

19 February 2021

Botanix attends 2nd Dermatology Drug Development Summit Europe

Philadelphia PA and Sydney Australia, 19 February 2021: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “the Company”) is pleased to announce Matt Callahan, Executive Director, will be presenting at the 2nd Dermatology Drug Development Conference Europe, held virtually this year.

The Company will provide an update on the progress of the key clinical programs, including the BTX 1801 Phase 2a results and the implications of this data on the broader dermatology platform. The conference attracts industry experts focused on therapeutic innovation in the dermatology space and features company presentations, thematic panel discussions, workshops and one-on-one discussions. The conference presentation is attached to this release.

Release authorised by

Vince Ippolito

President and Executive Chairman

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 has two separate cannabinoid development platforms, dermatology and antimicrobial products, both of which leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly 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 is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabinoids with the BTX 1801 Phase 2a study nasal decolonization study announcing positive data in early February CY 2021. For the dermatology platform, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration and plans to initiate its Phase 1b rosacea study in 1H CY2021. 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.

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Unlocking the potential of synthetic cannabinoids

2nd Dermatology Drug Development Summit Europe

February 2021



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Overview of Botanix

Pharma focused

Leading pharmaceutical company leveraging unique properties of synthetic cannabinoids, including cannabidiol (CBD)

Antimicrobial opportunities

Novel antimicrobial platform with positive Phase 2a results that underpin potential to combat antimicrobial resistance



Dermatology opportunities

Targeting key dermatology indications with topical treatments that are safe, well tolerated and validated by clinical efficacy



World-class team

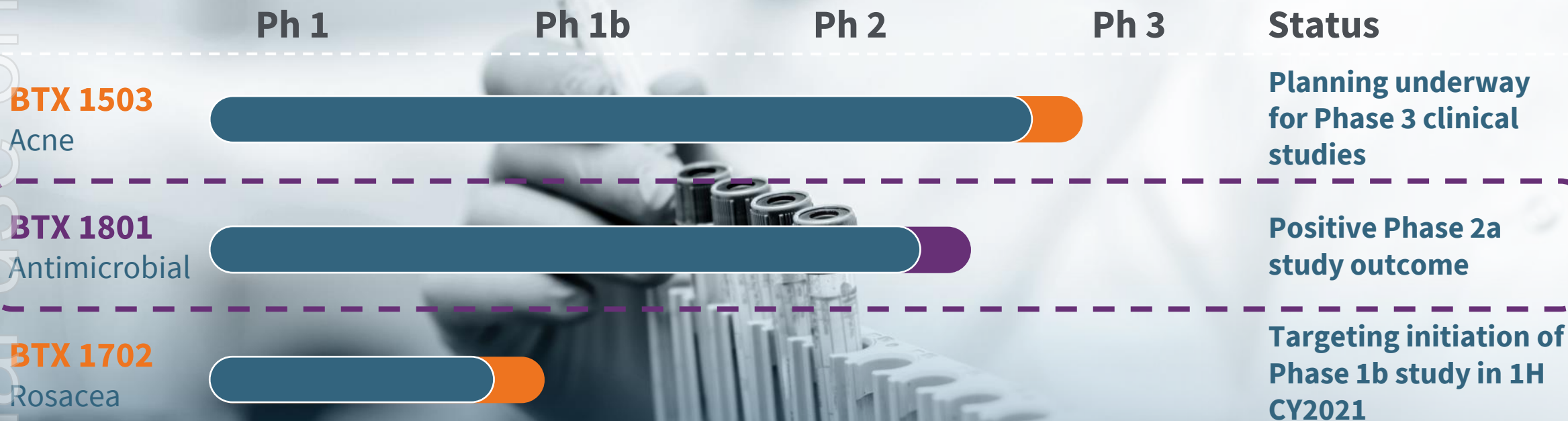
World-class and experienced team with significant cannabinoid, dermatology and antimicrobial drug development expertise



Near-term catalysts

Multiple upcoming key catalysts including progression of antimicrobial platform, launch of Phase 1b rosacea study and planning for Phase 3 acne study

Synthetic Cannabinoids Advanced Clinical Pipeline



Synthetic Cannabinoids are well suited to treat Skin Diseases and Infections

Botanix's studies show synthetic cannabinoids:

- ✓ Safe and well tolerated
- ✓ Broad anti-inflammatory properties relevant to infections
- ✓ Strong and consistent impact on inflammatory lesions
- ✓ Kill *S. aureus* and resistant *S. aureus* (MSRA - "Superbugs")
- ✓ MRSA bacteria are not prone to develop resistance¹
- ✓ Potential for widespread use across human and animal health

Background

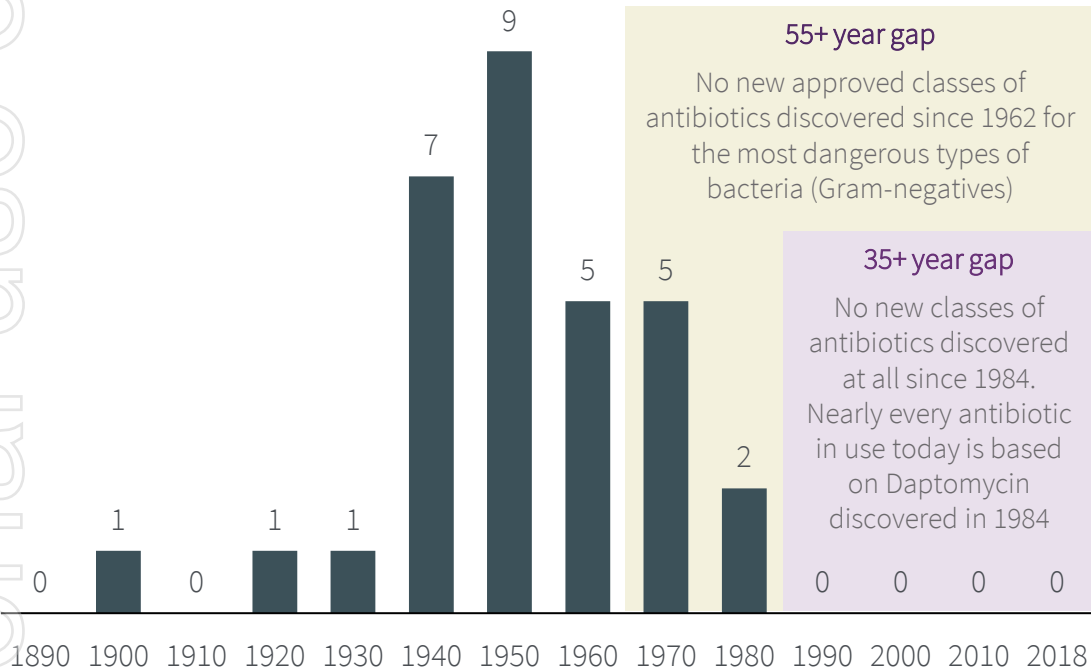
Anti-microbial resistance and cannabinoids



No new antibiotics have been discovered in over three decades

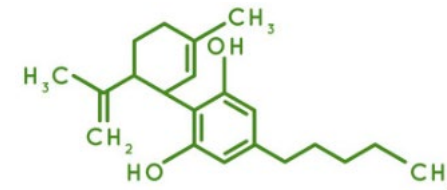
No new approved class of antibiotics has been discovered since 1984 and no new class of antibiotics has been discovered to treat Gram-negative bacteria since 1962

Number of antibiotic classes discovered or patented¹



Cannabinoids

New class of antibiotics



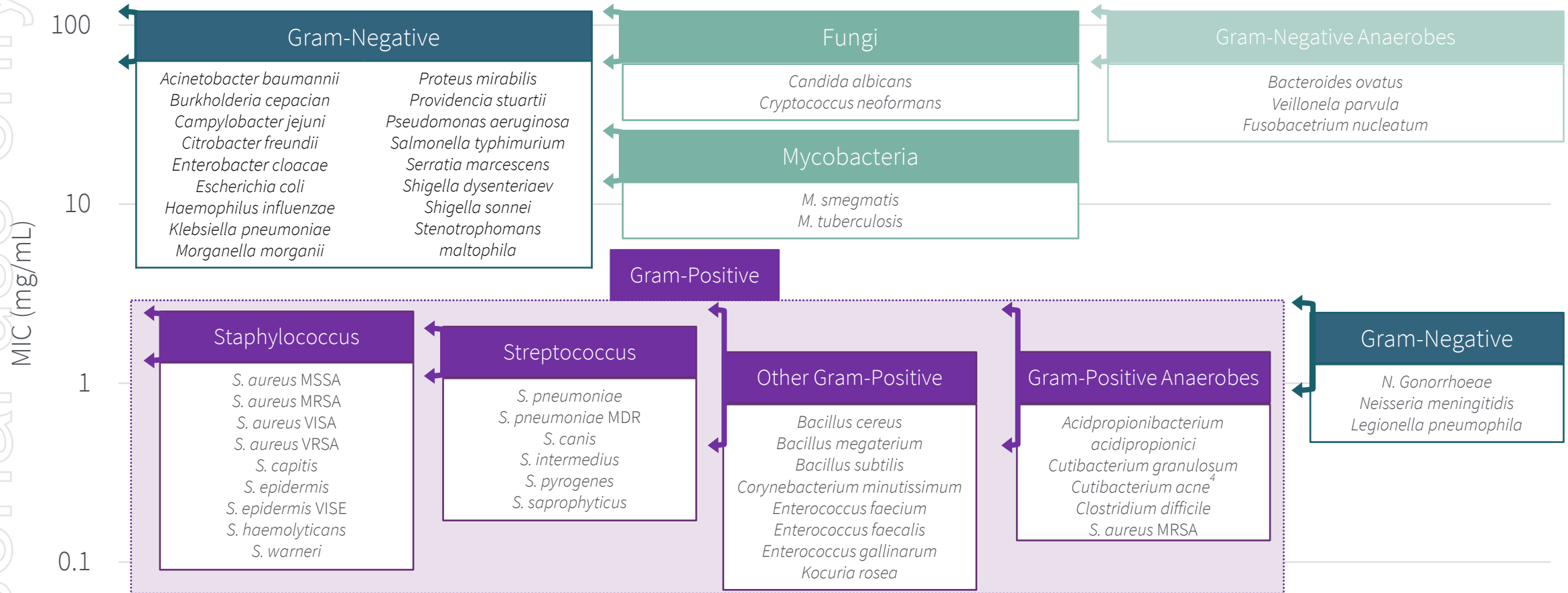
Structural activity characterized by Botanix (IP Position secured)

Examples

Cannabidiol (CBD), Cannabigerol (CBG), CBD analogs

CBD is a broad-spectrum Gram-positive antibiotic

CBD is a powerful new antibiotic that is effective against a range of problematic Gram-positive bacteria at MICs comparable to currently approved antibiotics^{1,2,3}



Remarkable activity against MRSA without inducing resistance

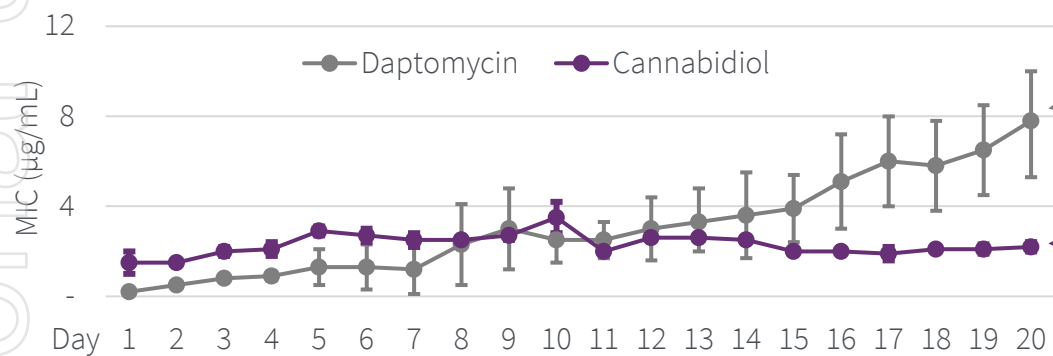
CBD shows remarkable activity against 132 isolates of *S. aureus* and MRSA¹

Antibiotic Minimum Inhibitory Concentration (MIC) comparison¹

Antibiotic	<i>S. aureus</i> all isolates (mg/mL)			MRSA (mg/mL)		MSSA (mg/mL)	
	MIC ₅₀	MIC ₉₀	Range	MIC ₅₀	MIC ₉₀	MIC ₅₀	MIC ₉₀
CBD	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

MIC₅₀ = min conc to inhibit growth of 50% of isolates. MIC₉₀ = min conc to inhibit growth of 90% of isolates. MRSA = methicillin resistant *S. aureus*. MSSA = methicillin susceptible *S. aureus*

MIC daily variability²



26x fold increase

An increase in MIC over time shows MRSA can develop resistance to the drug

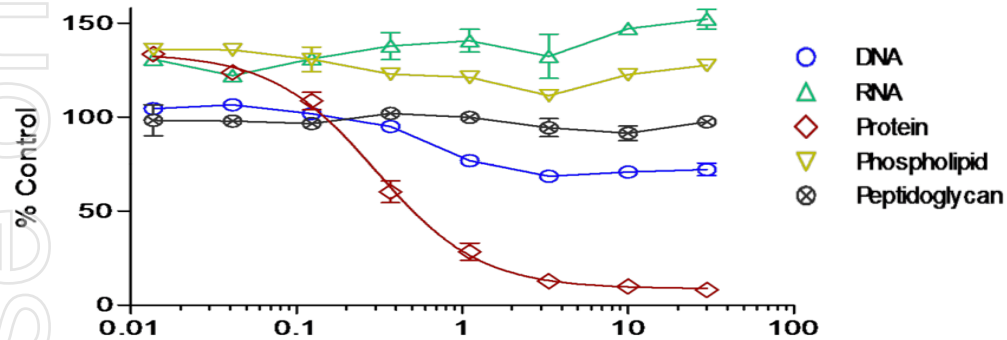
1.5x fold increase

Repeat challenge experiments demonstrate that MRSA bacteria form resistance to commonly-used antibiotics such as daptomycin, but not easily to synthetic CBD

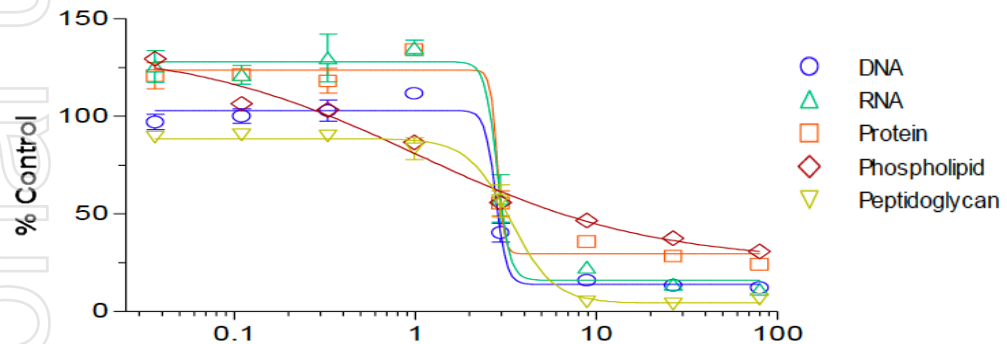
Unique mechanism of action – bactericidal

Novel mechanism of action with unique ability to rapidly kill bacteria without allowing resistance to develop

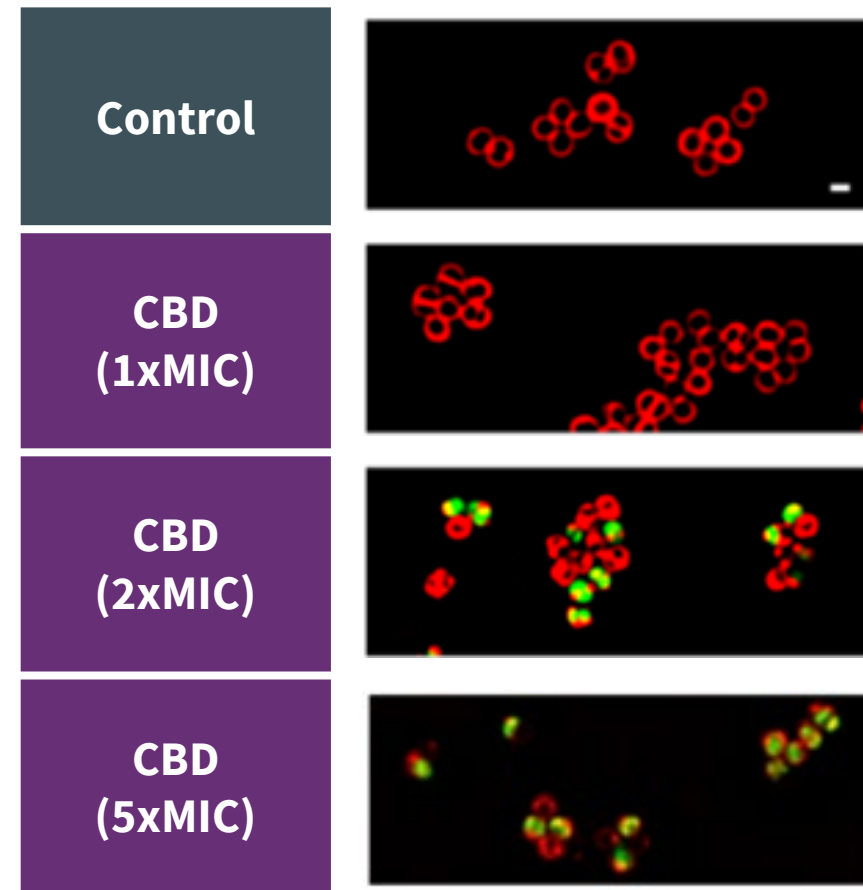
Mupirocin – targets only protein synthesis¹



CBD – affects all macromolecular pathways¹



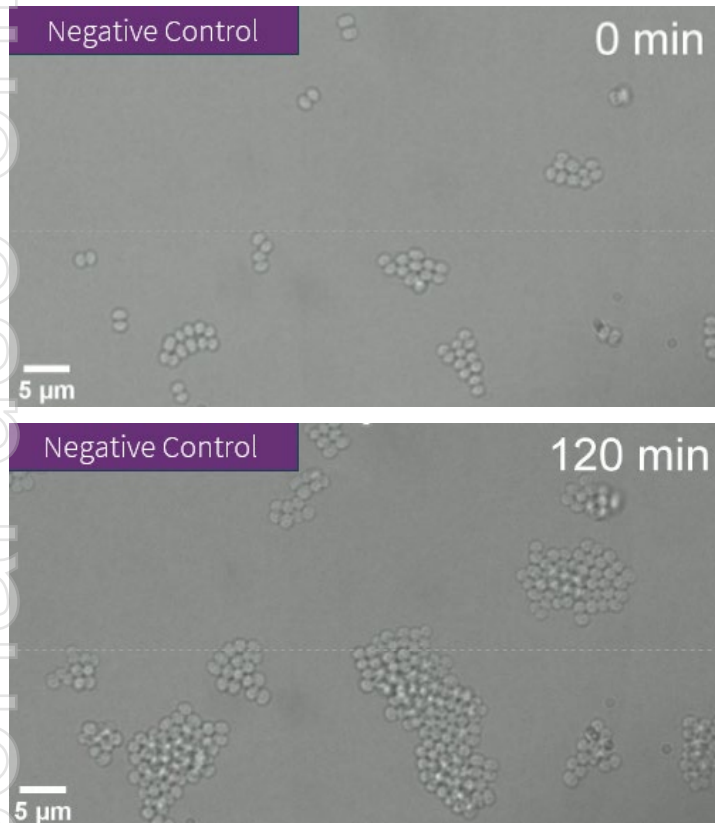
CBD – MRSA bacteria dead within 10 minutes²



Novel Mechanism of Action Confirmed

The time-lapse shows CBD causes rapid permeabilization of the bacterial membrane and cell death

S.aureus treated with 2.5% methanol (negative control)¹

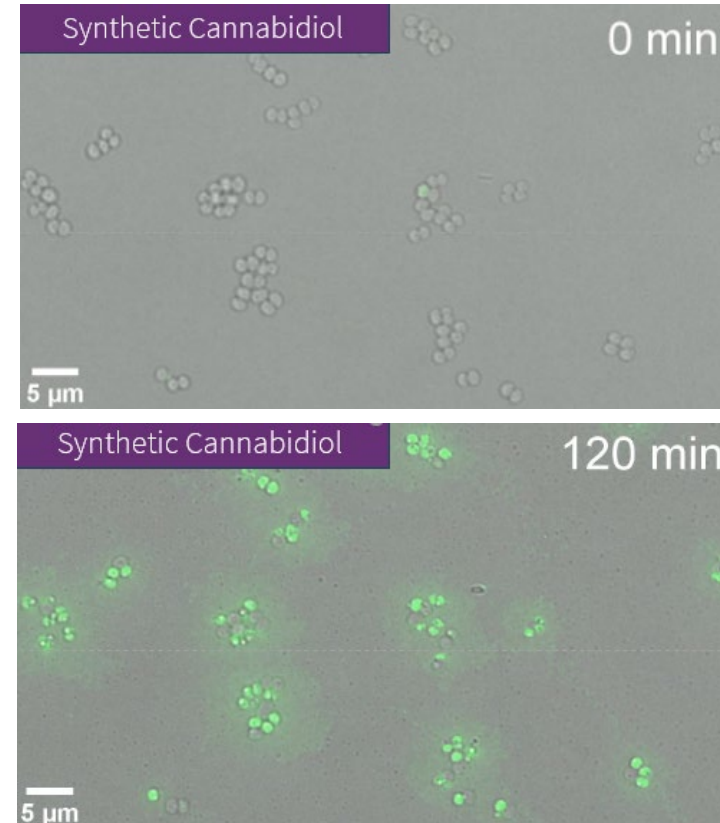


Staph bacteria treated with negative control



Bacteria are not affected over 120 mins

S.aureus treated with synthetic cannabidiol¹



Staph bacteria treated with synthetic CBD



Green staining indicates uptake of dye and disintegration of bacteria

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Clinical data for BTX 1801 and implications for dermatology



BTX 1801 – First CBD-based program to receive QIDP

Strict QIDP criteria:

- ✓ Requires provision of a **detailed package of data**
- ✓ Must be a **novel product**
- ✓ Must treat a **serious or life threatening illness**

FDA QIDP creates multiple commercial benefits

Exclusivity

5 additional years of regulatory exclusivity on top of the standard 5 years

Up to 10 years of sales where generics cannot enter the market

Priority

Eligible for an expedited six-month review period (rather than 12 months)

Accelerating the FDA review process reduces time to market

Fast track

Enables more frequent communication with the FDA during development

FDA guidance throughout development de-risks clinical trials

BTX 1801: Phase 2a Clinical Study Successfully Completed

Study update

- ✓ Phase 2a study completed in 4Q CY20
- ✓ Positive top-line data announced 1Q CY21
- ❖ Study evaluated safety and local tolerability of 2 formulations to decolonise *Staph* from the nose of healthy adults
- ❖ Phase 2a study supports rapid progression into pivotal studies for FDA registration
- ❖ FDA 'fast-track' status application for BTX 1801 to be pursued post IND filing

Study design

- ❖ Double-blind, vehicle-controlled Phase 2a clinical study
- ❖ 4 dose groups: 66 healthy volunteers:
 - BTX 1801 Formulation A
 - BTX 1801 Formulation B
 - Vehicle A
 - Vehicle B
- ❖ Sites: single Australian site
- ❖ Patients: adults: 18 years and older with positive nasal SA
- ❖ Treatment: twice daily treatment for a 5-day period
- ❖ Primary endpoints: safety and local tolerability, proportion of volunteers carrying *Staph* / *MRSA* at Day 12

Phase 2a study: Successful at eradicating *Staph*¹

BTX 1801 met study end points



Safety & tolerability

- ✓ Safe and well tolerated at doses up to 20% drug active
- ✓ All 66 participants successfully completed the BTX 1801 study
- ✓ No severe adverse events reported²



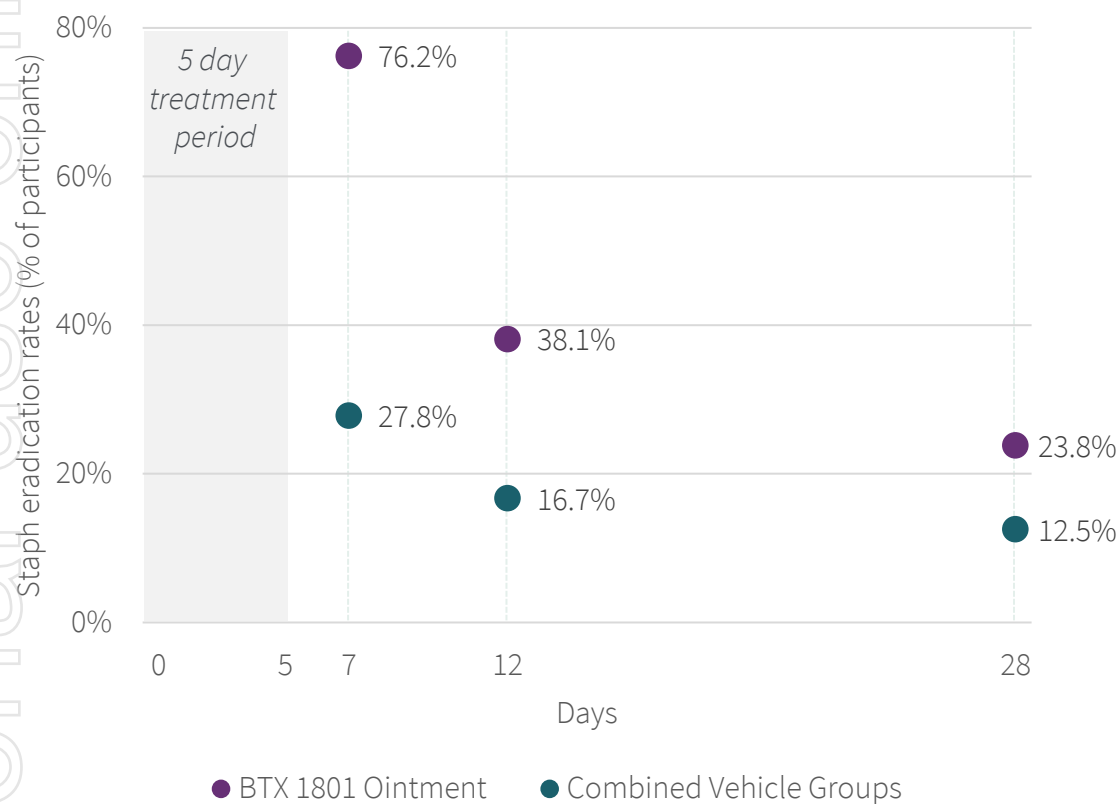
Efficacy

- ✓ Efficacy of ointment and gel formulations demonstrated at primary endpoint of Day 12
- ✓ Eradication rates as high as 76.2% at Day 7, with eradication effects extending through to Day 28, despite no treatment after Day 5

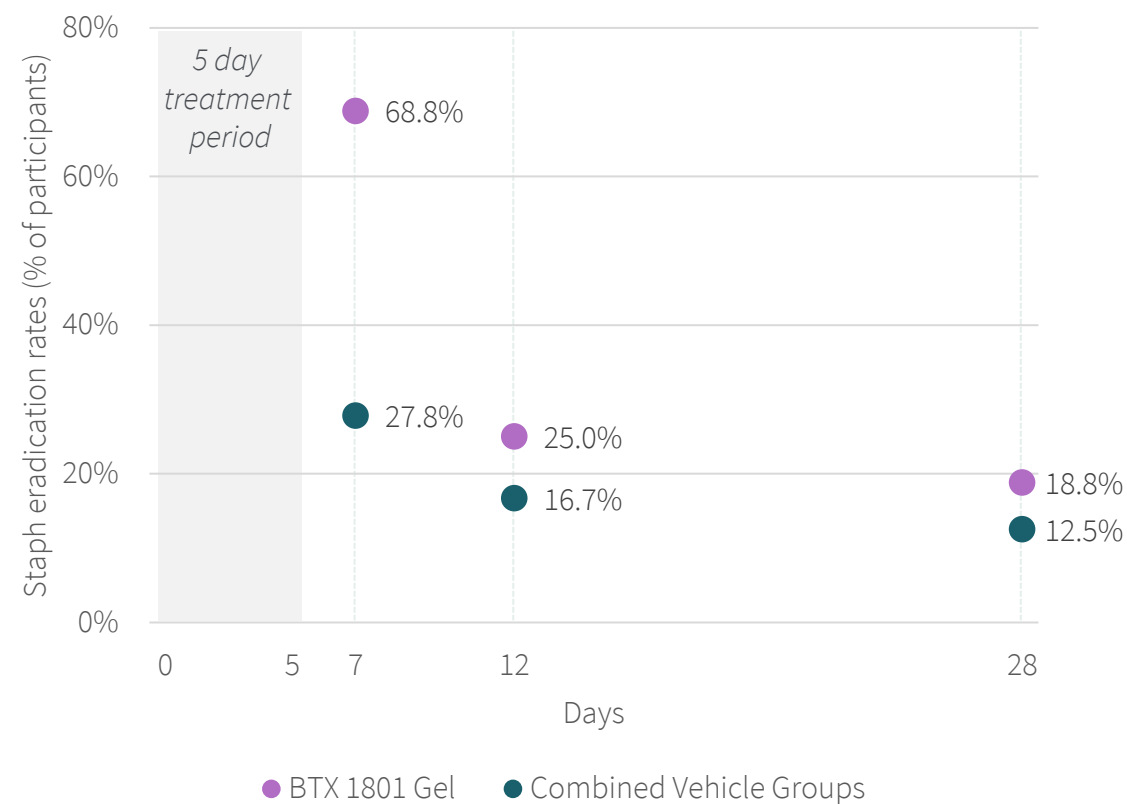
Phase 2a study data: staph eradication

World first human data demonstrating synthetic CBD has clinical utility as an antimicrobial agent

BTX 1801 Ointment: Staph eradication rates (% of participants)¹

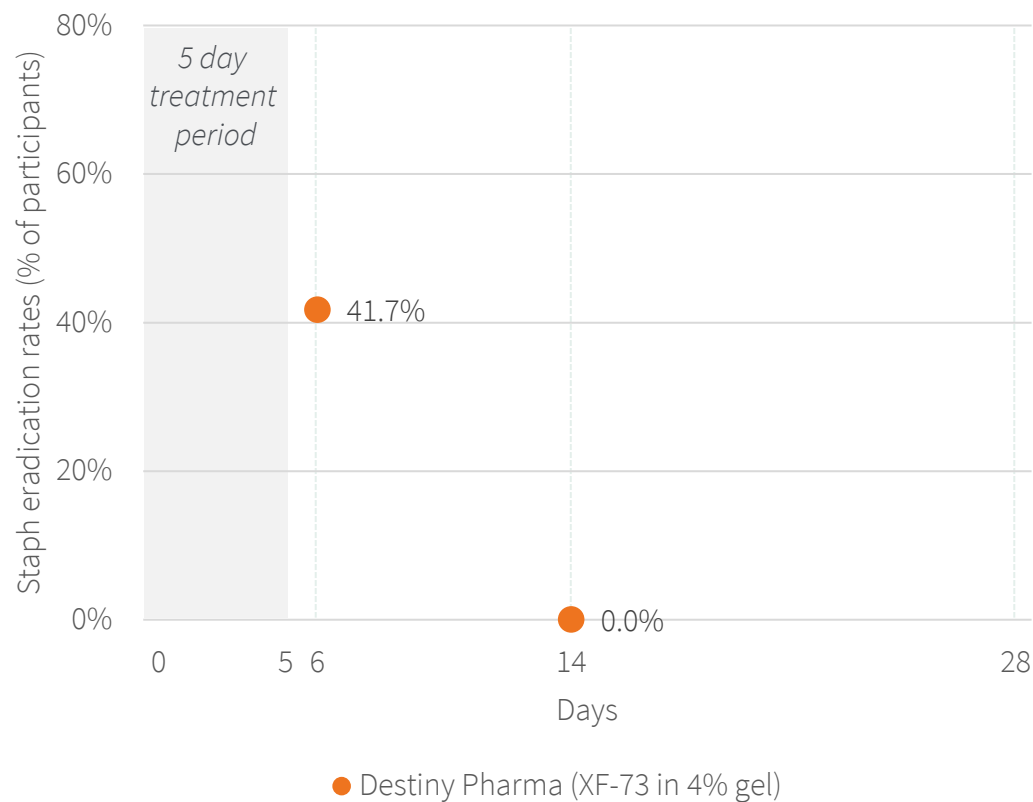


BTX 1801 Gel: Staph eradication rates (% of participants)¹



Phase 2a study data: context

Destiny Pharma (XF-73): Staph eradication rates (% of participants)¹



- ❖ Destiny XF-73 study examined eradication at day 6 (i.e 1 day after treatment period) and Day 14 (9 days after treatment period)
- ❖ Like most comparative studies, Destiny XF-73 study included full body chlorhexidine wash during the 5-day treatment period to remove reservoirs of bacteria (helps prevents recolonisation)
- ❖ BTX 1801 Phase 2a study did not include this wash protocol

Significant upside potential– Multiple AMR Opportunities

- ❖ **Dialysis related infections**
from catheter usage
- ❖ **C. Diff (Clostridium Difficile)**
causes diarrhea and colitis
- ❖ **N. Gonorrhoeae (Gonorrhea)**
re-emerging STD with significant AMR challenges
- ❖ **N. meningitidis (Meningitis)**
particular risk for infants
- ❖ **Legionella pneumophila (Legionnaires disease)**
severe form of pneumonia



... further novel cannabinoid work underway

- ✓ Awarded Innovation Connection Grant² to accelerate the medicinal chemistry program
- ✓ Medicinal chemistry program being conducted in collaboration with the University of Queensland
- ✓ Targeting creation of new synthetic analogs to improve the efficacy and bioavailability of “natural” cannabinoids
- ✓ New analogs have a unique structure and activity profile and are patentable as new chemical entities
- ✓ Potential in multiple human and animal health applications

Potential for synthetic CBD in dermatology – Safe and effective antimicrobial and anti-inflammatory

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Impetigo



Cellulitis



Folliculitis



Acne

Streptococcus

Bacillus subtilis

S. Aureus

S. epidermis

MRSA.

Corynebacterium minutissimum

Cutibacterium

Erysipelas



Dermatitis



SSI and ulcers



Erythrasma



A close-up, blue-tinted photograph of a microscope. The central focus is on the objective lens, which is positioned above a glass slide. The lens has technical markings: 'HI 100/1,25' and '160/0,17'. The slide is held in place by the microscope's stage. The background is softly blurred, showing other parts of the microscope and a person's hand. An orange rounded rectangle is overlaid on the top left, containing white text. A vertical watermark is on the left side.

Other clinical programs for synthetic CBD in dermatology

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BTX 1702: Phase 1b Rosacea Study: commencing 1H 2021



Study design

❖ Four dose groups, ~120 patients:

- BTX 1702 high dose - twice daily: 40 patients
- BTX 1702 low dose - twice daily: 40 patients
- Vehicle - twice daily: 40 patients

❖ Sites: ~12 dermatology sites across Australia and NZ

❖ Patients: adults (18+ years) with moderate to severe papulopustular rosacea

❖ Treatment period: 8 weeks

❖ Screening: facial photos with Canfield imaging

❖ Endpoints:

- Safety and tolerability
- Change in inflammatory lesion counts from baseline at days 15, 29 and 57
- Proportion of patients with Investigator's Global Assessment (IGA) treatment success
- Change in Clinician's Erythema Assessment (CEA) scale
- Imaging and patient reported outcomes

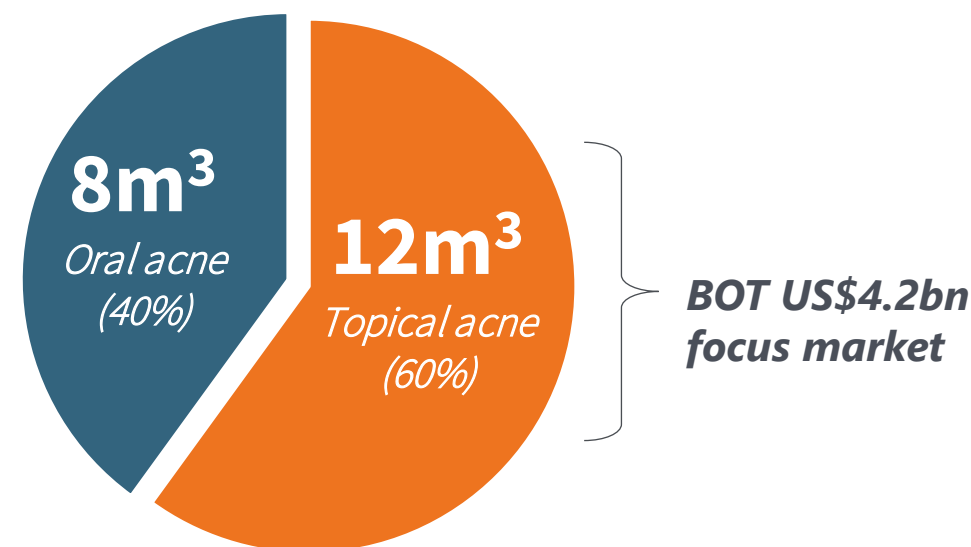
BTX 1503: Successful End-of-Phase 2 FDA Meeting

Study update

- ✓ End of Phase 2 meeting with FDA successfully completed
- ✓ FDA highlighted excellent safety profile of BTX 1503, and allowed several waivers for studies that are typically required for dermatology drug registration
- ✓ Co-primary efficacy endpoints¹ agreed for Phase 3 studies
- ✓ Confirmed drug development plan to support registration of BTX 1503 for treatment of moderate and severe acne
- ❖ Planning underway for Phase 3 clinical studies to be informed by completion of BTX 1702 Phase 1b study and lifting of COVID-19 restrictions

Sizable acne prescription market

The global acne market expected to reach US\$7bn by 2024²



Executing on Key Near-Term Milestones

❖ **Antimicrobial:** BTX 1801 Phase 2a study completion
Positive results announced

❖ **Rosacea:** BTX 1702 Phase 1b study start
Targeting study start in 1H CY2021

❖ **Acne:** BTX 1503 planning for Phase 3 clinical studies
Pending completion of BTX 1702 Phase 1b clinical study

Strong cash position - ~A\$26.0m

As at 31 December 2020 (including R&D tax return ~A\$6.9m)



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