ASX/Media Release

21 November 2019

Botanix presents at Dermatology Drug Development Summit

Key highlights

- Botanix presented at the Dermatology Drug Development Summit in Boston, USA
- Botanix shared the podium with other leading dermatology and pharmaceutical companies including speakers from LEO Pharma, Galderma, Dermavant Sciences and Sanofi
- The summit provided an opportunity to showcase Botanix's expanding dermatology pipeline and its accelerated approach to clinical development and commercialisation

Philadelphia PA and Sydney Australia, 21 November 2019: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce that Dr Bill Bosch, Executive Director and Chief Scientific Officer, presented at the 3rd Annual Dermatology Drug Development Summit held in Boston, MA, USA. The presentation titled *Topical Formulations of Cannabidiol for the Treatment of Skin Diseases* is attached to this release.

The Dermatology Drug Development Summit brings together more than 150 dermatology industry leaders globally from more than 50 leading organisations. The summit provides a valuable opportunity for dermatology professionals and leading industry stakeholders to share latest ideas and pioneering insights. The summit is a unique industry-focused forum dedicated to innovating, accelerating and sharing pharmaceutical best practice on the development and commercialisation of new dermatological drugs in the treatment of high unmet needs.

Botanix shared the podium with LEO Pharma, Galderma, Dermavant Sciences, Sanofi and other leading pharmaceutical and biotechnology executives, academic researchers and industry experts. Botanix's presentation highlighted its novel approach to maximising drug delivery through its proprietary drug delivery technology, Permetrex™. The Company also took the opportunity to provide an update on its clinical development pipeline.

Dr Bill Bosch, Executive Director and Chief Scientific Officer, commented: "The annual Dermatology Drug Development Summit provided us a great opportunity to showcase Botanix's unique approach for the treatment of serious skin diseases including acne and atopic dermatitis. It is well understood by the broader industry, that there is a significant unmet medical need for each of the indications that Botanix is targeting. Lastly, the clean safety profile of cannabidiol, combined with the anti-inflammatory, immune-modulating and antimicrobial properties represents an exciting opportunity to improve patient outcomes."

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage synthetic 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 serious skin diseases, leveraging the unique anti-inflammatory, immune modulating and antimicrobial properties of synthetic cannabidiol. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases.

The Company has announced data from its Phase 2 acne patient study and is moving forward with its clinical program with a Phase 2 FDA meeting. A Phase 2 patient study in atopic dermatitis is on target to complete enrolment in 4Q CY2019 with data in 1Q CY2020. The Company has successfully completed a mechanism of action study for synthetic cannabidiol in skin disease, with positive data announced in June 2019 and is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabidiol, with first products planned to enter the clinic in 2H CY2019.

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

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Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate, "expect," "intend," "may," "plan," "predict," "project," "target, "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Topical Formulations of Cannabidiol for the Treatment of Skin Diseases

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www.botanixpharma.com

World class team

Global team with proven experience and an unrivalled track record

Vince Ippolito

President and Executive Chairman

- COO of Anacor and Medicis with 17 years at Novartis
- More than 30 years experience in pharma with 20+ years within dermatology

Dr Michael Thurn

COO and Board Director

Operations + Regulatory

- Extensive start up life sciences experience in dermatology
- Previous MD of Spinifex Pharmaceutical, which sold to Novartis for A$700m

Howie McKibbon

Chief Commercial Officer

- SVP of Commercial at Anacor and Medicis
- More than 20 years dermatology and pharma commercial experience

Matt Callahan

Founder and Consultant

- Developed 4 products through FDA approval and launch
- Serial founder and ex-investment director of 2 venture capital firms in life sciences

Dr Stephane Levy

Chief Medical Officer

Medical + Clinical

- Ex-CMO of Almirall US operations and VP Clinical with Sanofi and Novartis
- Broad commercial and clinical development experience

Ric Peterson

Chief Financial Officer

US Finance + Corporate

- CFO of Sienna, Novan and Medicis
- Unrivalled dermatology commercial experience across multiple companies for more than 30 years

Jack Lawler

VP Development

Development + Clinical

- 20 years clinical trial and development experience
- Most recently VP at Egalet Corporation and Director at Viropharma (Shire)

Dr Joyce Rico

Strategic Advisor

Medical, Research & Development

- Recent CMO for Novan Pharmaceuticals
- Prior experience as a Board Member for the Society of Investigative Dermatology, VP, Medical Affairs at Astellas and dermatology faculty at Duke, NYU and Northwestern

Dr Judith Plon

VP Regulatory Affairs

Regulatory

- 30 years regulatory experience with multiple FDA approved dermatology products
- Ex-AVP Global Regulatory Affairs at Sanofi

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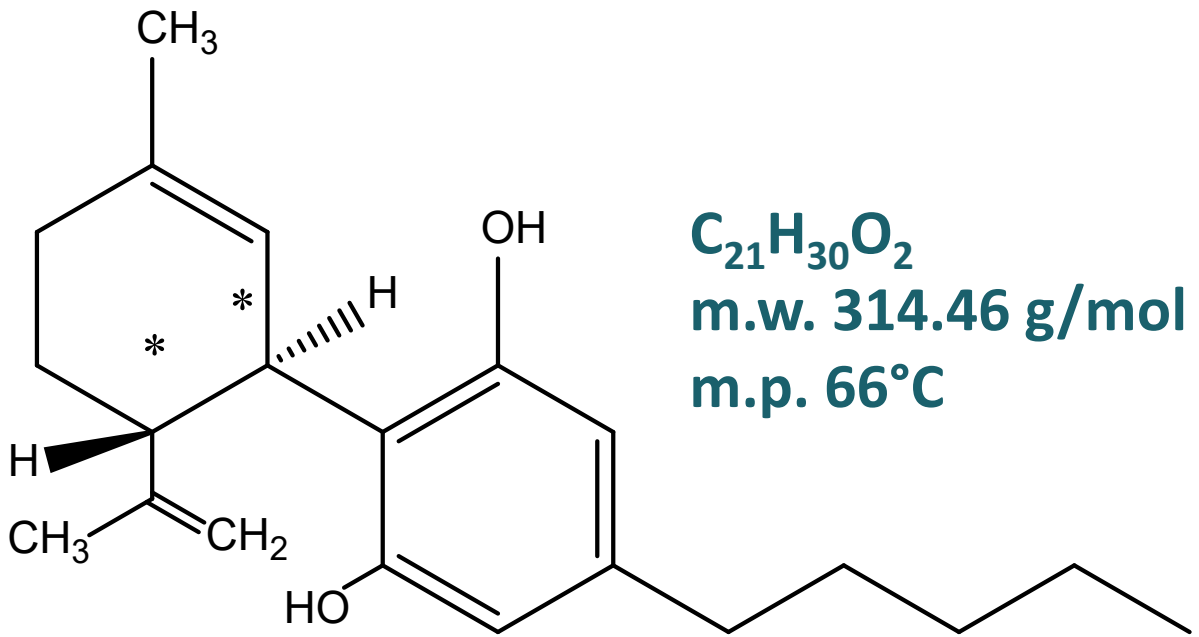
Cannabidiol (CBD)

2-[(1R,6R)-6-Isopropenyl-3-methylcyclohex-2-en-1-yl]- 5-pentylbenzene-1,3-diol



$C_{21}H_{30}O_2$
m.w. 314.46 g/mol
m.p. 66°C

Botanix products in development use only synthetic, high purity material

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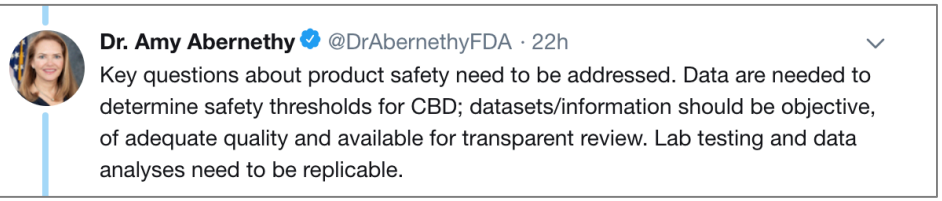
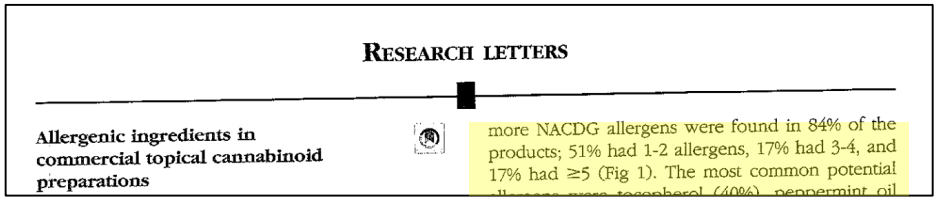
Over-the-counter CBD products are not what they seem

Over-the-counter (OTC) or internet purchased CBD products often contain a fraction of labelled CBD content, are not currently regulated and may come with other quality and allergenic risks[1]

Product name	Manufacturer	Product type	Label claim CBD content (mg/tube)	Tested CBD content
OTC 1	Green Roads	Cream	300	24.5
OTC 2	Medix CBD	Cream	150	11.2
OTC 3	Highland Pharms	Cream	200	24.6
OTC 4	MGC Derma	Cream	Undisclosed	8.8
OTC 5	CBDMEDIC	Ointment	Undisclosed	14.9



Dr Amy Abernethey Principal Deputy Commissioner and Acting CIO – FDA[2]



J Am Acad Dermatol Sep 2019 Pp 847-848

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 labelled 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*

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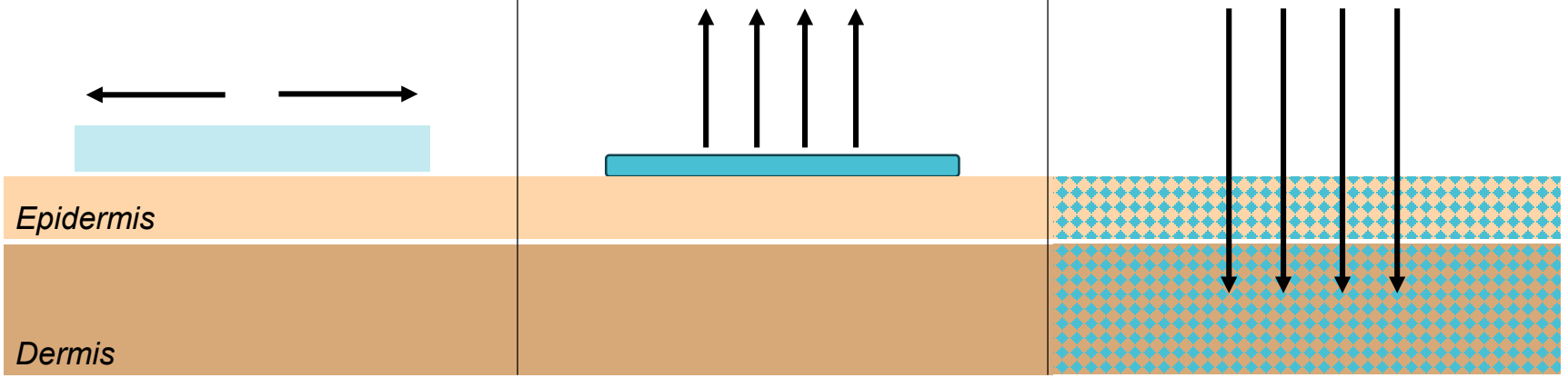
Permetrex™ is a proprietary novel skin delivery technology

Enables formulation of innovative topical products[1] that deliver very high doses of drug into the layers of skin without using permeation enhancers, preservatives or irritating levels of alcohol / petrol derivatives

Concentration gradient effect

Initial application	Evaporation of solvent	Delivery into the skin
CBD drug is encapsulated in Permetrex™ formulation which spreads easily over skin surface	Volatile parts of the formulation evaporate - leaving a highly concentrated solution on skin surface	The rapid change in concentration of the drug as a result of evaporation, drives CBD into the skin



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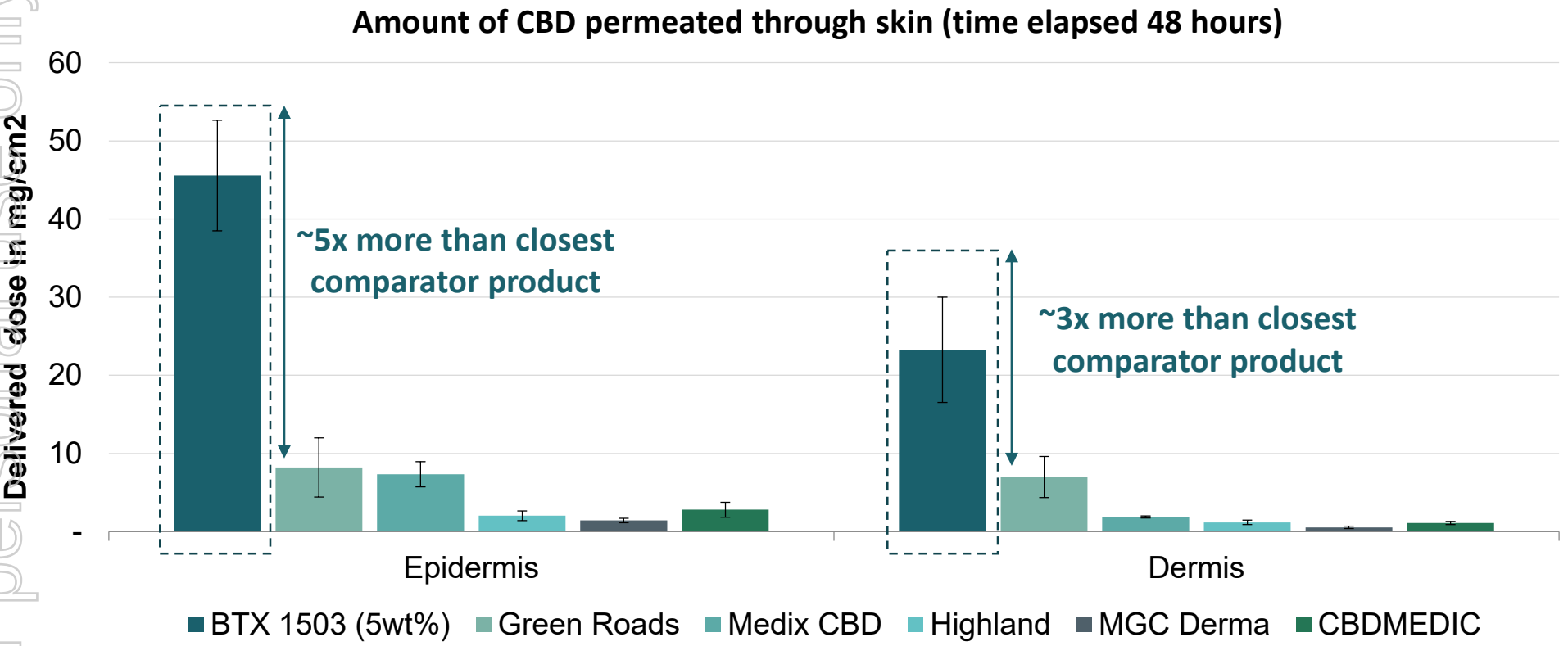
1. Topical dosage forms include: solutions, creams, gels, ointments, foams or pastes

Independent comparative analysis of CBD delivered[1]

Data indicate that BTX 1503 significantly outperformed the other CBD topical products in delivering drug to targeted layers of the skin (*ex-vivo* model)[1]



Relative to the closest comparator, BTX 1503 delivers >5 times as much CBD to the epidermis and >3 times as much CBD to the dermis **- significantly more than other 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 Tioga Research. Botanix data on file.

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Advanced dermatology pipeline with recent successful data readouts

Combination of clinical, safety and mechanism of action data from recent Botanix studies provide support to near term completion of Phase 2 atopic dermatitis study

Synthetic CBD with Permetrex™ topical technology

Product	Indication	Ph 1	Ph 1b	Ph 2	Ph 3	Status
BTX 1503 Gel	Moderate to severe acne					Preparing for FDA end of Phase 2 meeting
BTX 1204 Solution	Moderate atopic dermatitis					Study data 1Q CY2020
BTX 1702 Solution	Rosacea					Study start 4Q CY2019
BTX 1801 Gel	Antimicrobial					Successful MOA[1] study
BTX 1308 Ointment	Psoriasis					Successful MOA[1] study

1. MOA: Mechanism of Action

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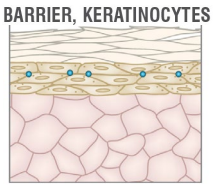
Topical CBD is a well suited to treat skin disease

Botanix has generated strong scientific support for synthetic CBD's anti-inflammatory and immune modulation mechanisms of actions, combined with newly identified antimicrobial effects

CBD anti-inflammatory / immune modulating effects

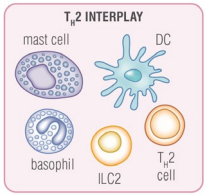
CBD inhibits a key cytokine which affects skin barrier disfunction

IL-6 → CBD ✗



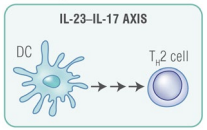
CBD attenuates a well-known cytokine which drives the inflammatory response

IL-13 → CBD ✗



CBD inhibits a pathway which disrupts the signaling driving the body's immune response

P38 MAPK → CBD ✗

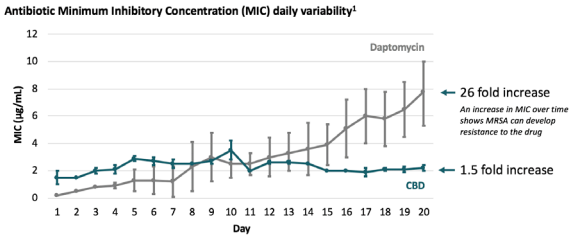


CBD antimicrobial effects

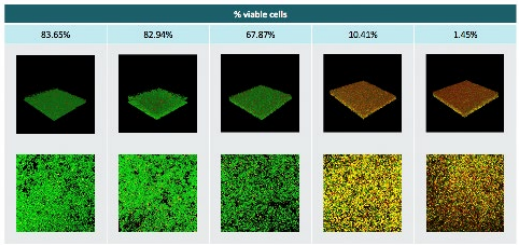
CBD is active against all tested gram +ve bacteria

Antibiotic	*S. aureus* all isolates (µg/mL)			MRSA[1] (µg/mL)		MSSA[2] (µg/mL)	
	MIC_{50}	MIC_{50}	Range	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}
Cannabidiol	2	4	0.25 - 8	2	2	2	4
Mupirocin	0.5	0.5	0.125 – 64	0.5	0.5	0.5	0.5
Vancomycin	1	2	0.5 – 64	1	1	1	2
Daptomycin	2	4	0.5 – 16	2	2	2	4
Clindamycin	0.125	64	0.03 - 64	0.125	0.1875	0.125	64

Bacteria cannot form resistance to CBD's rapid killing power



CBD disrupts the bacteria's biofilm protective cover



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BTX 1503: CBD mechanism of action – supported by data

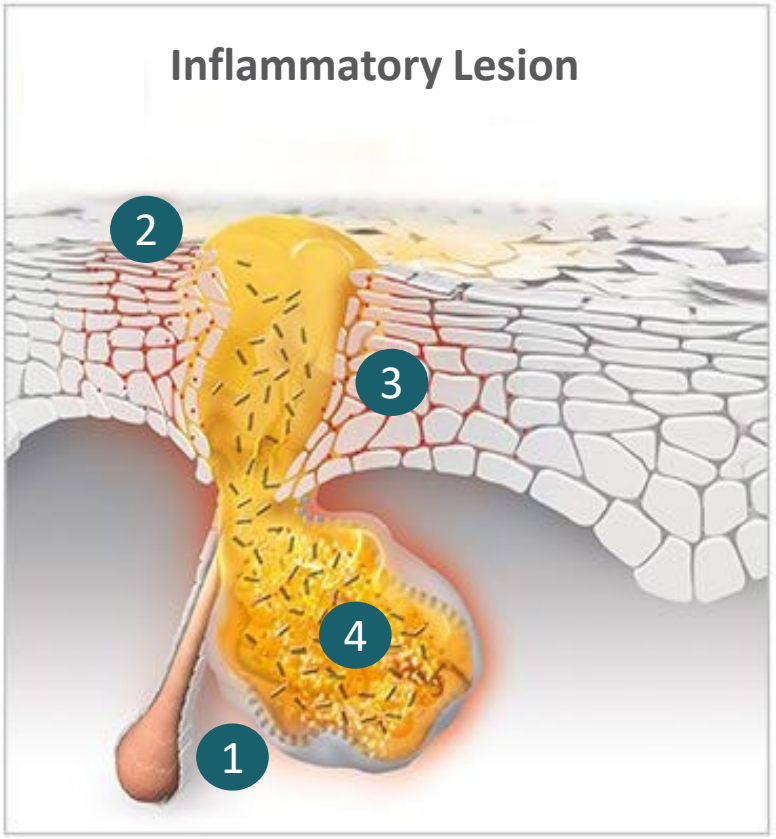
BTX 1503 is a safe and well tolerated topical acne treatment that potentially addresses all the key causes of acne

1 CBD normalises sebum production

- Inhibits lipogenesis and sebocyte proliferation in response to "pro-acne" agents (androgens)[1]

2 CBD inhibits keratinocyte hyperproliferation

- Antiproliferative effects mediate through PPAR agonism[2]



3 CBD exerts a broad anti-inflammatory effect

- Inhibits *P. acnes*[3] induced p38 MAP Kinase-dependent inflammatory responses in keratinocytes[4,5]
- Inhibits *P. acnes* induced inflammation mediated by proinflammatory cytokines TNFα, IL-1, IL-6, IL-8, and IL-12[4,6]

4 CBD is a potent Gram-positive antibiotic

- Potent bactericidal activity against clinical isolates and antibiotic resistant strains of *P. acnes*[7]

1. *Olah et al. J Clin Invest. 2014:124(9):3713-3724*
2. *Wilkinson & Williamson. J Derm Sci. 2007;45:87-92*
3. *Recently renamed Cutibacterium acnes*
4. *Based on BTX 1308 Phase 1b study and BTX 1503 Phase 1b study – BOT data on file*
5. *Li, Wen-Hwa et al. Dermatology and therapy vol. 5,1 2015: 53-66*
6. *Petrosino et al. J Pharmacol Exp Ther. 2018 Jun;365(3):652-663*
7. *Based on University of Queensland testing – BOT data on file*

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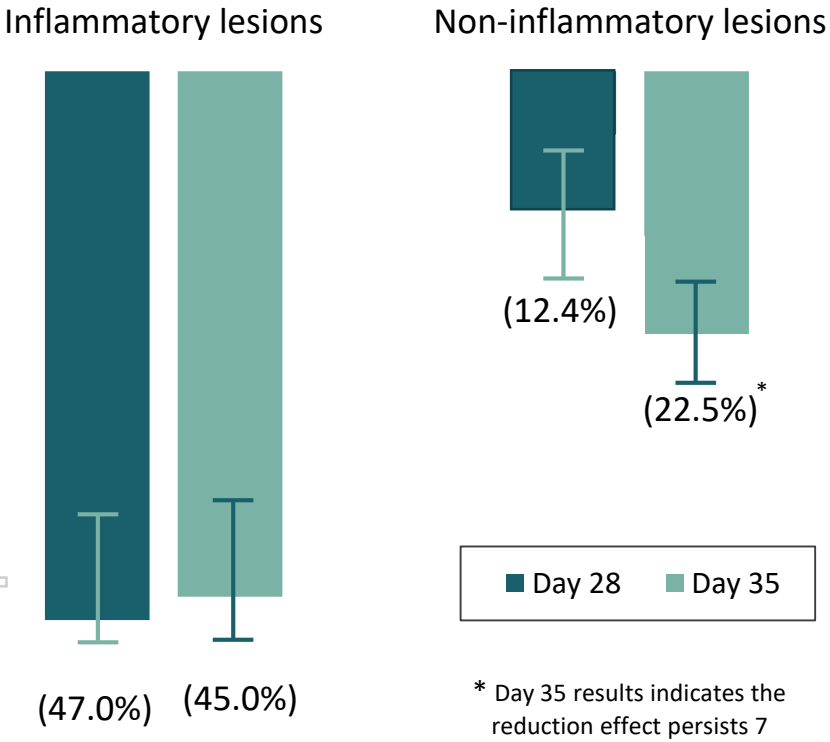
Phase 1b lesion count data for BTX 1503 (acne)

A 4 week Phase 1b open-label study showed a marked reduction in inflammatory lesions and was safe and generally well tolerated

Lesion count reduction (%)[1]



* Day 35 results indicates the reduction effect persists 7 days after the last treatment

Other FDA approved products[2]

Product	Owner	Lesion count reduction (%)[3]	Peak revenue[4]
Epiduo®	Galderma	~42%	~US$700m

✓ Combination of two drugs – benzoyl peroxide and adapalene

✗ Common side effects include redness, skin peeling mild burning / stinging and dryness

Aczone®	Allergan	~38%	~US$300m

✓ Few side effects

✗ Common side effects are site dryness and pruritus

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*

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BTX 1503: acne – Phase 2 study

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

Botanix BTX.1503 Phase 2 acne trial – See Botanix announcement on 22/10/19 and 23/10/19 - Botanix data on file

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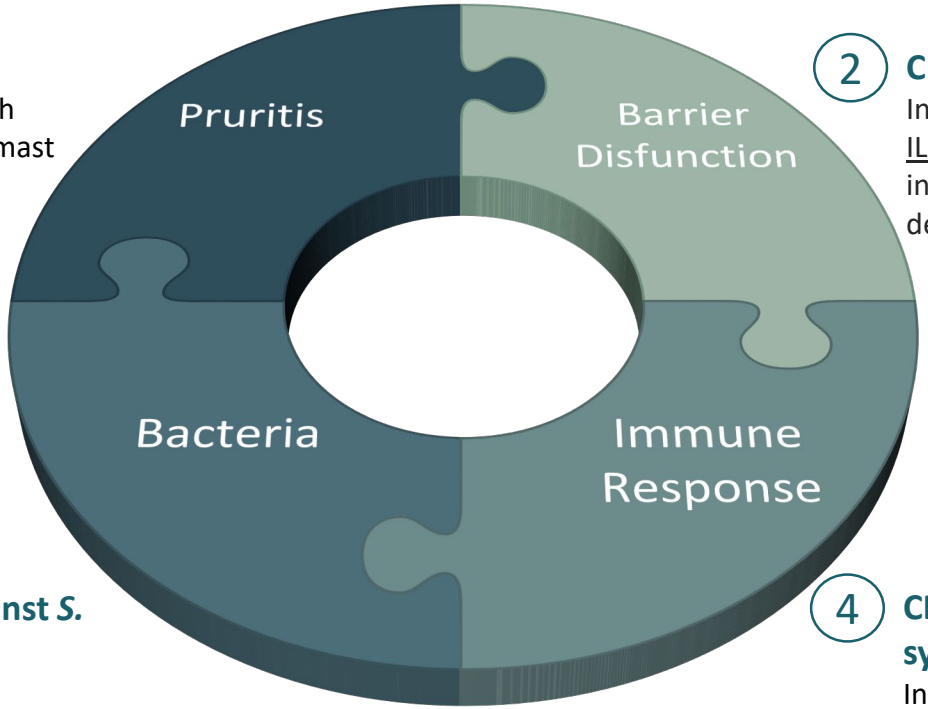
BTX 1204: CBD mechanism of action in atopic dermatitis

Ideal therapy that addresses multiple factors of disease pathology

1 CBD inhibits itch

Suppresses itch by interacting with VR/TRPV-1 receptors present on mast cells and keratinocytes[3]



2 CBD repairs barrier dysfunction

Inhibits p38 MAP Kinase activation and IL-6 production in keratinocytes which interrupts the signaling process to dendritic cells and Th2 helper cells[1,2]

3 CBD is potent antibiotic against *S. aureus*

Reduces *S. aureus* and *MRSA* colonisation responsible for triggering skin inflammation and secondary skin infections[4]

4 CBD modulates the immune system

Inhibits Th17 (IL-17) and Th2 responses (IL-13) responses limiting the release of pro-inflammatory cytokines (TNFα, IL-1, IL-6, IL-8, and IL-12)[1,5]

1. *BTX 1308 Phase 1b clinical study – BOT data on file*
2. *Tan et al. Mol Med Rep 2017:16((6) 8883-8867*
3. *Eagelston et al. Dermatol Onlin J. 2018 Jun 15;24 (6)*
4. *Based on University of Queensland testing – BOT data on file*
5. *Petrosino et al. J Pharmacol Exp Ther. 2018 Jun;365(3):652-663*

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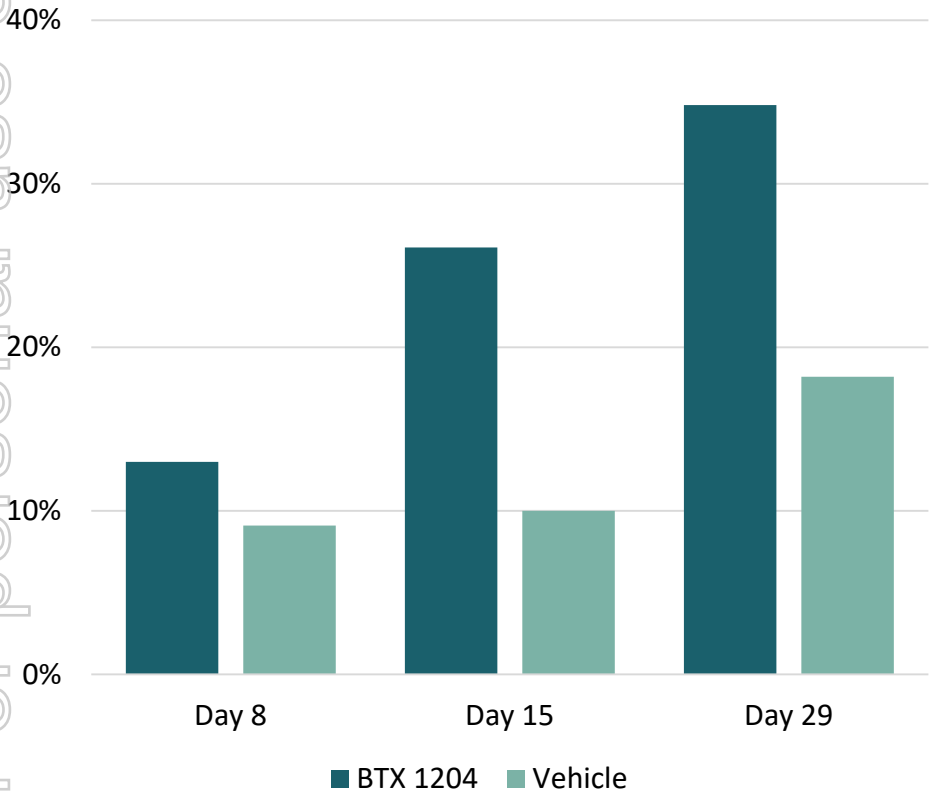
Phase 1b study results support efficacy and safety potential

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

Treatment success (%)[2]



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 allows 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*

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BTX 1204: atopic dermatitis – Phase 2 recruiting

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

Study 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

Data in 1Q CY2020

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BTX 1702: impact of papulopustular rosacea

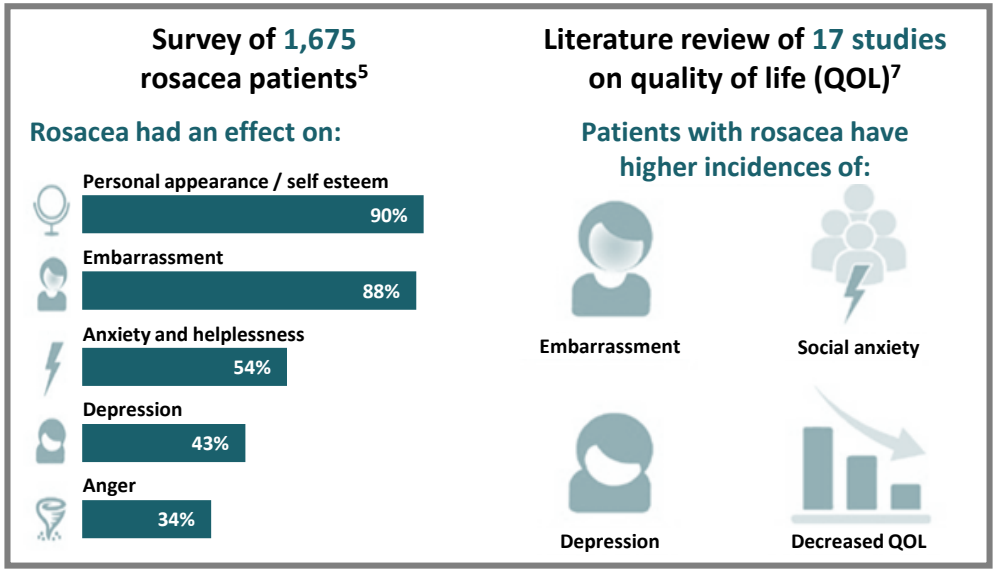
Papulopustular rosacea is a chronic skin disease characterised by redness (inflammation) and acne-like break-outs[1]

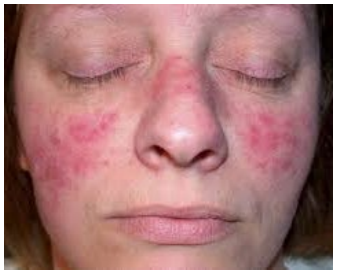
Affects ~16m Americans[3]

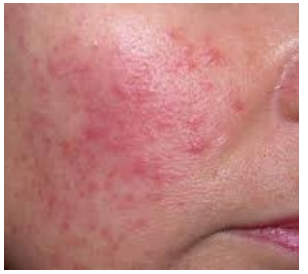
- ~5.5% of the adult population is affected by rosacea[4]
- only 10% seek treatment[2]
- misdiagnosis is common[2,5]
- 85% of patients are over 30 years old and have multiple co-morbidities and sensitivities to treatments[6]

Clearly identified unmet medical need[2]

Very high emotional and psychological impact[7]







1. Blount BW, Pelletier AL. Am Fam Physician. 2002;66:435-440.
2. Prevalence of rosacea. http://www.rosacea.org/rr/index.php.
3. National Rosacea Society. www.rosacea.org.
4. Gether L, et al. Br JDermatol. 2018;179:282-289
5. National Rosacea Society. http://www.rosacea.org/rr/2010/winter/article_1.php.
6. Syneos Health, Treatment Answers Prescriber Audit Data, MAT OCT18
7. Moustafa F. J Am Acad Dermatol. 2014;71:973-980.

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BTX 1702 study

6 week randomised, double-blind, vehicle-controlled study to evaluate the safety and tolerability of BTX 1702 in patients with papulopustular rosacea

Study Design

- 2 dose groups: ~36 patients
  - BTX 1702 twice daily: 24 patients
  - Vehicle twice daily: 12 patients
- Australian dermatology sites
- Adults: 18 years and older
- Moderate to severe papulopustular rosacea
- Treatment period of 6 weeks
- Facial photos with Canfield imaging

Endpoints

- **Primary endpoint**
  - Safety and local tolerability assessment
- **Exploratory endpoints**
  - Absolute change and percentage change in Inflammatory lesion counts (papules & pustules)
  - Proportion of subjects with a clear (0) or almost clear (1) IGA
  - Reduction of erythema severity assessments by patients and by the Investigator

Study start 4Q CY2019

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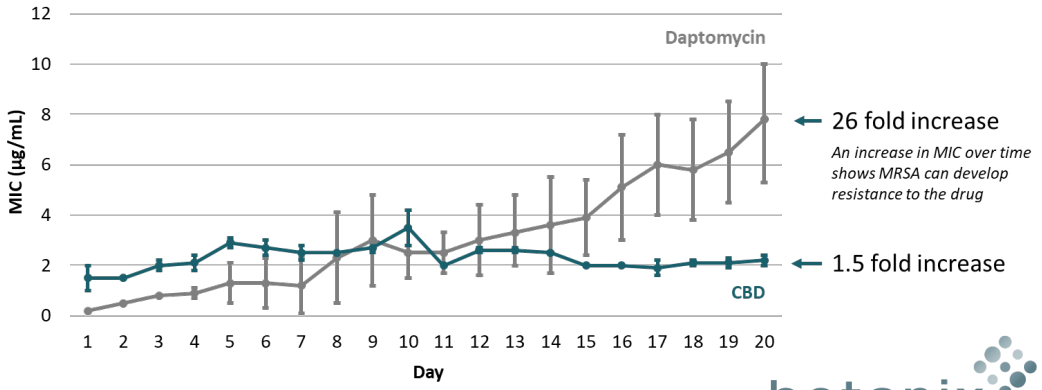
BTX 1801 - antimicrobial

Cannabidiol is a powerful new antibiotic that is effective in tests against *Staphylococcus aureus* ("staph") and *methicillin resistant Staphylococcus aureus* ("MRSA or golden staph")[1]

Antibiotic	*S. aureus* all isolates (μg/mL)			MRSA[1] (μg/mL)		MSSA[2] (μg/mL)	
	MIC_{50}	MIC_{90}	Range	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}
Cannabidiol	2	4	0.25 - 8	2	2	2	4
Mupirocin	0.5	0.5	0.125 – 64	0.5	0.5	0.5	0.5
Vancomycin	1	2	0.5 – 64	1	1	1	2
Daptomycin	2	4	0.5 – 16	2	2	2	4
Clindamycin	0.125	64	0.03 – 64	0.125	0.1875	0.125	64

MIC_{50} = minimum concentration to inhibit growth of 50% of isolates
MIC_{90} = minimum concentration to inhibit growth of 90% of isolates
MRSA = methicillin resistant *S. aureus*
MSSA = methicillin susceptible *S. aureus*

Antibiotic Minimum Inhibitory Concentration (MIC) daily variability[2]



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

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Summary

Cannabidiol (CBD)

- CBD is promising therapy for the treatment of various skin conditions including acne, atopic dermatitis, psoriasis, rosacea, and serious infections

Permetrex™

- Formulation technology provides a new and efficient way to deliver molecules into the skin without the use of irritating solvents or penetration enhancers that may damage skin layers

Phase 2 clinical studies

- Phase 2 clinical studies in atopic dermatitis ongoing with readout expected Q1 2020

Phase 1b clinical study

- Phase 1b clinical study in psoriasis completed; Phase 1b rosacea and anti-infective clinical studies to commence 4Q CY2019

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