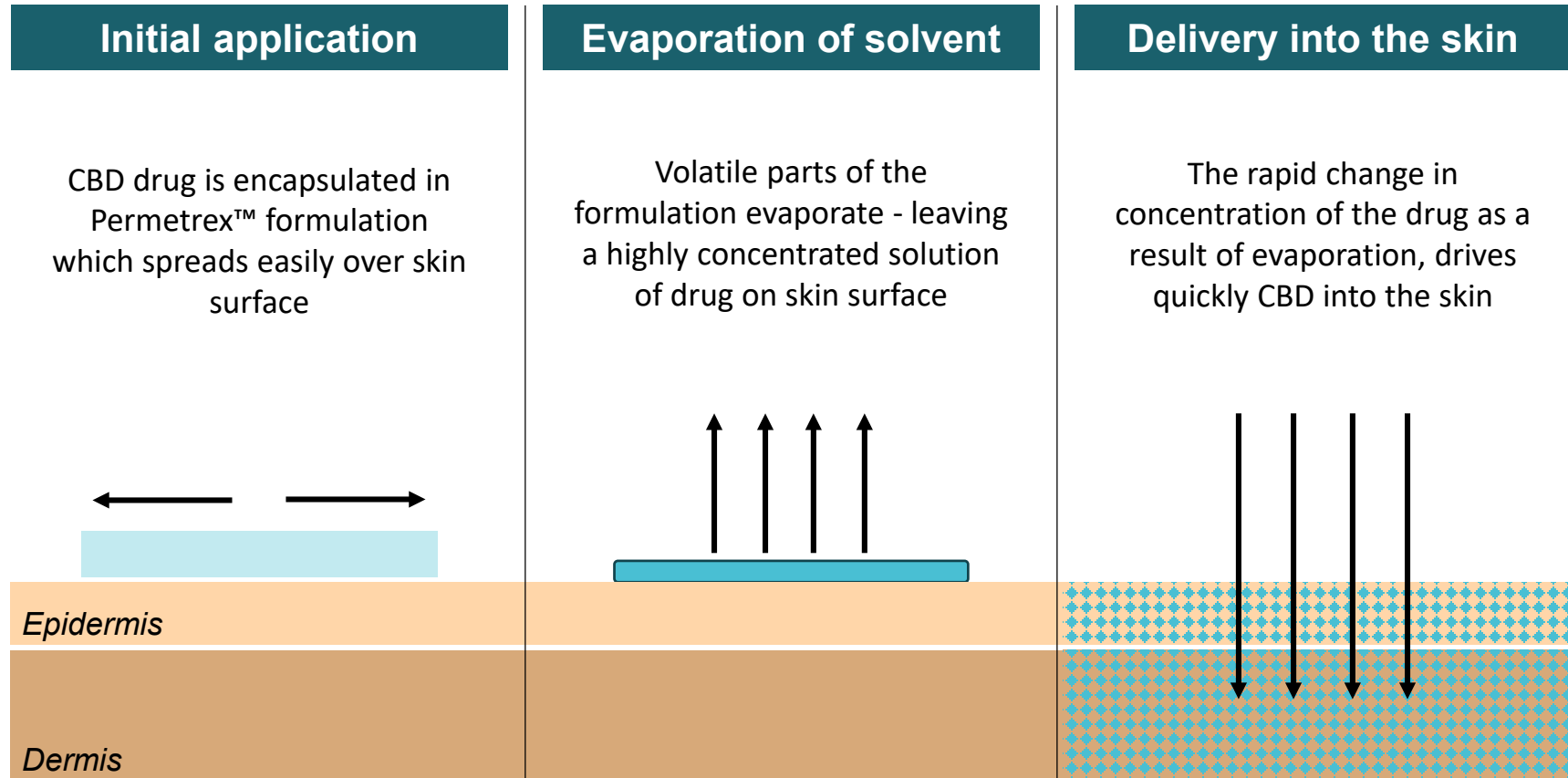
# Overview Permetrex™ Technology





# Permetrex™ - proprietary novel skin delivery technology

Makes new types of topical products<sup>1</sup>, that deliver very high doses of drug into the layers of the skin without using permeation enhancers, preservatives, or irritating levels of alcohol / petrol derivatives

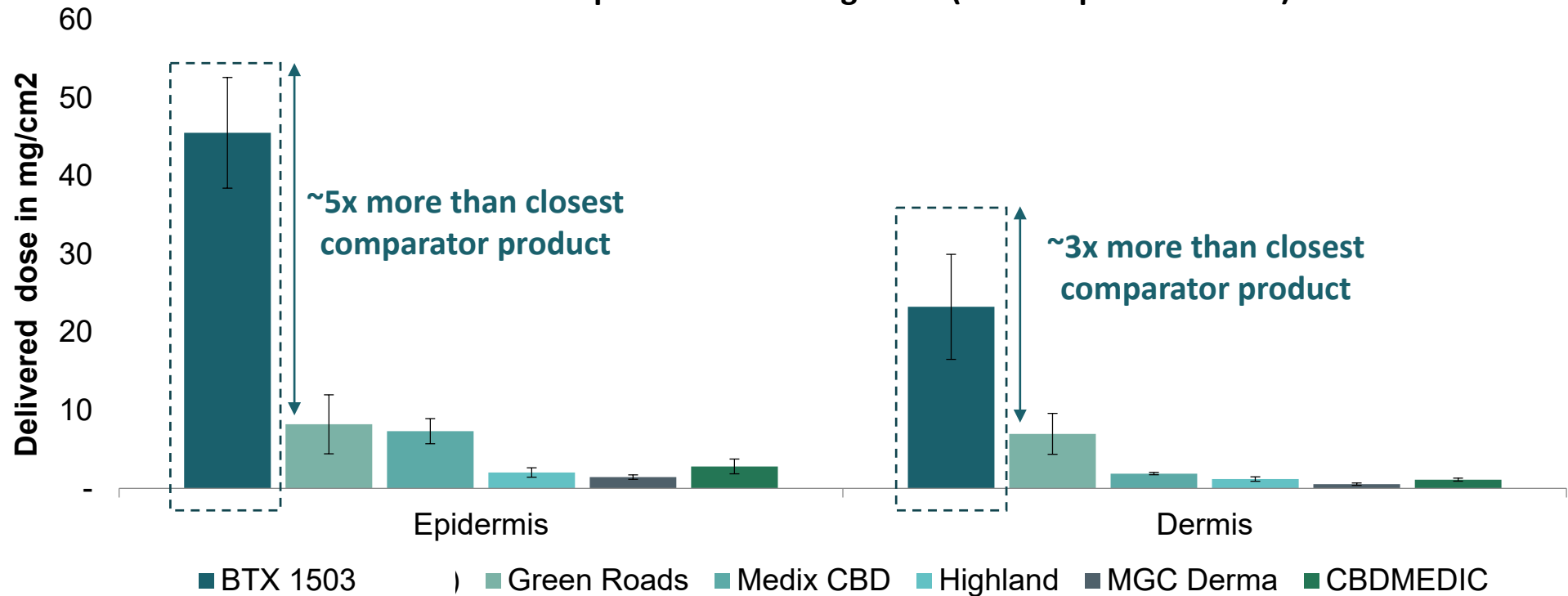


1. Topical dosage forms include: solutions, creams, gels, ointments, foams or pastes.

# Permetrex™ delivers 3-5 times more CBD into the skin

BTX 1503 (acne) significantly outperformed the other tested CBD products in delivering drug to the targeted layers of the skin <sup>1</sup>

Amount of CBD permeated through skin (time elapsed 48 hours)



**Relative to the closest comparator, BTX 1503 delivers significantly more CBD to the skin than other OTC creams and gels**

1. For further details on these tests – see BOT ASX release on 26/02/19. Skin penetration tested using franz cell human skin vessel with receiver fluid assayed for CBD content at each level (epidermis and dermis). Study conducted by Tiaga Research. Botanix data on file.

# Over-the-counter CBD products are not what they seem

Over-the-counter (OTC) or internet purchased CBD products often contain approximately one tenth of labelled CBD content, are not regulated and come with other quality risks <sup>1</sup>

Product name	Manufacturer	Product type	Label claim CBD content (mg/tube)	Tested CBD content
<b>TheraGreen™</b>	Green Roads	Cream	300	24.5
<b>Biotech Pain Relief</b>	Medix CBD	Cream	150	11.2
<b>Therapy+Hemp Cream</b>	Highland Pharms	Cream	200	24.6
<b>CBD Herbal Repair Cream</b>	MGC Derma	Cream	Undisclosed	8.8
<b>CBDMEDIC™ Back and Neck</b>	CBDMEDIC	Ointment	Undisclosed	14.9



**Dr. Amy Abernethy** @DrAbernethyFDA · 22h

Key questions about product safety need to be addressed. Data are needed to determine safety thresholds for CBD; datasets/information should be objective, of adequate quality and available for transparent review. Lab testing and data analyses need to be replicable.

**Dr Amy Abernethy**  
Principal Deputy  
Commissioner and Acting  
CIO – FDA<sup>2</sup>

1. For further details on these tests – see BOT ASX release on 26/02/19. Products purchased from internet websites of respective vendors and tested by independent laboratory testing service Tioga Research. HPLC analysis of CBD content compared labeled CBD or cannabinoid content to Tioga test results.. Botanix data on file.

2. Dr Amy Abernethy Twitter post during FDA Public Hearing “Scientific Data and Information about Products Containing Cannabis or Cannabis Derived Compounds” – 31 May 2019

## New mechanism of action data for CBD in skin disease

1. BTX 1801: antimicrobial
2. BTX 1308: psoriasis



# 1. Psoriasis disease overview

Psoriasis is a chronic, inflammatory disease characterised by red patches and plaques with silvery scales on the skin

## Psoriasis affects ~6m to ~8m people in the US

- ~90% have mild to moderate disease
- CDC surveys suggest only 2m patients are actively treated

## Lack of innovation in topical therapies for decades

- Most used pharmacologic treatments are topical corticosteroids which suffer from limitations on use
- Limited topical options for long-term use before moving to orals and biologics
- While highly efficacious, biologics are costly and limited to use in more severe disease
- More than 30% of patients exclusively use topical agents, but as many as 72% are non-adherent



Source: American Academy of Dermatology Guidelines; CDC: 2015 NAMCS; Devaux, et al. JEADV. 2012. 26 (Suppl.3): 61-67; Feldman et al. JAAD. 2007 (5):81-83

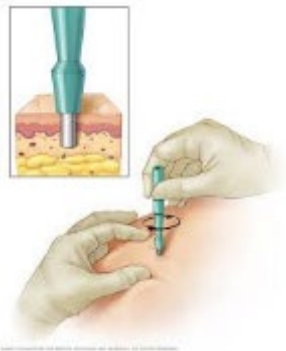
# 1. BTX 1308 Phase 1b mechanism of action study

Phase 1b patient study tested BTX 1308 in a model that allows biopsies to be collected which helps validate the mechanism of action of CBD in psoriasis

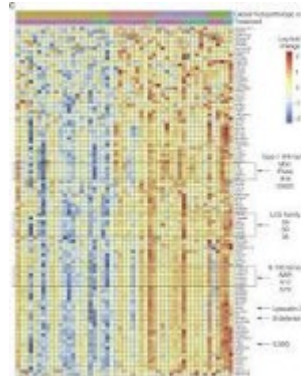
## Psoriasis plaque model



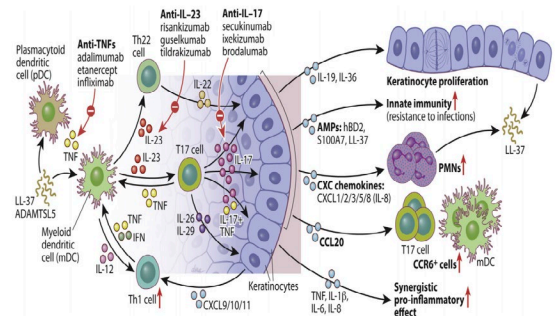
Biopsies of each drug zone and also healthy skin data help elucidate the mechanism of action



Skin biopsy



Gene profile

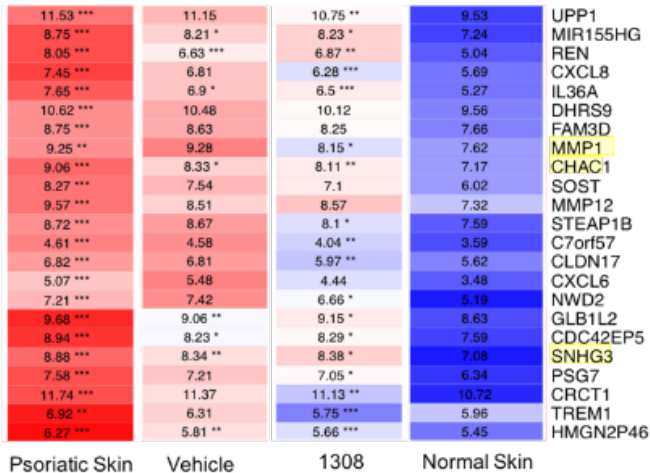


Targets for CBD in skin disease

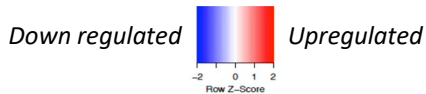
# BTX 1308 targets anti-inflammatory and immune modulating pathways

Permetrex™ effectively delivers CBD to the skin layers involved in the pathogenesis of skin disease and triggers significant alterations in inflammatory and immune response pathways

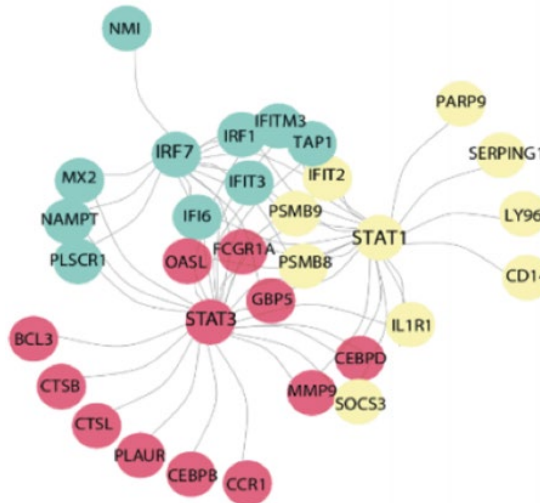
Heat map of genes regulated by treatment with BTX 1308




Psoriatic Skin    Vehicle    1308    Normal Skin




Ingenuity pathway analysis



Target pathways identified

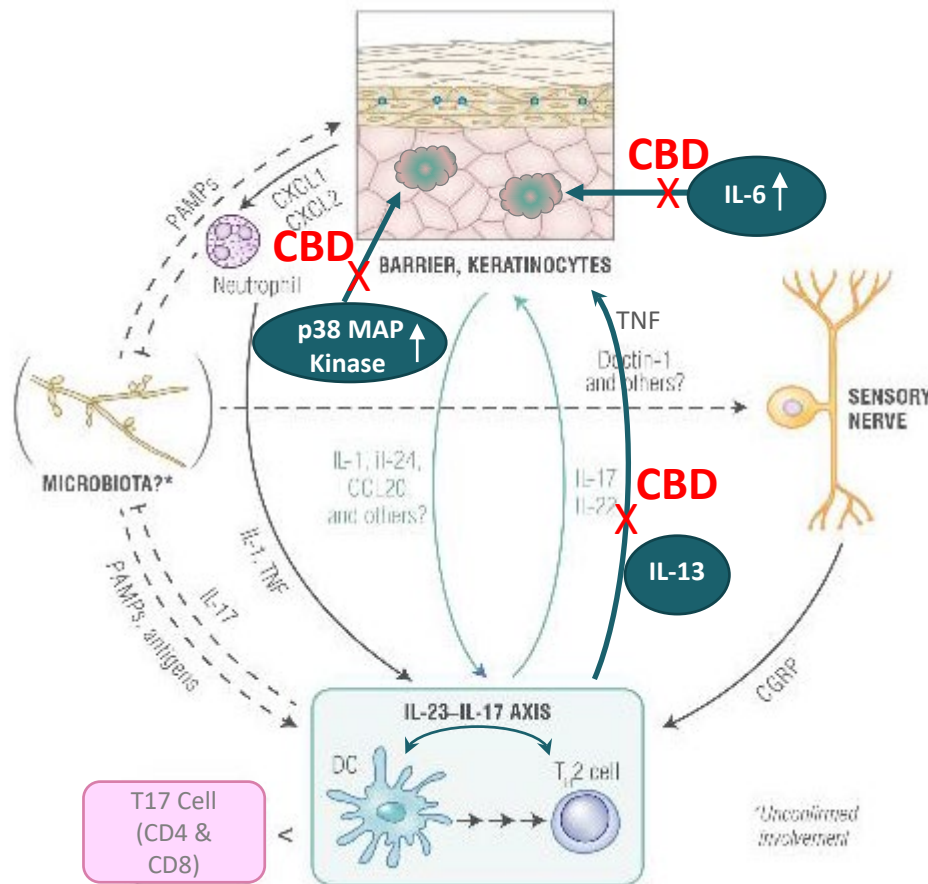
**Anti-inflammatory pathway**  
  
 p38 MAP Kinase  
 Interleukin-6  
**Keratinocytes**

**Immune modulating pathway**  
  
 Interleukin-13  
**Th2 Helper Cells**

Regulated genes were uploaded and mapped algorithmically using the Ingenuity Pathways Knowledge Database to identify target pathways

## Dual mechanism of BTX 1308 has effect on skin barrier function

Both p38 MAP kinase and Interleukin-6 (anti-inflammatory pathways) are positively modulated as well as Interleukin-13 (immune modulating pathway), after less than 3 weeks of treatment









- BTX 1308 has a **direct effect on skin barrier function** (keratinocytes) via IL-6 inhibition and an **indirect effect via inhibition of IL-13**
- **Inhibiting p38 MAP kinase activation interrupts the signaling process** to dendritic cells (DC) and Th2 helper cells (Th2 Cell)
- Systemic P38 MAPK targeting drugs have failed for toxicity – **topical delivery of CBD provides a new and exciting option**



## 2. BTX 1801: first non-resistance forming antibiotic against superbugs

Natural potential of CBD is enhanced by delivery with Permetrex™ technology

Target profile	BTX 1801	Antibiotics
 Kills <i>S. aureus</i> and resistant <i>S. aureus</i> (MSRA - “Superbugs”) <sup>1</sup>	✓	✗
 Shows broad-spectrum Gram-Positive activity <sup>1</sup>	✓	✗
 MRSA bacteria do not develop resistance <sup>1</sup>	✓	✗
 Disrupts bacterial biofilms <sup>1</sup>	✓	✗
 Potential for widespread use across human and animal health <sup>2</sup>	✓	✗
 Broad anti-inflammatory properties relevant to infections <sup>3</sup>	✓	✗

1. Based on University of Queensland testing – BOT data on file

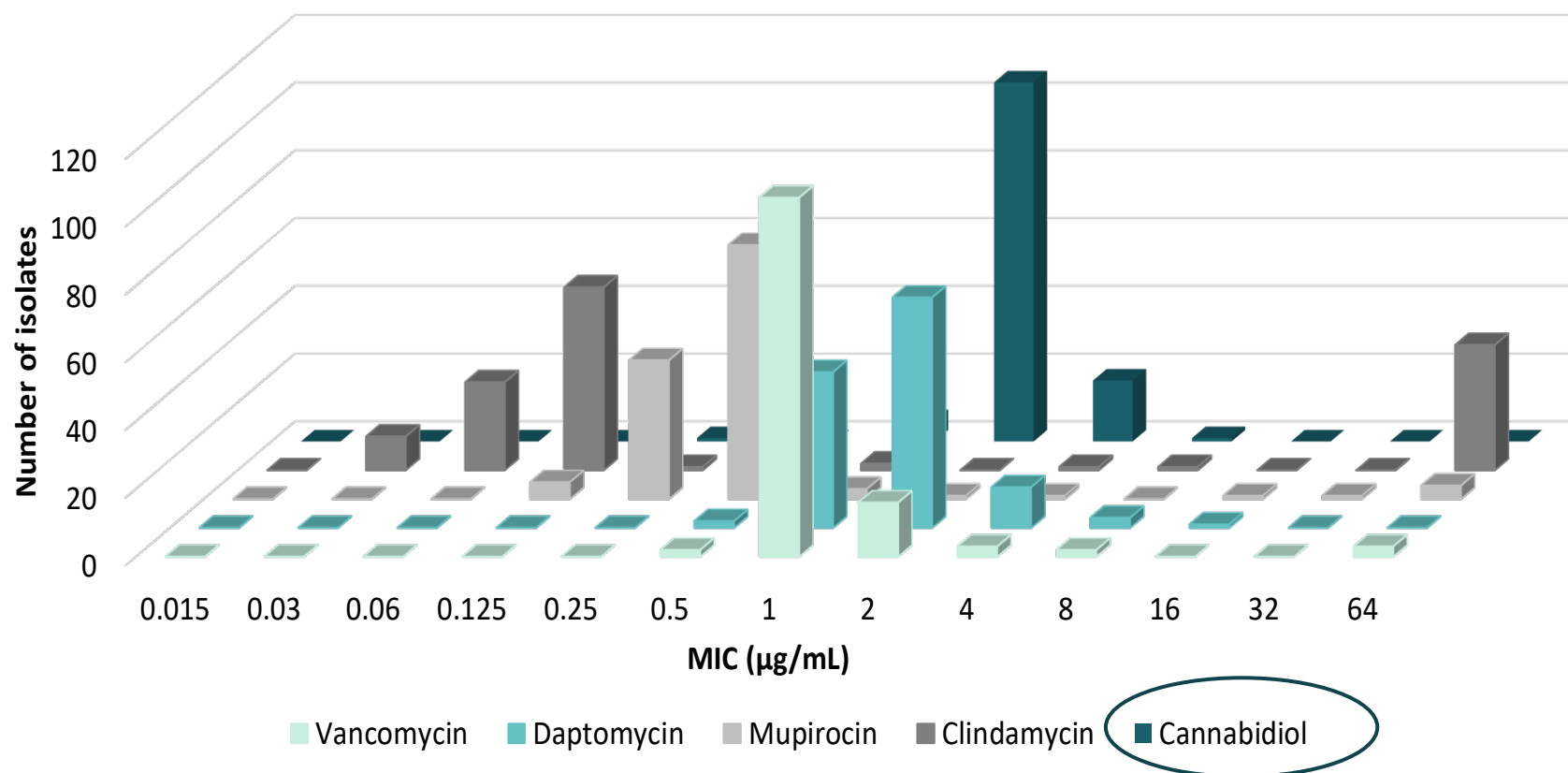
2. Based on mouse infection model – Charles River BOT data on file

3. Based on BTX 1503 Phase 1b clinical data on inflammation – BOT data on file

# BTX 1801 is effective against 132 different Gram-Positive bacteria

Cannabidiol is a powerful new antibiotic that is effective in tests against *Staphylococcus aureus* (“staph”) and *methicillin resistant Staphylococcus aureus* (“MRSA or golden staph”) <sup>1</sup>

## MIC<sub>90</sub> S.aureus 132 isolates

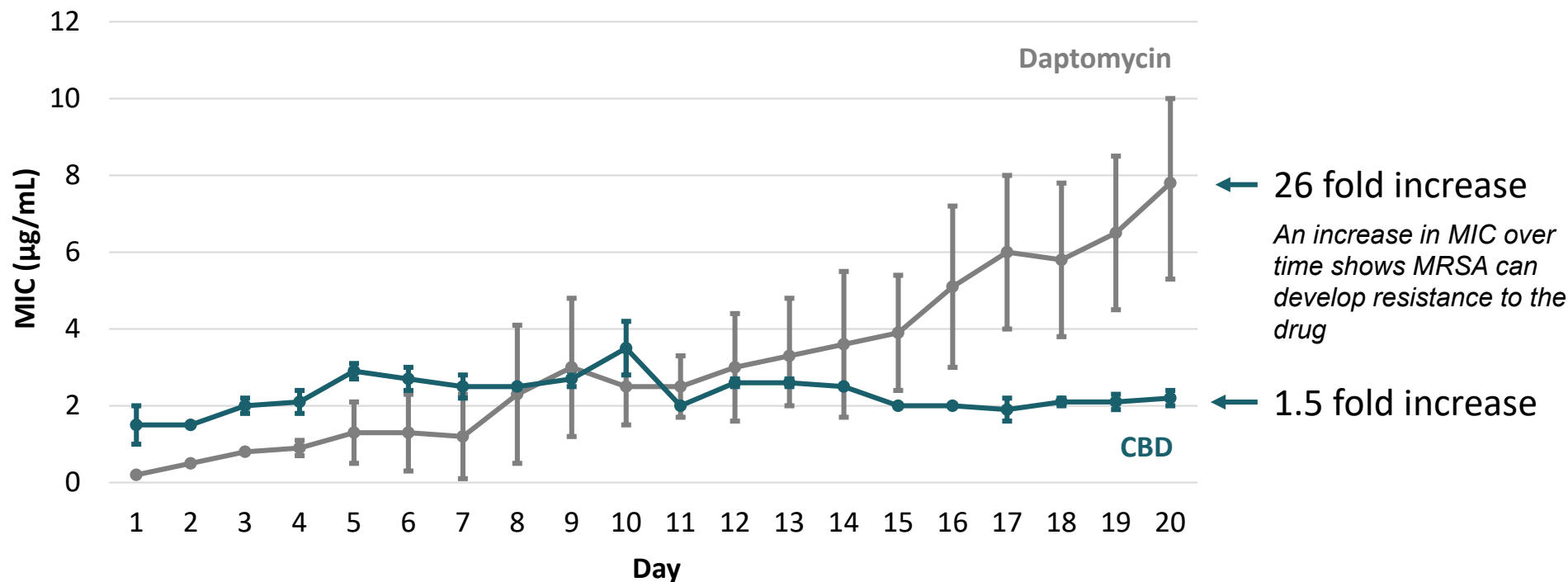


■ Vancomycin   
 ■ Daptomycin   
 ■ Mupirocin   
 ■ Clindamycin   
■ Cannabidiol

# MRSA ('golden staph') bacteria do not form resistance to BTX 1801

If the antibiotic does not kill the bacteria quickly and completely, repeated dosing allows bacteria to mutate and form resistance to the drug

## Antibiotic Minimum Inhibitory Concentration (MIC) daily variability<sup>1</sup>



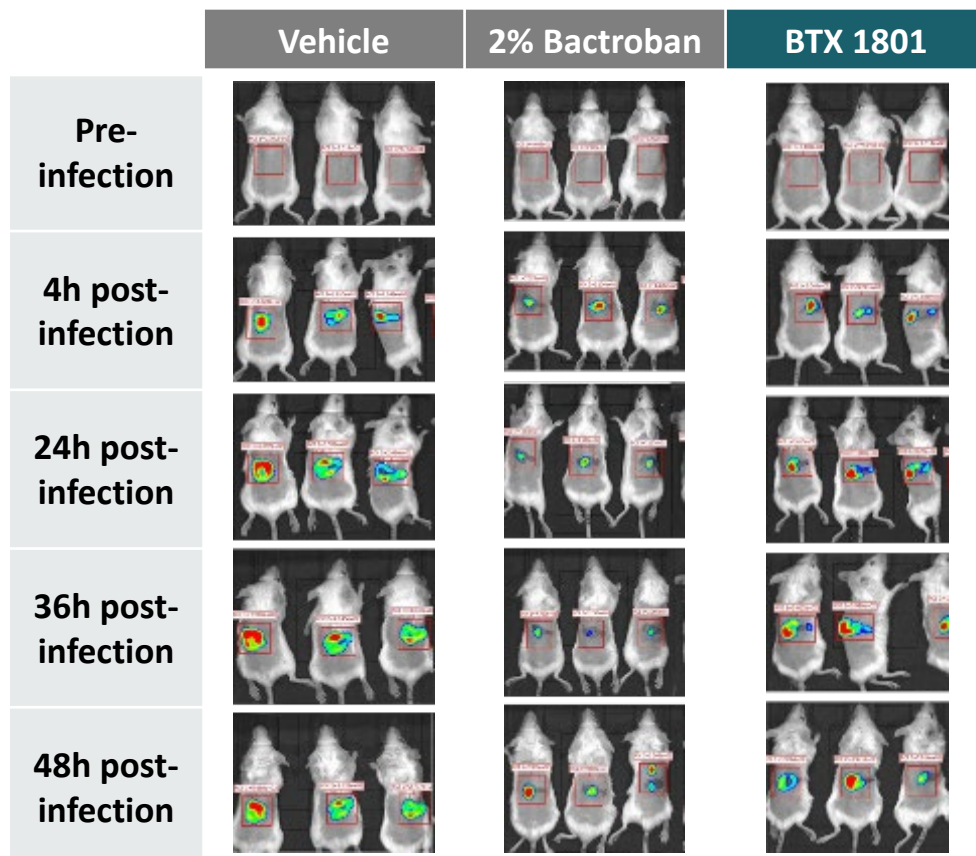
**Dr. Mark Blaskovich** Principal Investigator and Program Coordinator at The University of Queensland's Institute for Molecular Bioscience:  
*"The pipeline of new antibiotics in clinical development is way too small to combat the growing threat of antimicrobial resistance. Most of these agents are really only modifications of existing antibiotics and will not provide long-term solutions to the problem."*

1. Based on average of 8 replicates (University of Queensland – BOT data on file)

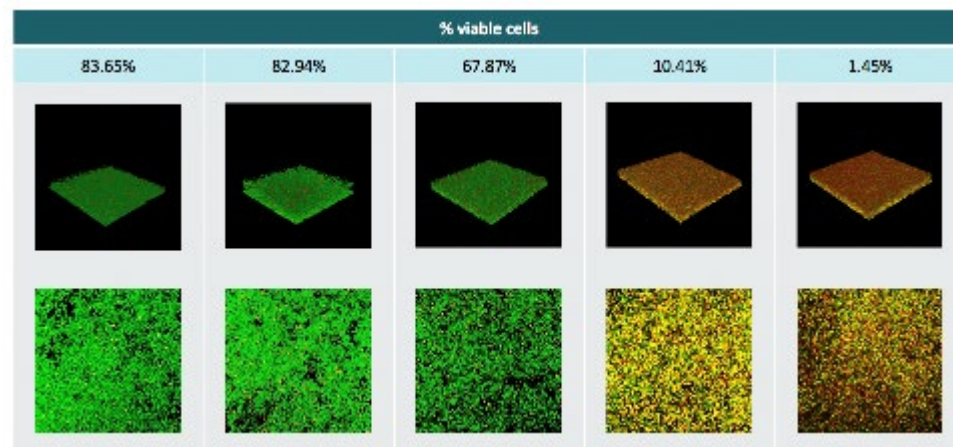
# BTX 1801 animal proof of concept and biofilm tests successful

Not just effective in the laboratory – BTX 1801 shows efficacy in an independently tested animal model and also is effective against biofilms

## In vivo mouse model<sup>1</sup>



## Biofilm model<sup>2</sup>



- Biofilms are the protective barriers that bacteria construct to protect themselves from antibiotics
- BTX 1801 disrupts those biofilms and kills the bacteria quickly

1. Preliminary topical infection model completed with immunocompromised mice (Charles River – BOT data on file)  
 2. Biofilm cell viability model (University of Queensland – BOT data on file)

# Inflammation + bacterial infection are important to most skin diseases<sup>1</sup>

Newly announced data from BTX 1308 and BTX 1801 studies provide scientific support for CBD's mechanism of action, which is highly relevant to both Phase 2 acne and atopic dermatitis studies

## Acne



Relevance	CBD Mechanism of Action	Relevance
✓	Kills relevant bacteria ( <i>P. Acnes</i> and <i>Staph/MRSA</i> ) <sup>2</sup>	✓
✓	Anti-inflammatory effect <sup>3</sup>	✓
	Immune modulating <sup>3</sup>	✓
✓	Skin barrier protectant <sup>3</sup>	✓
✓	Safe and non-irritating <sup>4</sup>	✓

## Atopic dermatitis



**New data helps de-risk Phase 2 studies for BTX 1503 and BTX 1204 and opens up a number of new opportunities in skin disease, antimicrobials and other new diseases**

1. *Dainichi et al 2014 JDS Vol 76 Iss 2 81-86*
2. *Based on BTX1801 data (University of Queensland and Charles River testing) – BOT data on file*
3. *Based on BTX 1308 Phase 1b biopsy data – BOT data on file*
4. *Based on 3 Phase 1b studies for BTX1503, 1204 and 1308 respectively – BOT data on file*

## Late stage clinical programs in Phase 2 studies

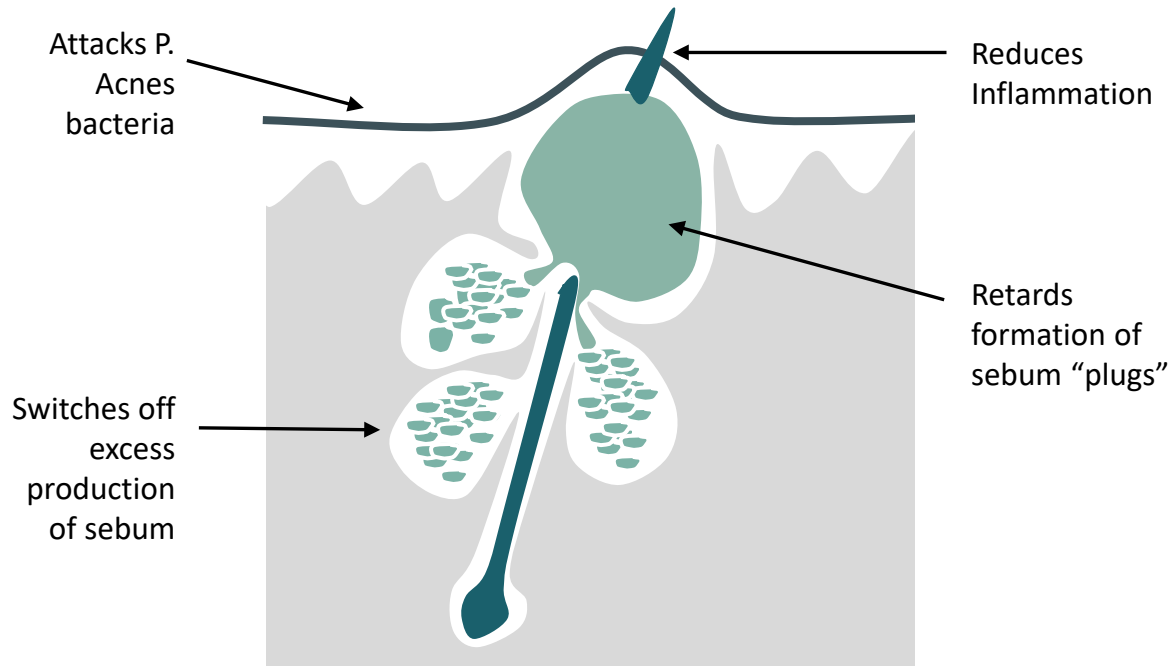
1. BTX 1503: acne
2. BTX 1204: atopic dermatitis



# 1. BTX 1503 – moderate to severe acne

BTX 1503 is a safe and well tolerated topical treatment that potentially addresses all of the 3 causes of acne

**BTX 1503 potentially addresses 3 key acne pathologies <sup>1</sup>**



**CBD has been shown in studies to...**

- 1 **Exert anti-inflammatory effects<sup>2</sup> and to suppress sebocyte proliferation<sup>3</sup>**
- 2 **Have potent anti-microbial activity against gram-positive bacteria<sup>4</sup>**
- 3 **Inhibit human keratinocyte proliferation, through a non CB1/CB2 mediated mechanism<sup>5</sup>**

1. Rocha & Bagatin Acne Vulgaris: an Inflammatory Disease Even Before the Onset of Clinical Lesions (2014). *Inflammation and Allergy – Drug Targets* June 13(3)  
 2. Based on BTX 1308 Phase 1b study and BTX 1503 Phase 1b study – BOT data on file  
 3. Olah et al. *J Clin Invest.* 2014;124(9):3713-3724  
 4. Based on BTX 1801 data – University of Queensland and Charles River – BOT data on file  
 5. Wilkinson & Williamson. *J Derm Sci.* 2007;45:87-92

# Botanix's acne target market share exceeds US\$1.5bn p.a.

Competitive products with less ideal safety profiles and potentially poorer efficacy generate more than US\$1.5bn per annum between them in revenue

## Top oral brands

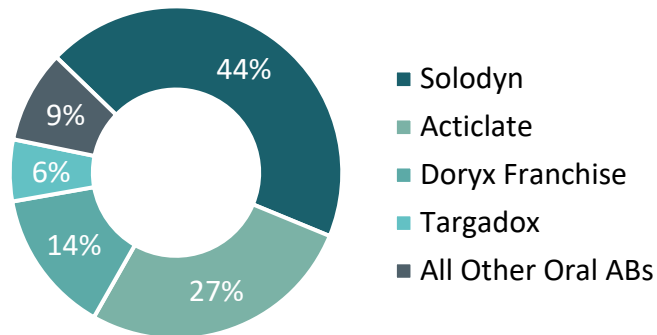
Rank	Brands	Revenue (US\$m) <sup>1</sup>	Scripts ('000)
1	<b>SOLODYN</b> Minocycline, Valeant	\$492	434
2	<b>ACTICLATE</b> Doxycycline, Almirall	\$234	261
3	<b>DORYX FRANCHISE</b> Doxycycline, Mayne	\$65	132
4	<b>TARGADOX</b> Doxycycline, Journey	\$40	63

## Top topical brands

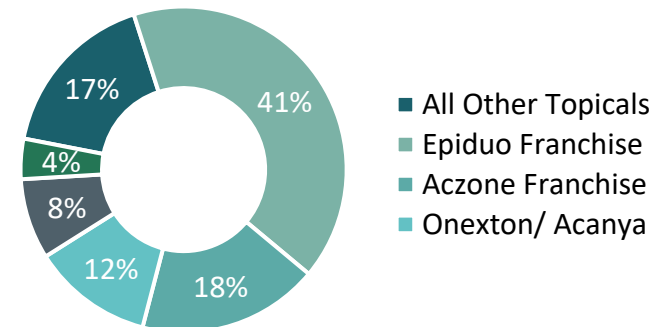
Rank	Brands	Revenue (US\$m) <sup>1</sup>	Scripts ('000)
1	<b>EPIDUO FRANCHISE</b> Adapalene+BPO, Galderma	\$659	1,431
2	<b>ACZONE FRANCHISE</b> Dapson, Allergan	\$298	625
3	<b>RETIN-A FRANCHISE</b> Tretinoin, Valeant	\$219	304
4	<b>ONEXTON/ACANYA</b> Clindamycin+BPO, Valeant	\$200	410

Target  
market  
share

## Prescription market share oral brands<sup>2</sup>



## Prescription market share topical brands<sup>2</sup>



Source: Symphony Health Solutions PHAST (accessed 1.2018)

1. US \$ represent SHS metric (TRx MBS) or dollarized prescriptions

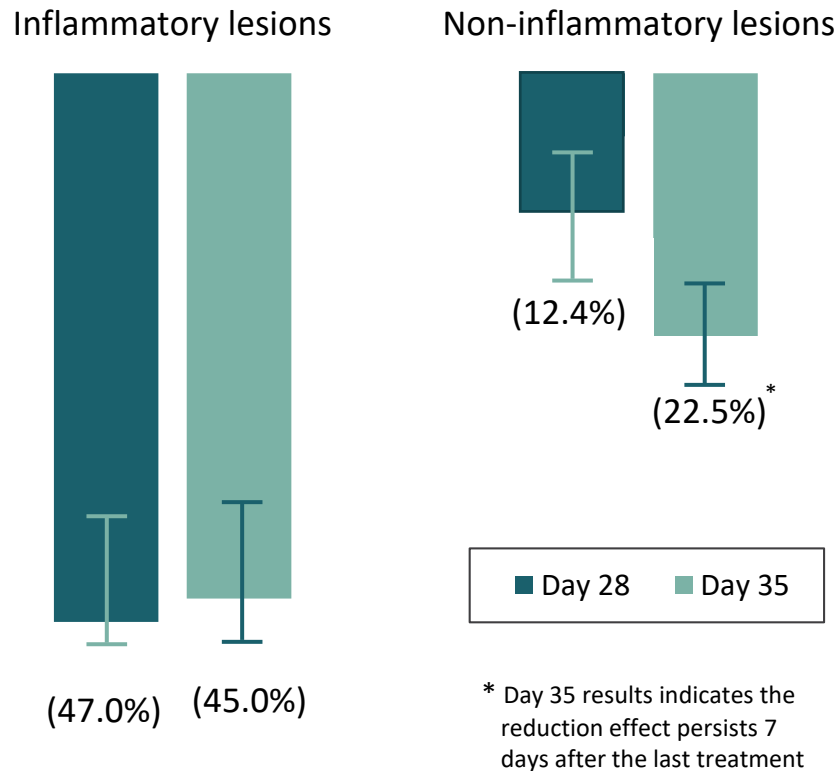
2. Market shares of the oral branded prescription acne drug market and the topical branded prescription acne drug market according to the total number of prescriptions.





# Phase 1b patient data for BTX 1503 (acne)

4 week Phase 1b study data shows a marked reduction in inflammatory lesions and no serious adverse events

## Lesion count reduction (%)<sup>1</sup>



## Other FDA approved products<sup>2</sup>

Product	Owner	Lesion count reduction (%) <sup>3</sup>	2017 annual revenue <sup>4</sup>
 Epiduo <sup>®</sup>	Galderma	~42%	US\$659m
	<ul style="list-style-type: none"> <li>✓ Combination of two drugs – benzoyl peroxide and adapalene</li> <li>✗ Common side effects include redness, skin peeling mild burning / stinging and dryness</li> </ul>		
 Aczone <sup>®</sup>	Allergan	~38%	US\$298m
	<ul style="list-style-type: none"> <li>✓ Few side effects</li> <li>✗ Studies showed large placebo / vehicle effect – i.e. at 12 weeks Aczone reduced inflammatory lesions by 54% while vehicle achieved 48% reduction</li> </ul>		
BTX 1503	Botanix	~47%	-

1. Botanix BTX.2017.002 trial - Botanix data on file

2. Botanix BTX.2017.002 trial with reported 4 week data from Epiduo and Aczone as published Am J Clin Dermatol (2016) 17: 293-303 and Journal of Drugs in Dermatology (2016) Vol 15 Issue 8 P 962.

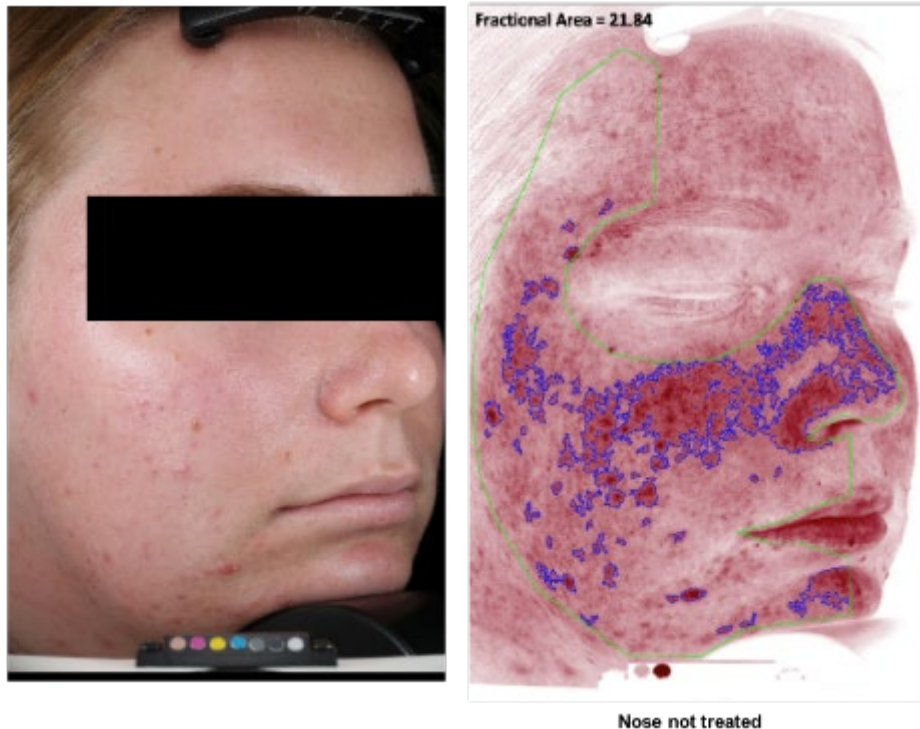
3. Lesion count reduction based on average inflammatory lesion reduction at 4 weeks

4. Symphony Health solutions PHAST 2018

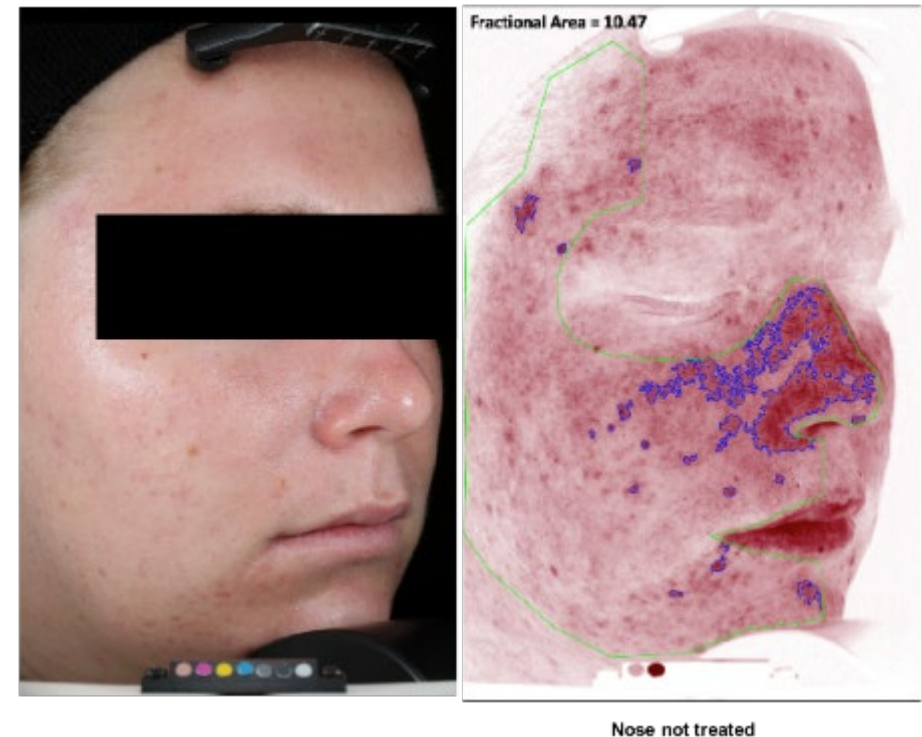
## BTX 1503 (acne) - anti-inflammatory effects of CBD

Canfield RBX® images from the Phase 1b acne patient study, demonstrate a clear anti-inflammatory effect over the 4 week treatment course<sup>1</sup>

**Baseline (day 1)**



**Visit 4 (4 weeks)**



1. Botanix Pharmaceuticals data on file – VISIA Complexion Analysis System – Canfield Imaging Systems

## BTX 1503: acne – Phase 2 study well advanced

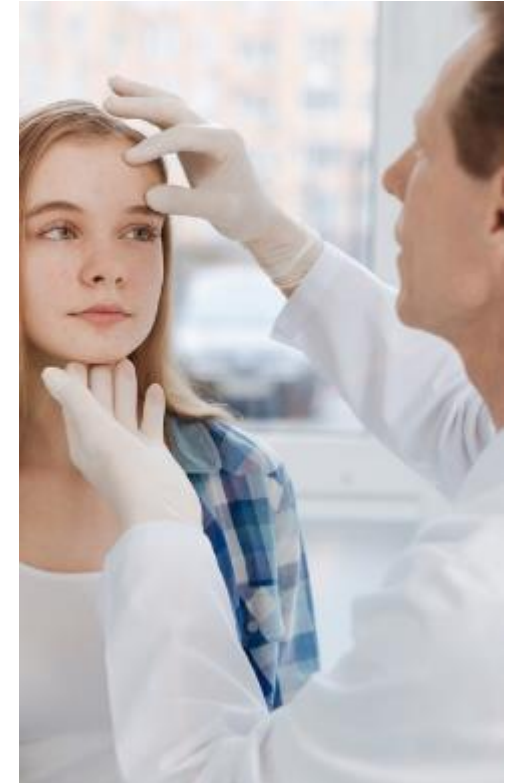
12-week randomised, double-blind, vehicle controlled study to evaluate the safety and efficacy of BTX 1503 in patients with moderate to severe acne

### Design

- 5 dose groups: ~360 subjects
  - High Dose twice a day: ~90 subjects
  - High Dose once a day: ~90 subjects
  - Low Dose once a day: ~90 subjects
  - Vehicle/Control: ~90 subjects
- ~28 US and Australian dermatology sites
- Children (> 12 years) and adults
- Moderate to severe acne patients
- Treatment Period 12 weeks

### Endpoints

- Primary endpoints:
  - Absolute change from Baseline to Week 12 in inflammatory lesions
- Secondary endpoints:
  - Absolute change from Baseline to Week 12 in non-inflammatory lesions
  - % change from Baseline to Week 12 in inflammatory and non-inflammatory lesions
  - Proportion of patients with at least 2 grade reduction from Baseline IGA at week 12
- Safety
  - Adverse events and local tolerability



✓ Study completion 3Q CY2019

# BTX 1503 Phase 2 patient study schedule

Recruitment is complete with final subjects completing in-life phase of study in Q3 2019

- No serious adverse events issues arising from treated patients to date
- Positive feedback from dermatologists on study

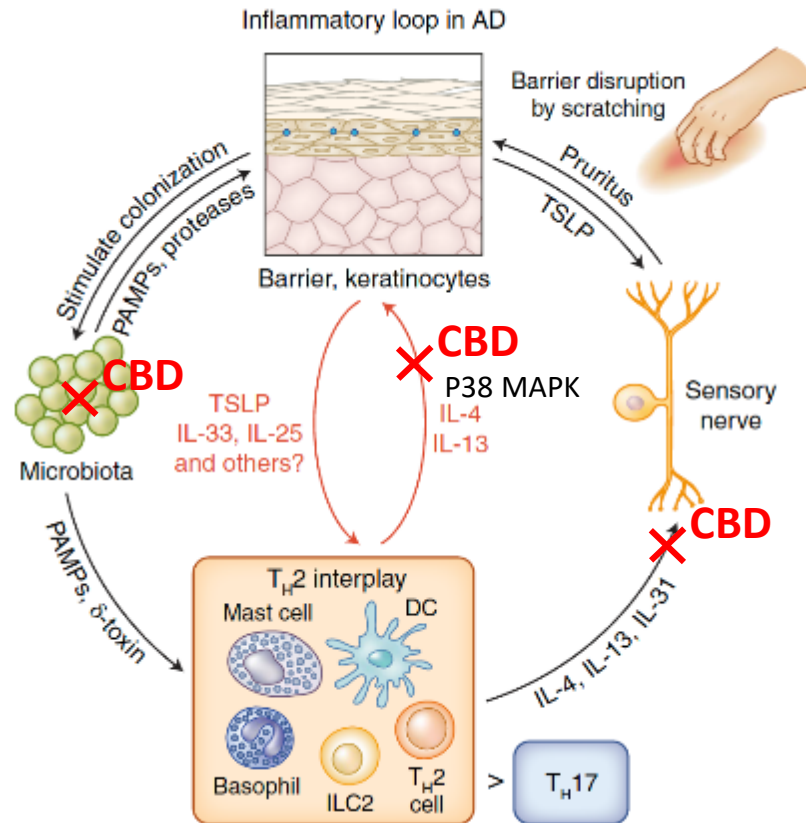


## BTX 1503 indicative clinical timeline (CY)



## 2. BTX 1204: moderate atopic dermatitis

New data from BTX 1308 mechanism of action study and BTX 1801 antimicrobial studies provides support for CBD's anti-inflammatory, antimicrobial and potential skin barrier preservation activities



- ✓ CBD inhibits P38 MAPK activation which interrupts the signaling process to dendritic cells (DC) and Th2 helper cells (Th2 Cell)<sup>1,2</sup>
- ✓ CBD inhibits **Th17 responses (IL17)**, anti-inflammatory effect (*in vitro* model of IL-17A-induced mucosal inflammation using human cells<sup>3, 4</sup>)
- ✓ CBD attenuates **Th2 responses (IL-13)**, anti-inflammatory effect (in psoriasis and mouse models of AD<sup>1,4,5</sup>)
- ✓ CBD reduces *S. aureus* colonization and infection responsible for triggering skin inflammation<sup>1,6</sup>

1. BTX 1308 Phase 1b clinical study – BOT data on file
2. Tan et al Mol Med Rep 2017;16((6) 8883-8867
3. Harvey et al. Cytokine. 2014;65:236-244
4. Kaplan et al. Biochem Pharmacol. 2008;76(6):726-737
5. Kim et al. Int J Derm. 2015;54:e410-e408
6. Leung DYM Acta Derm Venereol 2008; Suppl 216: 21–27

# Atopic dermatitis market projected to be ~\$25B in 2027

BTX 1204 addresses the need for a safe, non steroid topical option for chronic use with multiple mechanisms of action including anti-inflammatory, anti-microbial and immune modulating

## One of the most common skin diseases <sup>1</sup>

- 2% - 3% of adults, 25% of children
- 85% of patients are moderate to severe<sup>3</sup>

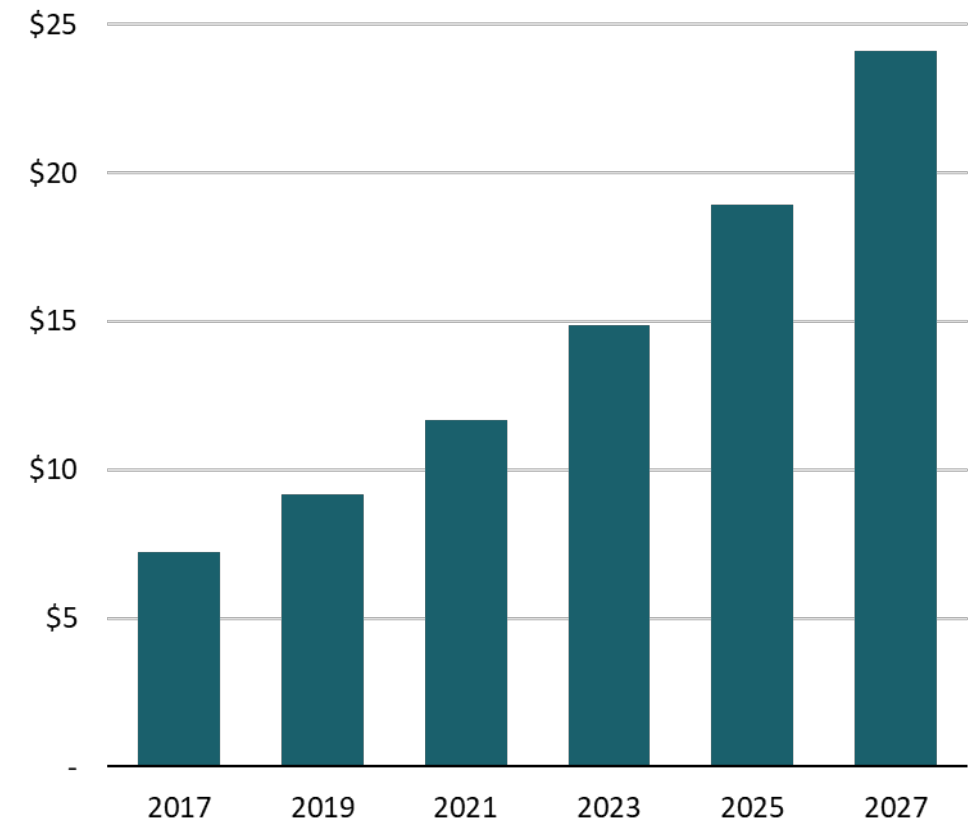
## Large unmet needs across the atopic dermatitis population <sup>2</sup>

- No safe and effective non-steroidal option for chronic use
- Biologics address only the severe population

## Pediatric population particularly has a need for a steroid free alternative <sup>1</sup>

- Safety concerns with steroids are high
- Topical Calcineurin Inhibitors (Protopic/Elidel) have a boxed warning
- Current non-steroidal options have been reported to have tolerability concerns

## Projected atopic dermatitis market by revenue (US\$bn)<sup>4</sup>

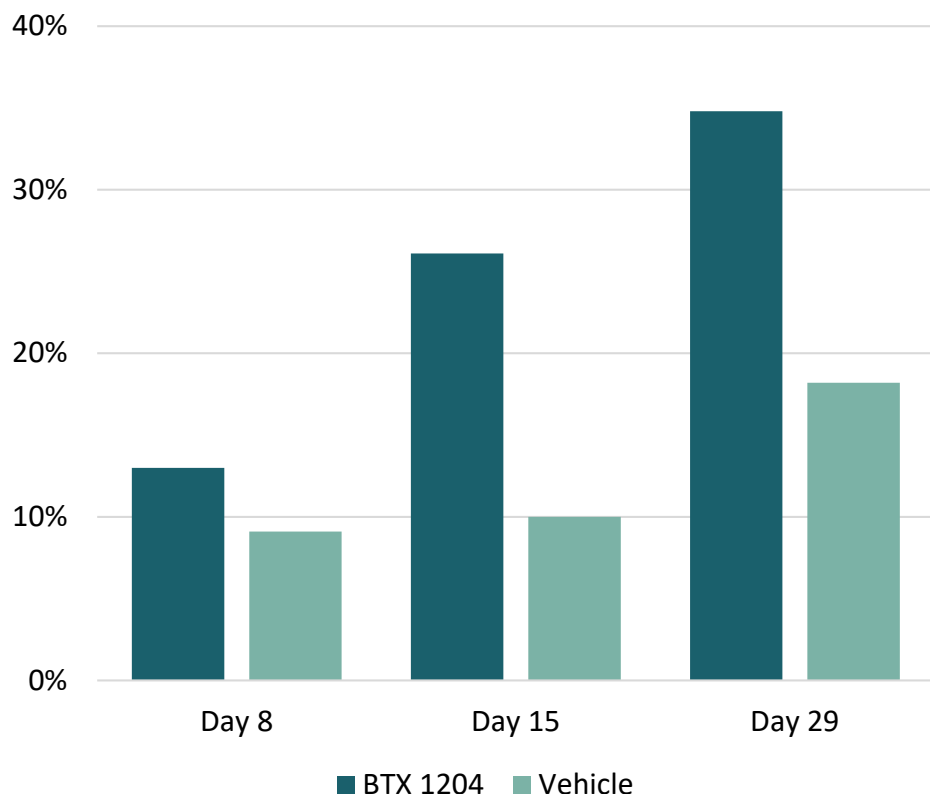


1. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al Guidelines of care for the management of atopic dermatitis, Section 1 diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol* 2014 Feb; 70(2):338-51.  
 2. Global Data. Pharmapoint Atopic Dermatitis Nov 2015.  
 3. Sanofi and Regneron Pharma. Dupixent (dupilumab) injection 300mg. Full Prescribing Information. Jan 2019.  
 4. Symphony Health Services (PHAST) 2017

# Phase 1b study results support efficacy and safety potential

BTX 1204 was twice as effective as vehicle (with efficacy still increasing) and displayed a substantial improvement in the key signs of atopic dermatitis<sup>1</sup>

## Treatment success (%)<sup>2</sup>



### Efficacy still increasing at 4 week timepoint

- Achieved treatment success similar to many competitive topical products
- Data suggests longer treatment period for BTX 1204 possible for increased efficacy

### Clear separation from vehicle (placebo)

- Despite being a small study, BTX 1204 shows superiority over vehicle, starting at early time points

### Excellent safety profile

- Safety and tolerability established with no burning, stinging or application site adverse events
- BTX 1204 profile may allow extended dosing which remains a key challenge with most available therapies

1. Botanix data on file. Results indicated substantial reduction in key signs of AD, providing confidence that unmet needs in AD can be addressed

2. Treatment success defined as a greater than, or equal to, a 4 point improvement in the signs and symptoms of AD

## BTX 1204: atopic dermatitis – Phase 2 study underway

12 week randomised, double-blind, vehicle controlled study to evaluate the safety and efficacy of BTX 1204 in patients with moderate atopic dermatitis (AD)

### Design

- 2 dose groups: ~200 subjects
  - BTX 1204: ~100 subjects
  - Vehicle/Control: ~100 subjects
- ~25 US and Australian dermatology sites
- Children (> 12 years) and adults
- Moderate AD patients
- Treatment period of 12 weeks

### Endpoints

- **Primary endpoint**
  - Proportion of subjects with ISGA success defined as an ISGA score of “Clear” (0) or “Almost Clear” (1) with at least a 2 grade improvement from Baseline at Week 12
- **Secondary endpoints**
  - Change from Baseline in the Signs of AD
  - % body surface area (BSA) affected by AD
  - Time to achieve IGA success
- **Safety**
  - Adverse events and local tolerability



✓ Study completion 4Q CY2019

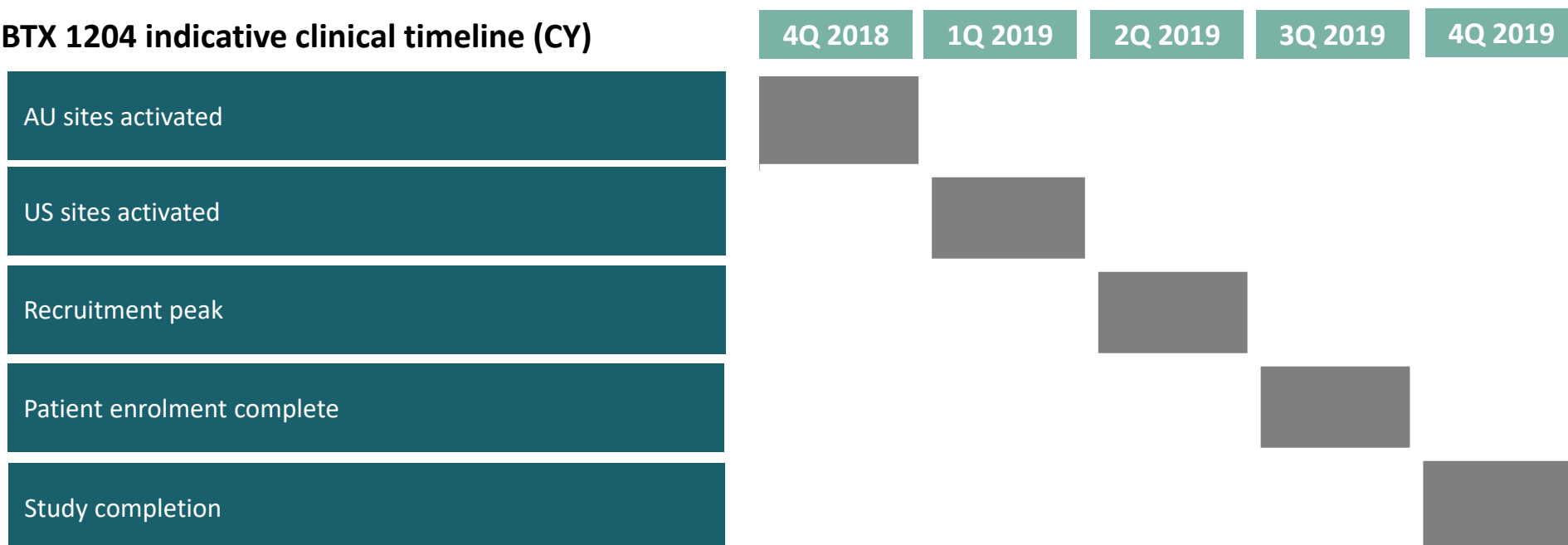


# BTX 1204: atopic dermatitis – Phase 2 study rapidly advancing

Randomised, vehicle controlled study in 200 moderate patients

- Program leverages existing data from BTX 1503 acne studies, lowering regulatory and safety hurdles
- Common DEA licensed dermatology clinics from BTX 1503 acne Phase 2 study, reduces cost and start-up timing

## BTX 1204 indicative clinical timeline (CY)



# Phase 1b clinical and MOA studies provide solid foundation

Clinical and safety data, as well as new mechanism of action (MOA) data from Botanix studies provide support to near term completion of Phase 2 studies in acne and atopic dermatitis

Product candidate	Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Status
Synthetic CBD with Permetrex™ technology	<b>BTX 1503</b>	Moderate to severe acne	✓	✓	✓	Completion pending 3Q 2019
	<b>BTX 1204</b>	Moderate atopic dermatitis	✓	✓	✓	Completion pending 4Q 2019
	<b>BTX 1308</b>	Psoriasis	✓	✓	✓	Successful data 2Q 2019
	<b>BTX 1801</b>	Antimicrobial skin infections	✓			Successful data 2Q 2019
Permetrex™ programs	External	Various				Ongoing collaborations with partners

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