

ASX/Media Release

14 May 2019

Botanix presenting at Canaccord Genuity Cannabis Conference

Key highlights

- Botanix invited to present at the 2019 Canaccord Genuity Cannabis Conference in New York
- Botanix will provide an update on its dermatology development programs, focusing on near term data read outs for the psoriasis, acne and antimicrobial skin infection programs
- The Company will share the podium with management from Canopy Growth, Aphria, Aurora and other leading cannabinoid companies
- Botanix is growing an international reputation as a leading cannabinoid drug developer, with the most advanced clinical pipeline of the upcoming conference attendees

New York and Sydney Australia, 14th May 2019: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or the “Company”) is pleased to announce that its Founder and Executive Director, Matt Callahan, has been invited to present at the 2019 Canaccord Genuity Cannabis Conference in New York. Mr Callahan’s presentation is attached to this release.

The 2019 Canaccord Genuity Cannabis Conference will feature presentations and one-on-one meetings with companies representing every facet of the global cannabis supply chain, including pharmaceutical companies from across America, Europe and Australia. Botanix will share the podium with CEO’s and visionaries from the largest and most diversified cannabis companies in the world, including Canopy Growth, Aphria and Aurora, amongst others.

Mr Callahan will provide an update on the progress of Botanix’s late stage clinical programs, including the psoriasis mechanism of action study (Phase 1b) and the acne study (Phase 2), which remain on track for data read outs in 2Q CY2019 and 3Q CY2019, respectively. The conference will also allow Botanix to establish links with various investors and potential strategic partners.

The conference comes at a pivotal time for Botanix as interest continues to grow in pharmaceutical applications of cannabinoids and clinical evidence of the effectiveness of this compound for treating a range of health conditions.

Matt Callahan, Founder and Executive Director of Botanix said: “The conference is a great opportunity to showcase the advanced progress of our clinical programs with two Phase 2 programs (acne and atopic dermatitis) and one Phase 1b (psoriasis) clinical program reading out in the coming months.”

“Our unique rapid development approach has allowed Botanix to distinguished itself from its peers. We are pleased to have the opportunity to showcase the most mature pipeline of any other cannabinoid company featuring at the conference, many of whom have been in development for 5 to 10 years and are only now commencing human studies for the first time.”

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage medical dermatology company based in Perth, Australia and Philadelphia, PA. The Company's focus is the development of safe and effective topical treatments for acne, atopic dermatitis, psoriasis, and other skin conditions. The active ingredient contained in Botanix' products is a synthetic form of a widely studied natural compound, cannabidiol. Treatment targets include inflammation, deterioration 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 patient treatment duration of clinical studies is generally completed within a 4 to 12-week timeframe.

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 completion of enrolment expected in mid-2019. The BTX 1204 atopic dermatitis Phase 2 study is also underway with enrolment expected to be completed by end 3Q CY2019. Finally, the Phase 1b BTX 1308 psoriasis study is nearing completion with data anticipated to be available in 2Q CY2019.

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

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RESTORING HEALTHY SKIN

Botanix Pharmaceuticals

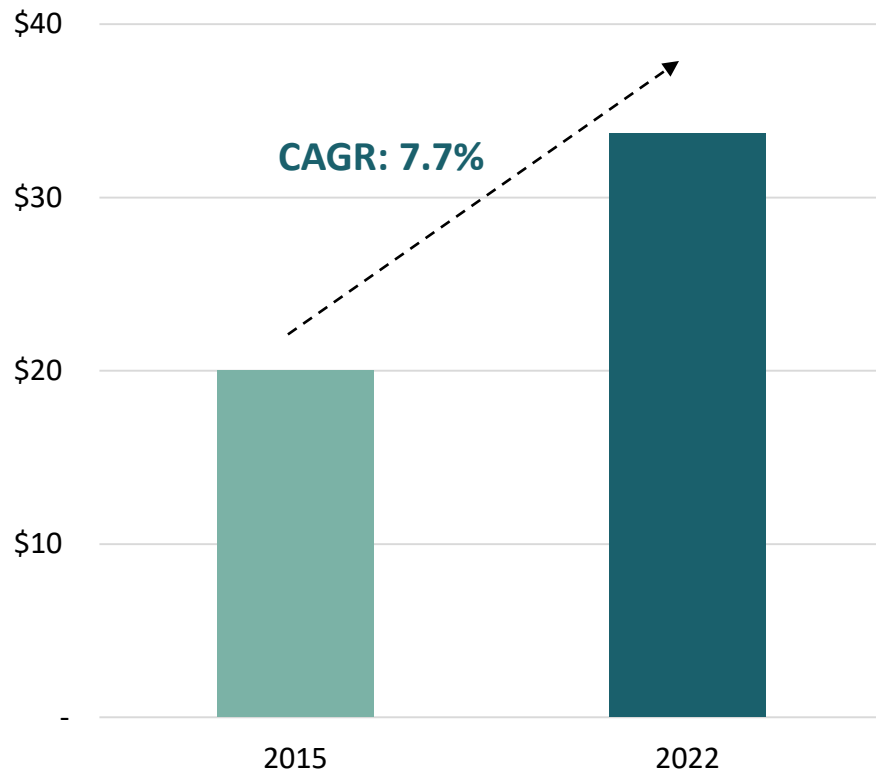
May 2019



Why dermatology?

Global market expected to expand to US\$33.7bn by 2022¹ and pipeline of new products remains impossibly thin

Global dermatology market (US\$bn)








- Approximately **one third of the US population** suffers from an active skin condition
- **Little innovation in more than 20 years**
- **Significant unmet medical need** for treatment options that:
 - Are effective via multiple pathways
 - Have improved safety/tolerability profiles
 - Allow for long-term use, especially in kids

1. *Koncept Market Research: Dermatology Market 2018*

Advanced cannabinoid company taking the FDA approval pathway

Multiple near-term clinical readouts with psoriasis study results in 2Q, acne study results in 3Q, and atopic dermatitis end 2019

Product candidate		Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Status
Synthetic cannabidiol	BTX 1308	Psoriasis					Top line data 2Q 2019
	BTX 1503	Moderate to severe acne					Top line data 3Q 2019
	BTX 1204	Moderate atopic dermatitis					Recruitment underway
	BTX 1801	Antimicrobial skin infections					Preparing for Phase 1b/2 study
Permetrex™ programs	Internal/external	Various					Ongoing studies with partners

Why not buy cannabidiol products off the internet?

Currently marketed cannabidiol (CBD) topical products do not contain what the labels says they do...

Product name	Manufacturer	Product type	Claimed CBD content (mg/tube)	Tested CBD content ¹ (mg/tube)
TheraGreen™	Green Roads	Cream	300	→ 24.5
Biotech Pain Relief	Medix CBD	Cream	150	→ 11.2
Therapy+Hemp Cream	Highland Pharms	Cream	200	→ 24.6
CBD Herbal Repair Cream	MGC Derma	Cream	Undisclosed	→ 8.8
CBDMEDIC™ Back and Neck	CBDMEDIC	Ointment	Undisclosed	→ 14.9

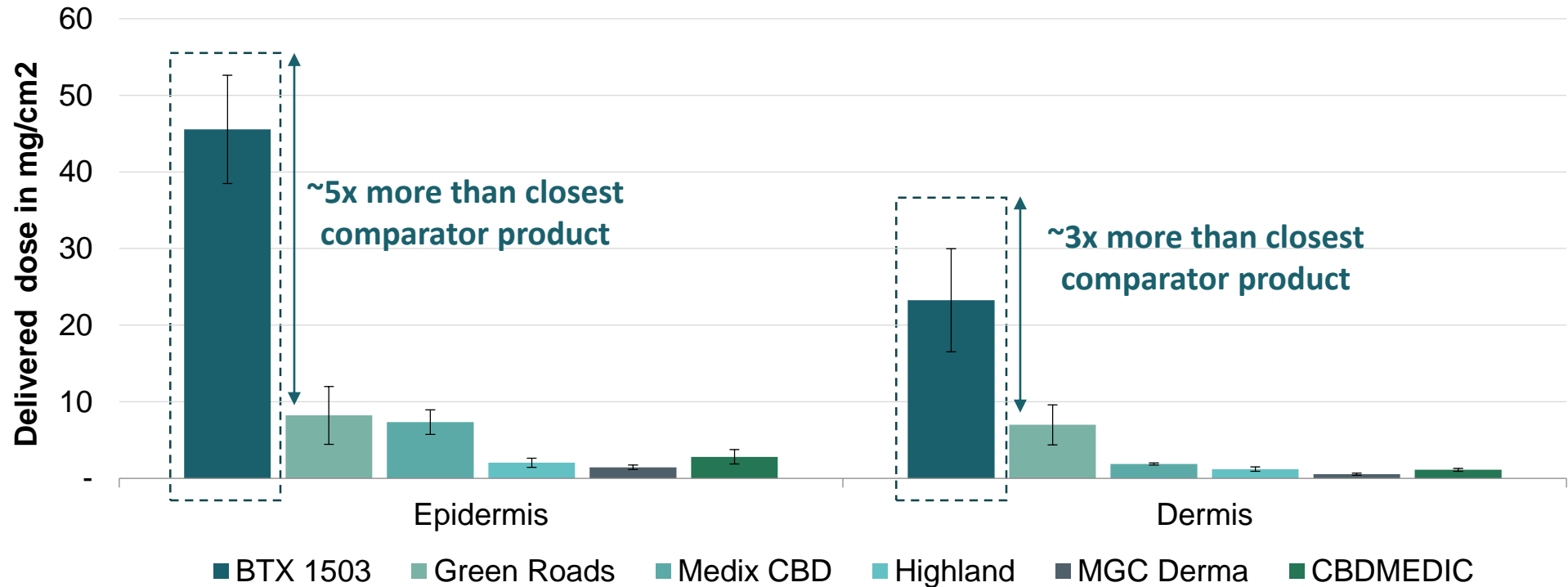


1. For further details on these tests – please refer to BOT ASX release on 26 February 2019. Products purchased online from websites of respective vendors and tested by independent laboratory testing service Tioga Research. HPLC analysis of CBD content compared labeled CBD or cannabinoid content to Tioga test results. Botanix data on file.

OTC product formulations do not deliver much CBD¹

BTX 1503 significantly outperformed the other CBD topical products in delivering drug to targeted layers of the skin

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



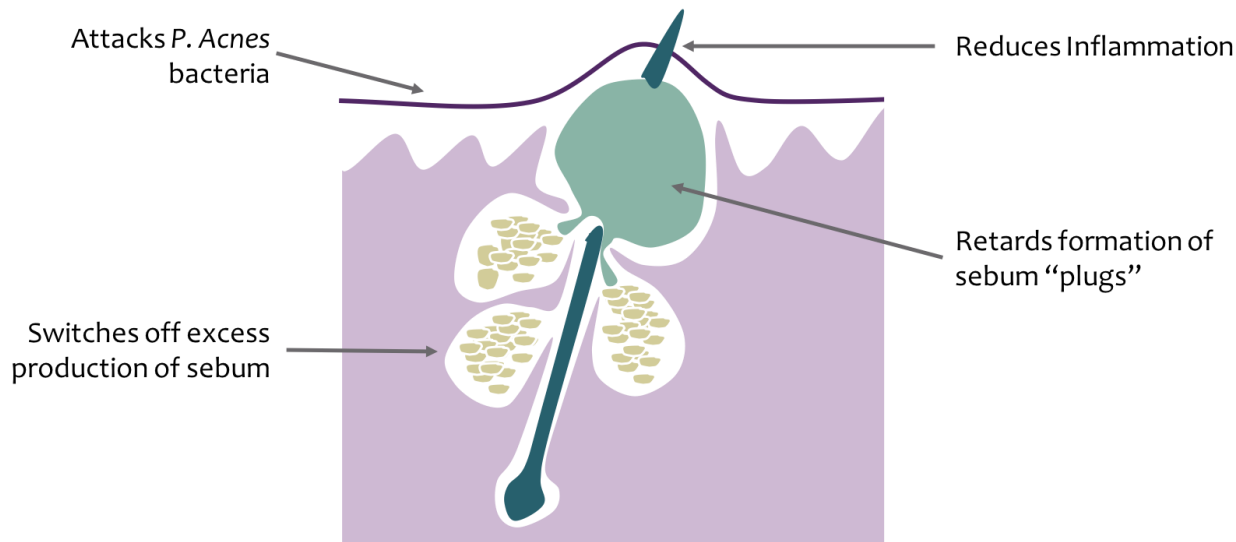
BTX 1503 delivers >5 times as much CBD to the epidermis and >3 times as much CBD to the dermis

1. For further details on these tests – please refer to BOT ASX release on 26 February 2019. 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.

1. Acne: potential novel mechanism of action

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

BTX 1503 addresses multiple acne pathologies ¹



Cannabidiol has been shown to...

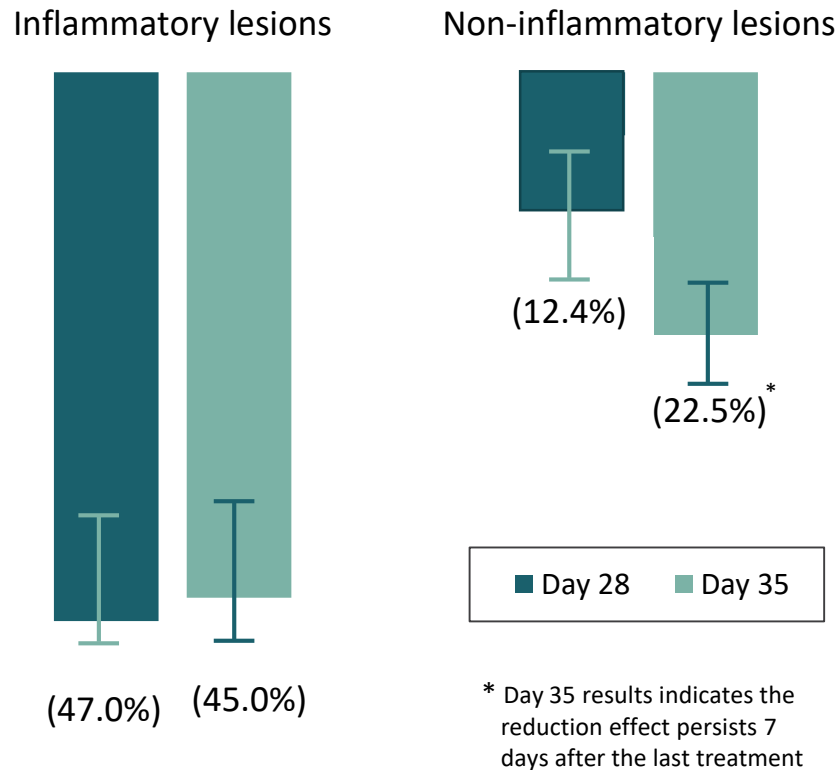
- ✓ Have anti-inflammatory effects on human sebocytes and to suppress sebocyte proliferation²
- ✓ Have potent anti-microbial activity against gram-positive bacteria³
- ✓ Inhibit human keratinocyte proliferation, through a non CB1/CB2 mediated mechanism⁴

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. Olah et al. *J Clin Invest.* 2014;124(9):3713-3724
3. Appendino et al. *J Natl Prod.* 2008;71:1427-1430
4. Wilkinson & Williamson. *J Derm Sci.* 2007;45:87-92



Acne: Phase 1b data for BTX 1503

4 week Phase 1b study data shows a marked reduction in inflammatory lesions¹

Lesion count reduction (%)¹



Comparison with other FDA approved products

Product	Owner	Lesion count reduction (%) ²	2017 annual revenue ³
 Epiduo®	Galderma	~42%	US\$659m
<ul style="list-style-type: none"> ✓ Combination of two drugs – benzoyl peroxide and adapalene ✗ Common side effects include redness, skin peeling mild burning / stinging and dryness 			
 Aczone®	Allergan	~38%	US\$298m
<ul style="list-style-type: none"> ✓ Few side effects ✗ Studies showed large placebo / vehicle effect – i.e. at 12 weeks Aczone reduced inflammatory lesions by 54% while vehicle achieved 48% reduction 			
BTX 1503	Botanix	~47%	-

1. Botanix data on file. See further detail in BOT ASX release on 29 January 2018

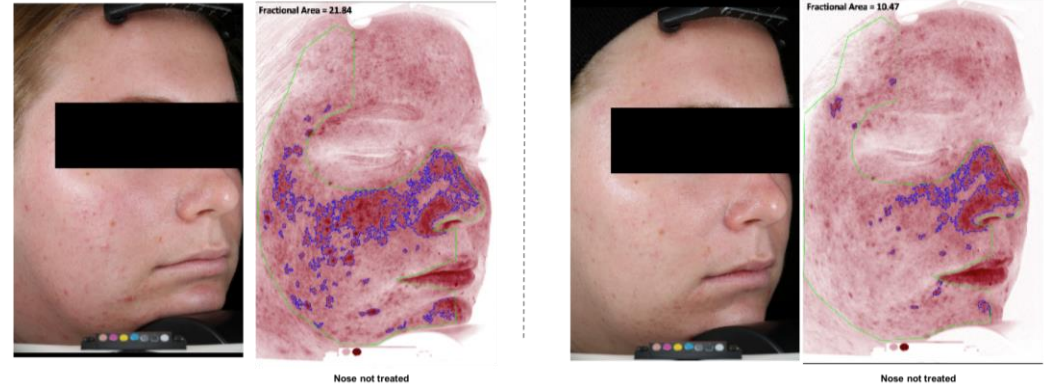
2. Lesion count reduction based on average inflammatory lesion reduction at 4 weeks. Am J Clin Dermatol (2016) 17: 293-303. Journal of Drugs in Dermatology (2016) Vol 15 Issue 8 P 962

3. Symphony Health solutions PHAST 2018

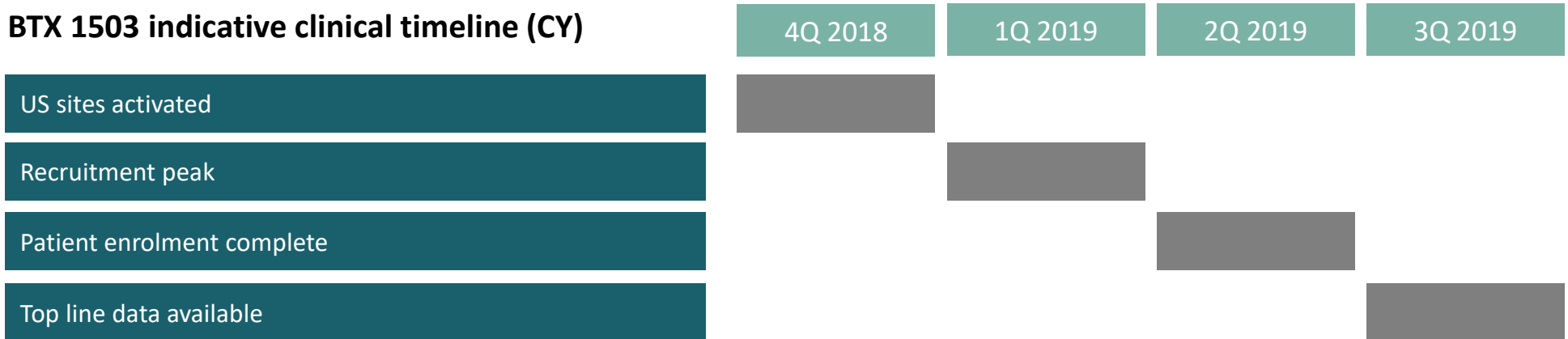
Acne: Phase 2 patient study nearing completion

Dose ranging double-blind, vehicle controlled study evaluating BTX 1503 in patients with moderate to severe acne

- ~360 patients
- 30 Australian and US sites
- Primary endpoint is change in number of lesions
- No SAE's notified to date



BTX 1503 indicative clinical timeline (CY)



2. Atopic dermatitis: severe eczema

Atopic dermatitis (and psoriasis) are both T-cell mediated inflammatory diseases of the skin



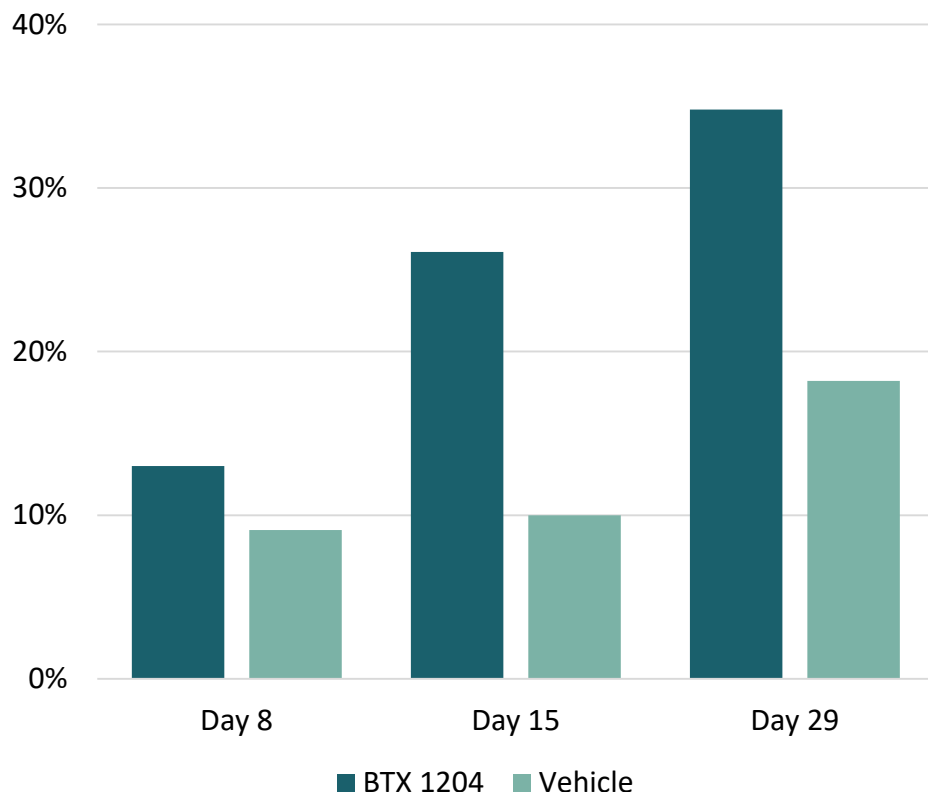
- ✓ Cannabidiol inhibits anti-inflammatory effects^{1,2}
- ✓ Cannabidiol modulates immune response^{3,4}
- ✓ Cannabidiol prevents deterioration of skin barrier function⁵

1. Harvey et al. *Cytokine*. 2014;65:236-244
2. Kaplan et al. *Biochem Pharmacol*. 2008;76(6):726-737
3. Gaffal et al. *Exp Derm*. 2014;23:401-406
4. Kim et al. *Int J Derm*. 2015;54:e410-e408
5. Lee et al. *Mol Med*. 2016;22:136-146

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 dermatitis¹

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

Phase 2 clinical study underway

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

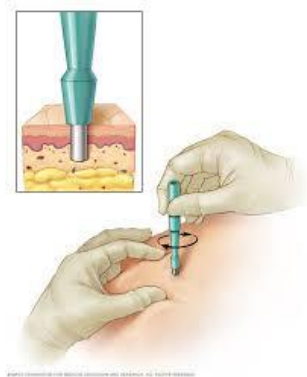
3. Psoriasis: MOA for cannabidiol study

Testing BTX 1308 in a model where detailed information on how CBD may modulate skin disease through the collection of biopsies

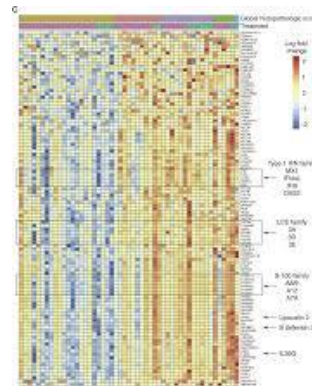
Psoriasis plaque model¹

Novel multi-drug comparison study format in the same patient

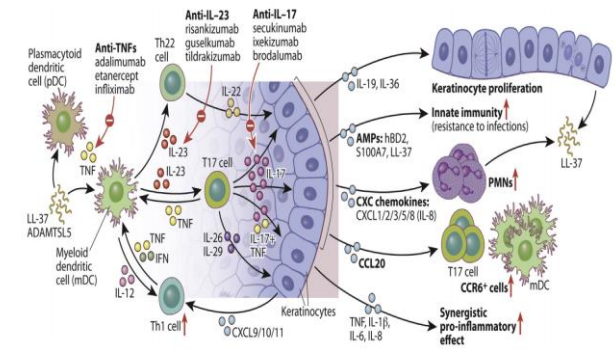
- ✓ Biopsies of treated skin can be compared to biopsies from untreated psoriatic and healthy skin
- ✓ For the first time, investigation of molecular pathways that CBD might modulate to produce a benefit in skin disease



Skin biopsy



Gene + histopathologic profile



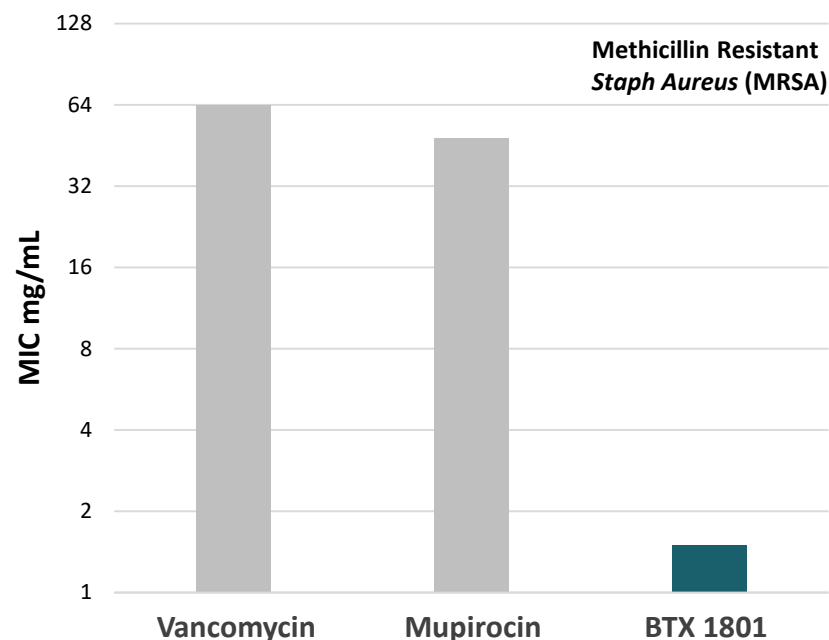
Targets for CBD in skin disease

1. Psoriasis model created by Bioskin GmbH. Biopsies allow molecular targets from skin tissue to be identified and compared to previously tested therapeutic agents.

4. BTX 1801: novel antimicrobial for serious skin diseases

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

Minimum Inhibitory Concentration (MIC) effect of BTX 1801 against industry standard antibiotics¹



The lower the MIC – the more effective the drug is at killing the target bacteria and the less drug is required to have the desired effect






BTX 1801 may have the following benefits

- ✓ Gram-positive bactericidal effect
- ✓ New mechanism of action
- ✓ Active against MRSA
- ✓ Topical application suited for skin infections
- ✓ Benign side effect profile based on previous clinical studies
- ✓ Anti-inflammatory and skin barrier improvement properties
- ✓ Suitable for treatment of children (due to established safety profile)
- ✓ Bacteria do not form resistance to BTX 1801

1. Vancomycin used to treat serious infections in many different parts of the body while Mupirocin used to treat certain skin infections

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