

ASX/Media Release

16 September 2019

Botanix announces new clinical program to target rosacea

Key highlights

- **Botanix has identified a compelling new product for the treatment of papulopustular rosacea, leveraging its proprietary drug delivery system Permetrex™ with synthetic cannabidiol**
- **Botanix has successfully completed the formulation development and pre-clinical studies of BTX 1702 and it is set to enter the clinic in 4Q CY2019**
- **New program is being expedited based on the recent mechanistic data generated by Botanix demonstrating cannabidiols powerful anti-inflammatory and antimicrobial actions**
- **BTX 1702 will leverage the growing safety database of Botanix's other mature dermatology pipeline products BTX 1503 (acne) and BTX 1204 (atopic dermatitis) to significantly accelerate clinical development timelines and regulatory approvals**
- **Papulopustular rosacea is a highly visible and distressing chronic inflammatory skin disease characterised by intensely inflamed skin and acne-like breakouts across the face**

Philadelphia PA and Sydney Australia, 16 September 2019: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce a new compelling product opportunity for the treatment of papulopustular rosacea. The product is referred to as BTX 1702 leverages its proprietary drug delivery system Permetrex™ with synthetic cannabidiol.

Botanix has successfully completed formulation development and pre-clinical studies for BTX 1702 and is set to enter the clinic (in a Phase 1b papulopustular rosacea study) in 4Q CY2019. BTX 1702 significantly expands the Company's dermatology pipeline and this initial study is supported through Botanix's recent A\$40m capital raising, led by US-based institutional investors.

The new BTX 1702 program is being expedited based on the recent mechanistic data generated by Botanix that showed synthetic cannabidiol exerts powerful anti-inflammatory and antimicrobial actions in skin – two key activities that are critical to successfully treating rosacea. These studies, along with Botanix's previous acne clinical data, suggest that synthetic cannabidiol delivered using the Permetrex™ skin delivery technology could represent a safe and effective new option for rosacea patients.

Rosacea is a chronic inflammatory skin disease that often begins with a tendency to blush or flush more easily than other people, but can progress into many subtypes, including papulopustular rosacea. Papulopustular rosacea is a highly visible and distressing chronic inflammatory skin disease characterised by intensely inflamed skin and acne-like breakouts across the face, which affects more

than 16m Americans. Women are more likely to have rosacea than men and more than 85% of patients are over the age of 30 years old.

Director of Dermatology Clinical studies and Division Head of Dermatology at Henry Ford Health System in Michigan USA, Dr Linda Stein Gold commented: “Rosacea has a tremendous emotional impact on our patients. They feel as if society is judging them and studies show that this is true. They are often viewed negatively due to their flawed complexion. Synthetic cannabidiol offers a novel potential option for papulopustular rosacea with a unique mechanism of action. It could target several aspects in the pathogenesis including proven anti-inflammatory and immune modulating activity.”

An overview presentation describing papulopustular rosacea and the Company’s plans for BTX 1702, is attached with this release.

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 successfully completed its first acne patient studies and has recently completed enrolment of a Phase 2 clinical study which is on target to be completed in 3Q CY2019 with data shortly thereafter. A Phase 2 patient study in atopic dermatitis is also underway with enrolment expected to complete in 4Q CY2019. The Company has successfully completed a mechanism of action study for synthetic cannabidiol in skin disease, with positive interim 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 its 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.



RESTORING HEALTHY SKIN

Rosacea Opportunity

September 2019



Botanix overview

Botanix is a clinical stage synthetic cannabinoid company focused on developing topical cannabidiol products for the treatment of skin diseases



Pharma focused

One of the world's **most advanced pharmaceutically focused synthetic cannabinoid (CBD) companies**



Technology driven

Proprietary Permetrex™ technology **enhances topical delivery of synthetic cannabinoid** and provides **novel IP position**



Clinical data

Lead dermatology indications validated by **robust clinical efficacy and safety data** with mechanistic **support for expansion into other diseases**



World class team

Experienced and growing team with **significant dermatology and cannabinoid drug development expertise**



Near-term catalysts

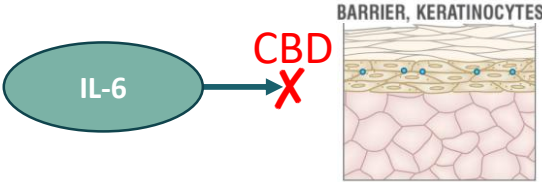
Multiple near-term catalysts including Phase 2 acne data, Phase 2 atopic dermatitis data and commencement of a Phase 1b rosacea study

Topical CBD is a well suited to treat skin disease

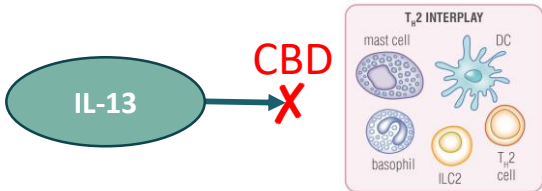
Botanix has generated strong scientific support for synthetic CBD’s anti-inflammatory and immune modulation mechanisms of actions, combined with newly identified antimicrobial effects

CBD anti-inflammatory / immune modulating effects

CBD inhibits a key cytokine which affects skin barrier disfunction



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



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

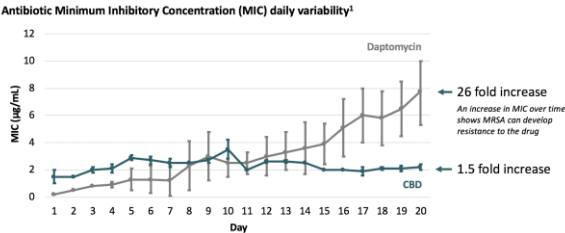


CBD antimicrobial effects

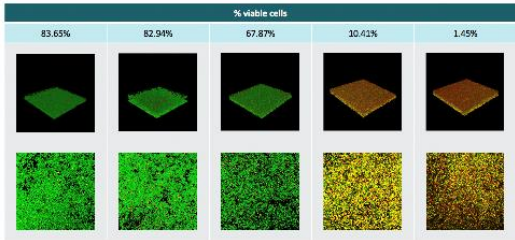
CBD is active against all tested gram +ve bacteria

Antibiotic	S. aureus all isolates (µg/mL)			MRSA ¹ (µg/mL)		MSSA ² (µg/mL)	
	MIC ₅₀	MIC 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

Bacteria cannot form resistance to CBD’s rapid killing power



CBD disrupts the bacteria’s biofilm protective cover



Impact of papulopustular rosacea

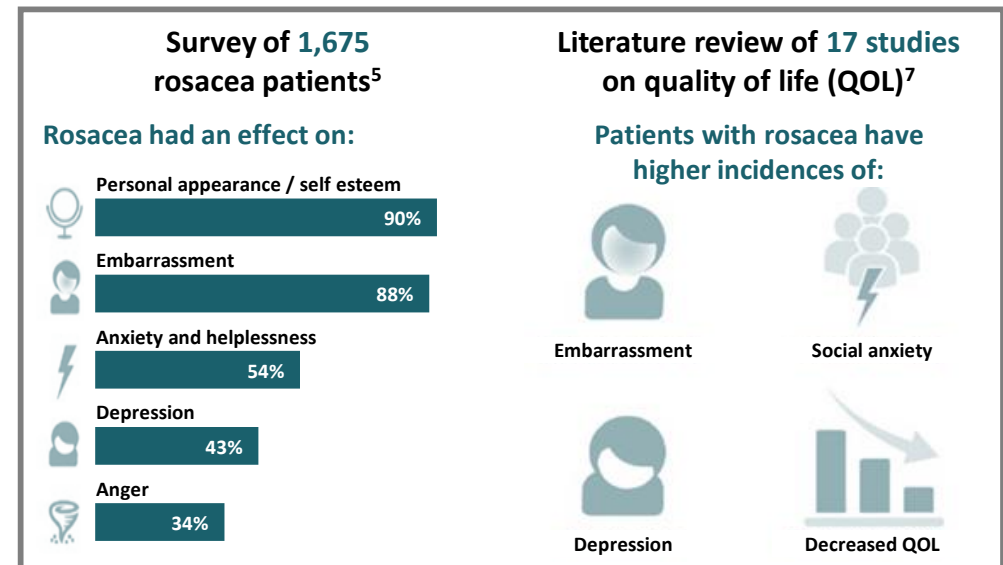
Papulopustular rosacea is a chronic skin disease characterised by redness (inflammation) and acne-like break-outs¹

Affects ~16m Americans³

- ~5.5% of the adult population is affected by rosacea⁴
- only 10% seek treatment²
- misdiagnosis is common^{2,5}
- 85% of patients are over 30 years old and have multiple co-morbidities and sensitivities to treatments⁶

Clearly identified unmet medical need²

Very high emotional and psychological impact⁷



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 J Dermatol. 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.

Market overview of papulopustular rosacea treatments

Existing treatments with systemic adverse safety issues and undesirable side effects have generated more than US\$1bn in annual sales

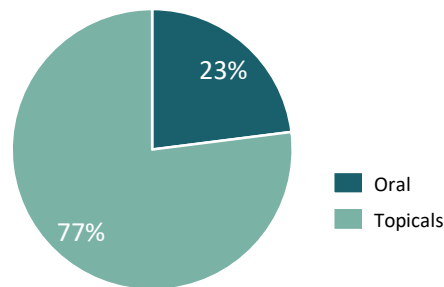
US market potential: ~US\$1.1 bn¹
(~16m people)

	US\$	Total prescriptions
Oral antibiotics	US\$270m	1.1m
Topical drugs	US\$830m	3.6m
Total	US\$1.1bn	4.7m

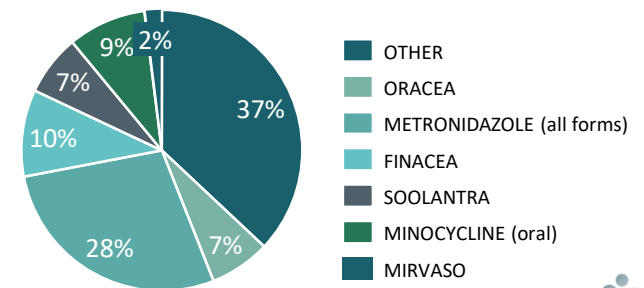
US market share: top brands¹
(>2/3 of total market – US\$ and prescriptions)

Top Brands	US\$	Prescriptions
METROGEL / METRONIDAZOLE All forms, Galderma & Generics	US\$255m	1,350,300
ORACEA² Doxycycline, Galderma	US\$220m	338,160
FINACEA² Azelaic Acid, Bayer	US\$149m	520,061
SOOLANTRA Ivermectin, Galderma	US\$102m	334,932
MINOCYCLINE (oral) Valeant & Generics	US\$44m	439,525
MIRAVASO² Brimonidine, Galderma	US\$41m	99,378

US prescriptions: topicals vs. orals¹
(LTM December 2016)



US prescriptions: top brands¹
(LTM December 2016)



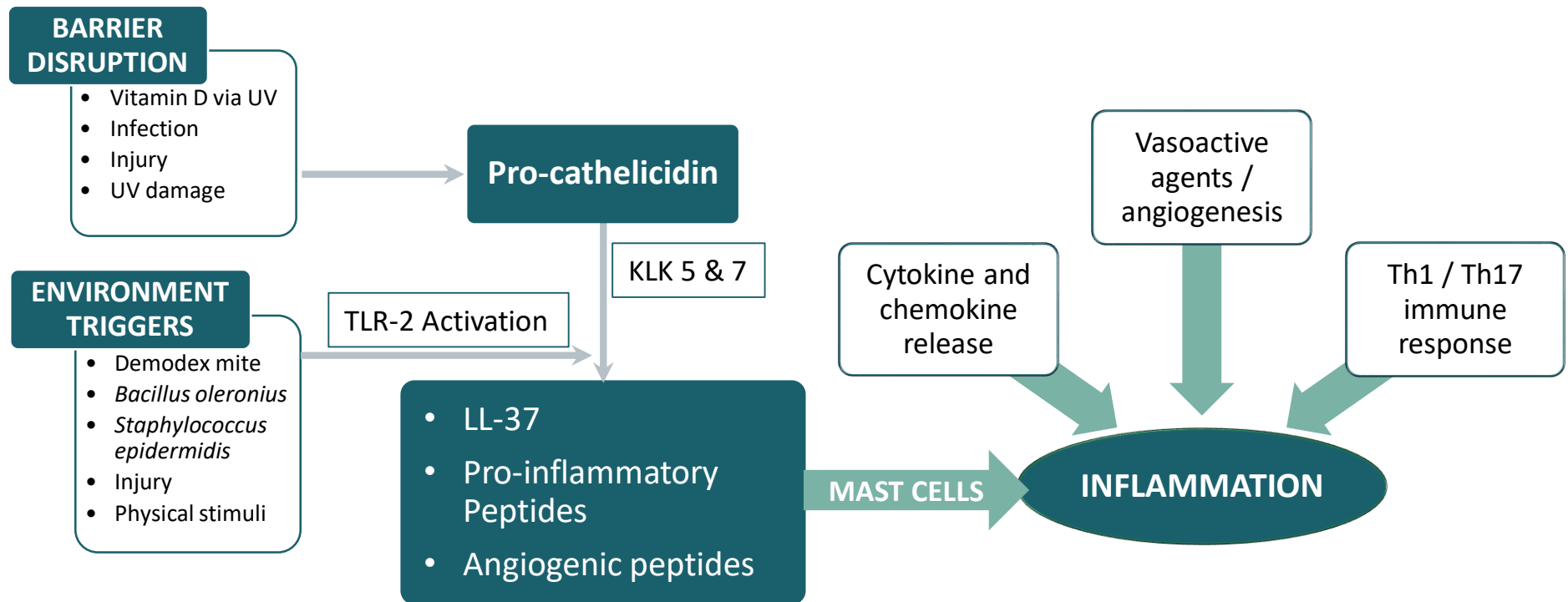
1. Symphony Health Services (PHAST) 2016

2. Select Brands

Overview of papulopustular rosacea

Papulopustular rosacea is a chronic skin disease characterized by redness (inflammation) and acne like break-outs

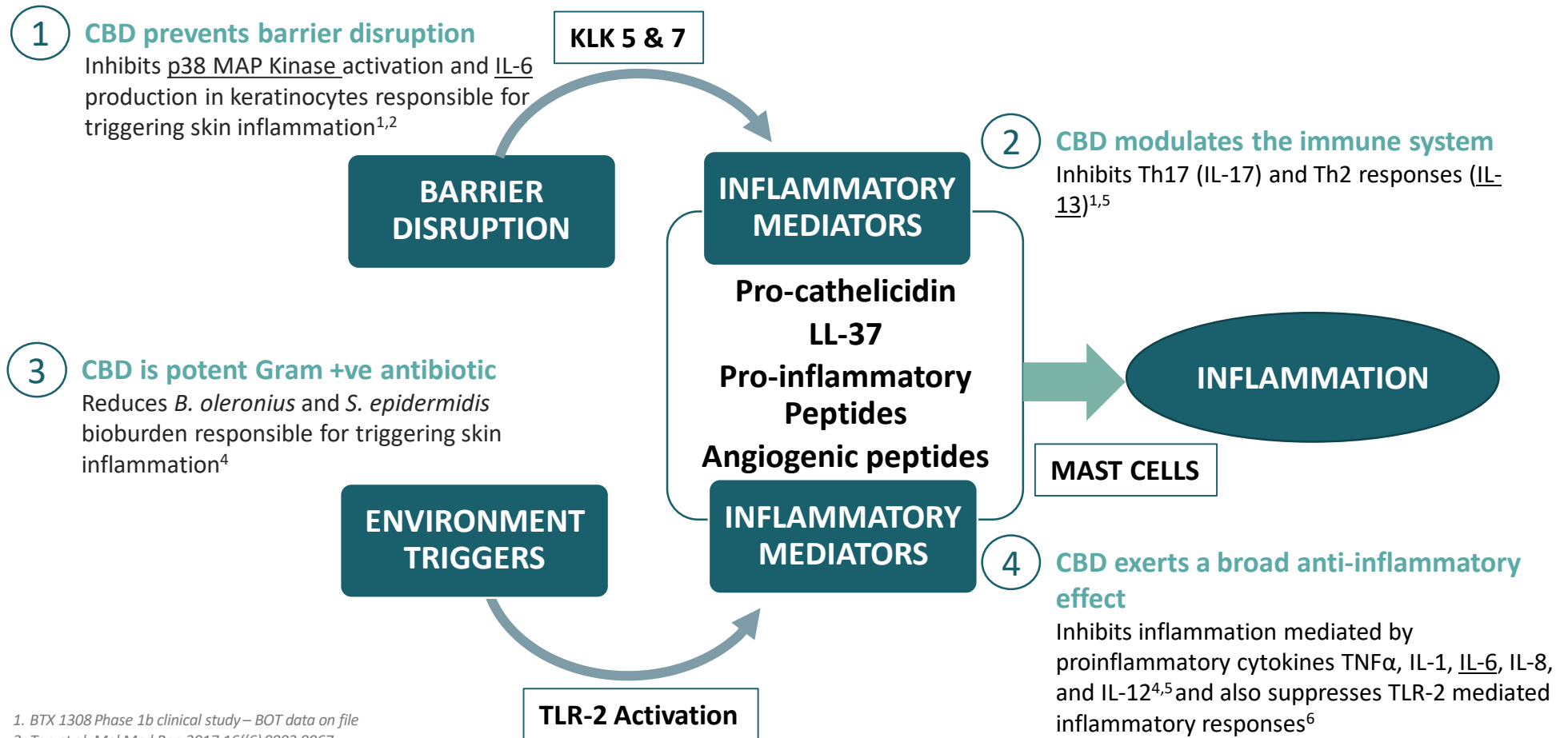
Disease mechanisms for the development of rosacea¹



1. Adapted from Picardo et al. *Dermatol Ther (Heidelb)* (2017) 7 (Suppl 1):S43–S52

BTX 1702: CBD mechanism of action in rosacea

CBD has the potential to target multiple points in the rosacea inflammatory cascade and other mediators³

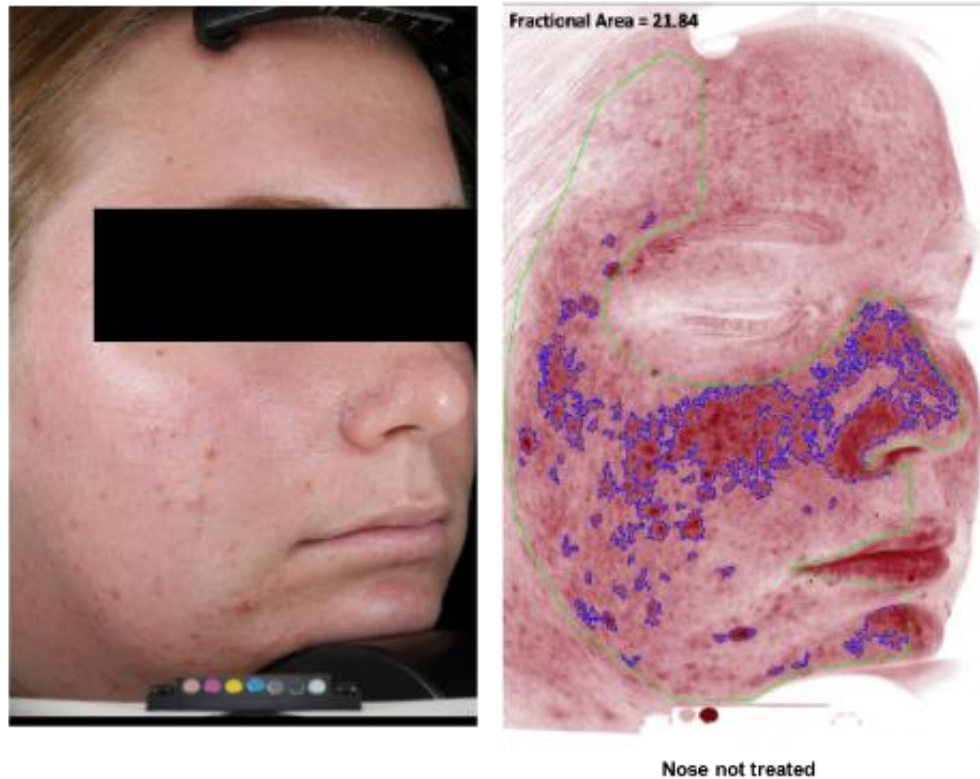


1. BTX 1308 Phase 1b clinical study – BOT data on file
 2. Tan et al. Mol Med Rep 2017;16((6) 8883-8867
 3. Egelston et al. Dermatol Onlin J. 2018 Jun 15;24 (6)
 4. Based on University of Queensland testing – BOT data on file
 5. Petrosino et al. J Pharmacol Exp Ther. 2018 Jun;365(3):652-663
 6. McCoy Mediators Inflamm. 2016;2016:5831315

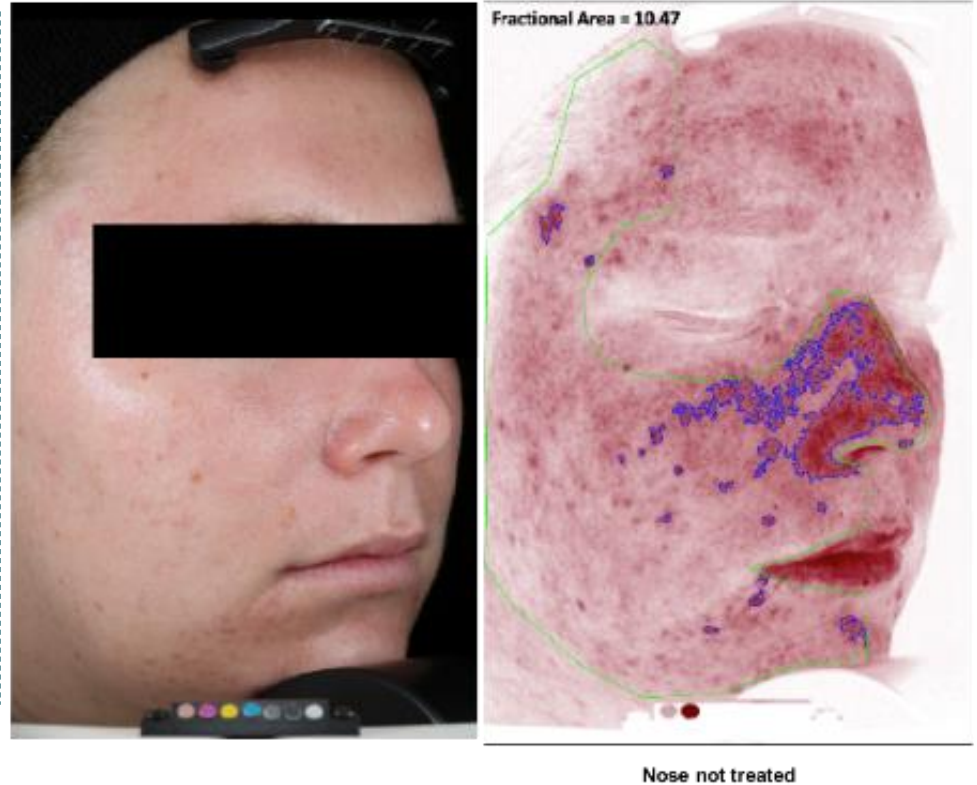
Anti-inflammatory effects of CBD already demonstrated

Photographic images from the Phase 1b acne patient study, demonstrate a clear anti-inflammatory effect over the 4 week treatment course¹

Baseline (day 1)²



Visit 4 (4 weeks)²



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

2. Nose not treated

BTX 1702: Phase 1b 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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