

ASX/Media Release

19 October 2018

Botanix presents at Fall Clinical Dermatology Conference

Philadelphia PA and Sydney Australia, 19 October 2018: Medical dermatology company Botanix Pharmaceuticals ("Botanix" or "the Company") is pleased to release an updated presentation for the annual Fall Clinical Dermatology Conference, held in Las Vegas on 18-21 October 2018.

Botanix will provide an update on progress across its portfolio, including the Company's acne, atopic dermatitis, psoriasis and antimicrobial programs. The presentation includes new data on the Permetrex™ skin delivery technology, where Botanix has compared the amount of cannabidiol that is delivered by its BTX 1503 acne formulation, against competing cannabidiol formulations at much higher doses.

The BTX 1503 Permetrex™ formulation at only 5% cannabidiol concentration was able to deliver much more active cannabidiol to the target layers of the skin, than comparative formulations that contained 10% (2x) and even 20% (4x) cannabidiol concentrations in alternative delivery systems. This new data provides additional validation of the superior drug delivery capabilities of the Permetrex™ technology and supports the potential of BTX 1503 to supply therapeutic levels of cannabidiol to relieve the burden of acne, for millions of patients worldwide.

The conference also provides the Company with an opportunity to engage with potential prospective partners, market leading pharmaceutical companies, and world class researchers that have an interest in dermatological treatments.

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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, psoriasis, atopic dermatitis and other skin conditions. The active ingredient contained in Botanix products is a synthetic form of a widely studied natural compound. 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 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 successful acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 clinical trial in June 2018 with completion expected in mid-2019. The Phase 1b BTX 1204 atopic dermatitis patient study successfully concluded in June 2018 and preparation is underway for a Phase 2 clinical trial. The Phase 1b BTX 1308 psoriasis patient study is planned to be completed in Q1 CY2019.

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



Fall Clinical presentation

October 2018

Agenda

1. Executive summary
2. Cannabidiol – target drug with significant potential
3. Phase 2 products – BTX 1204: atopic dermatitis and BTX 1503: acne
4. Pipeline products – BTX 1308: psoriasis and BTX 1801: antimicrobial
5. Outlook



1. Executive summary



Key investment highlights

Botanix is an emerging global **dermatology company** with advanced clinical programs and an exciting pipeline



Dermatology Focused

Advanced clinical programs targeting multi-billion dollar prescription markets for **atopic dermatitis, psoriasis** and **acne**



De-risked drug active

Products use a synthetic form of an FDA approved natural product - **greatly enhances the probability of success**



Clinical Stage

Successful clinical data from acne and atopic dermatitis patient studies, shows industry leading performance, after only 4 weeks of treatment



Novel Approach

Novel skin delivery system - **Permetrex™** - **greatly improves delivery of drug to the skin** compared to traditional approaches



Experienced Team

Predominantly US based leadership team with **20+ FDA approvals** between them and extensive dermatology industry experience

Clinical programs with near term milestones

Rapidly advancing acne and atopic dermatitis programs, with deep pipeline in development and Permetrex™ collaborations to augment revenue and news flow

Product candidate		Indication	Pre-Clin	Ph 1	Ph 1b	Ph 2	Next milestones
Synthetic form of natural product extract – cannabidiol	BTX 1503	Moderate to Severe Acne					Phase 2 clinical trial underway Data available mid-2019
	BTX 1204	Atopic Dermatitis					Phase 2 clinical trial pending IND Prep 3Q CY2018
	BTX 1308	Psoriasis					Phase 1b patient study pending Ethics approval 3Q CY2018
	BTX 1801	Antimicrobial					Phase 1b patient study Following pre-clin work 4Q CY2018
Permetrex™ programs	Internal/ External	Various	Collaborations				Ongoing

2. Cannabidiol

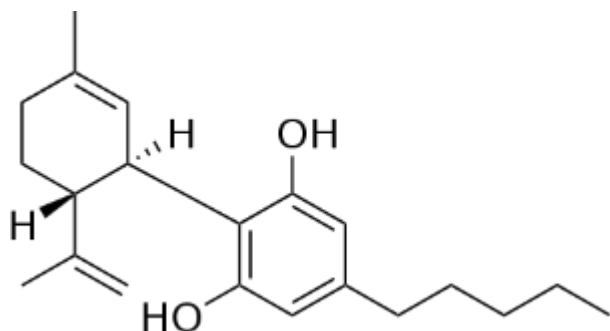
Target drug with
significant potential



Cannabinoids are emerging as a novel class

Cannabinoids are attracting strong interest as their efficacy and safety profiles are validated in clinical studies

Cannabidiol (CBD)



- One of ~ 113 cannabinoids identified in the *cannabis sativa* plant
- Accounts for up to 40% of natural plant extract
- Not psychoactive, nor addictive – does not convert to THC *in vivo*
- Broad MOA including CB1/2, immune response and inflammatory pathways

Significant clinical trial interest

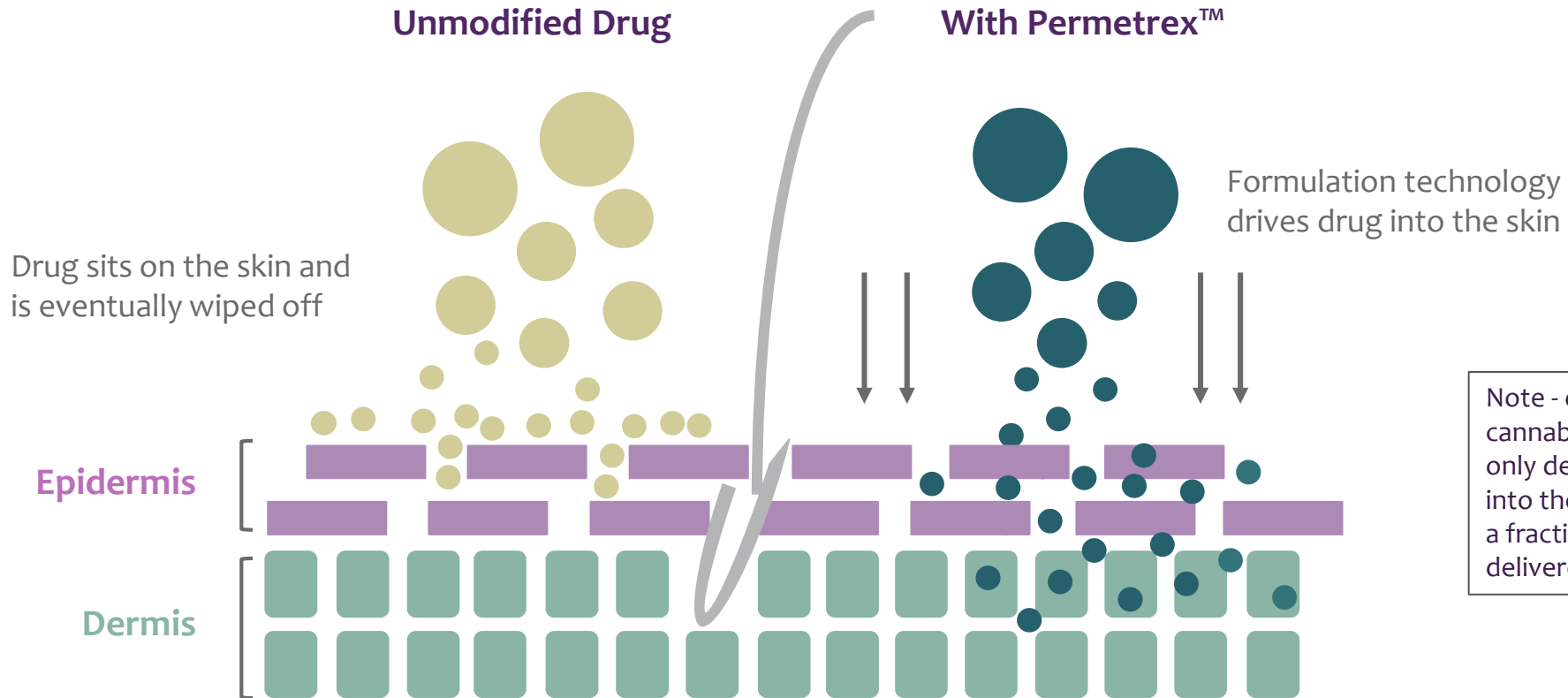


- 38 Epilepsy
- 15 Pain
- 6 Cancer
- 17 Multiple Sclerosis
- 9 Schizophrenia
- 53 Other

Only 1 trial in dermatology (Botanix)

Permetrex™ skin delivery technology

Proprietary Permetrex™ technology delivers high doses of drug into the layers of the skin without use of permeation enhancers, or the use of irritating alcohol/petrolatum additives



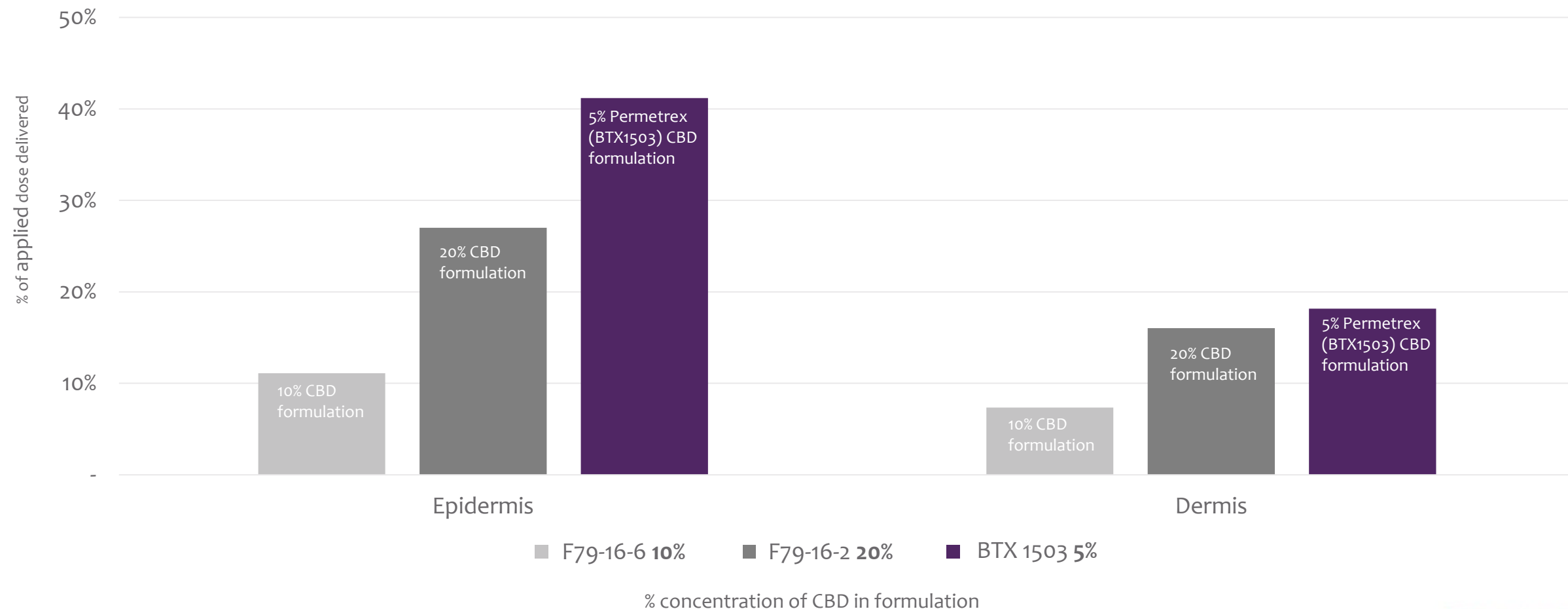
Note - oral administration of cannabidiol (oils and capsules) only delivers ~6% drug active into the blood stream and only a fraction of *that* amount is delivered into the skin

Botanix holds the **exclusive rights** to utilise Permetrex™ for all drugs that treat skin diseases

Permetrex™ technology enables superior delivery of cannabidiol

Permetrex delivers more much more cannabidiol (CBD) into the target layers of the skin, even though the CBD concentration of the BTX 1503 formulation is only ¼ to ½ the concentration of alternative formulations

Cannabidiol (CBD) percentage delivery (%)¹



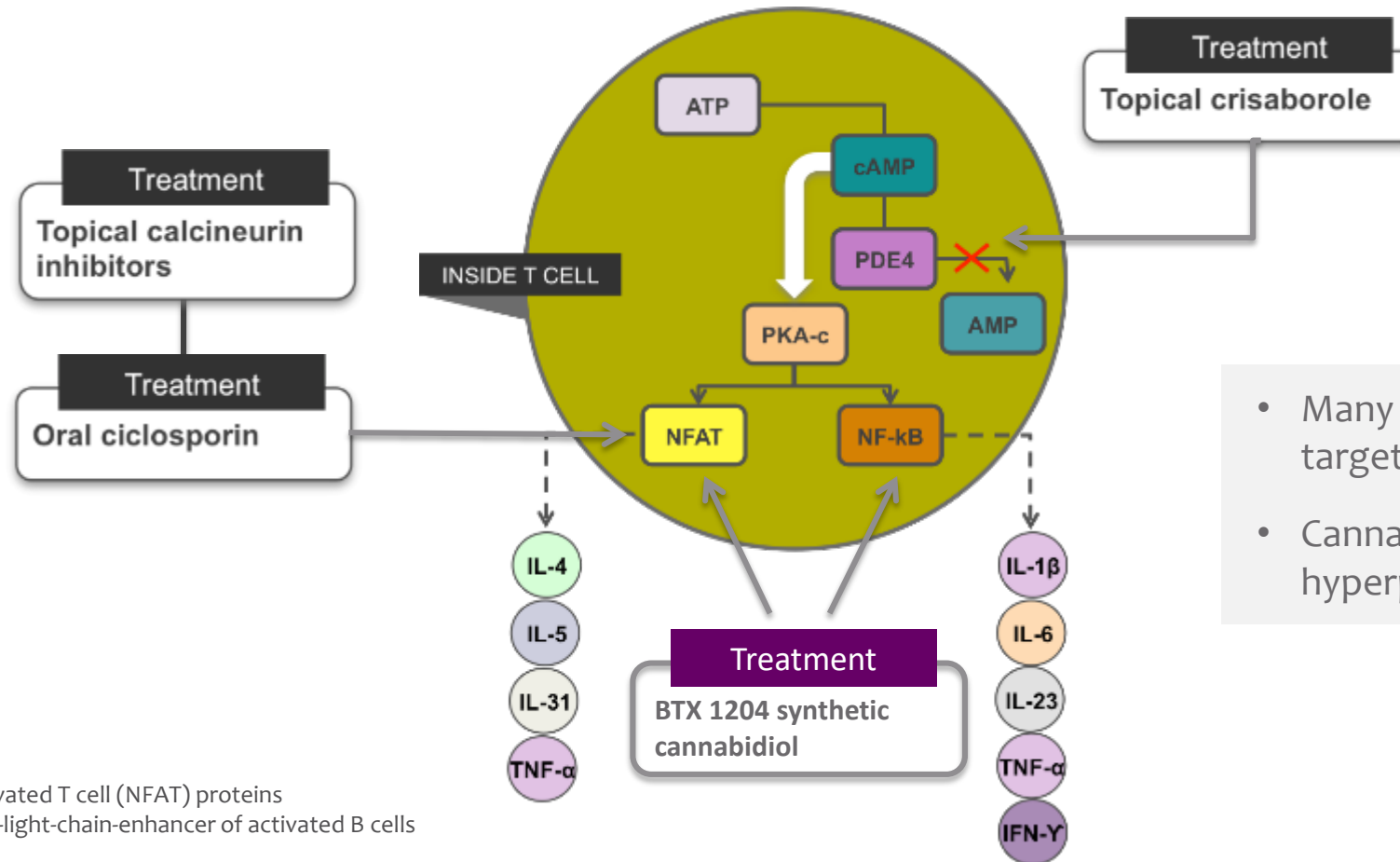
3. Phase 2 products

BTX 1204: atopic dermatitis

BTX 1503: acne

BTX 1204: atopic dermatitis – cannabidiol mechanism of action (MOA)

Atopic dermatitis (AD) and psoriasis are both T-cell mediated inflammatory diseases of the skin. Cannabidiol has been shown to inhibit immune responses via T-helper cell populations (including Th17, Th1 and also Th2) and to a decrease of IFN- γ amongst others

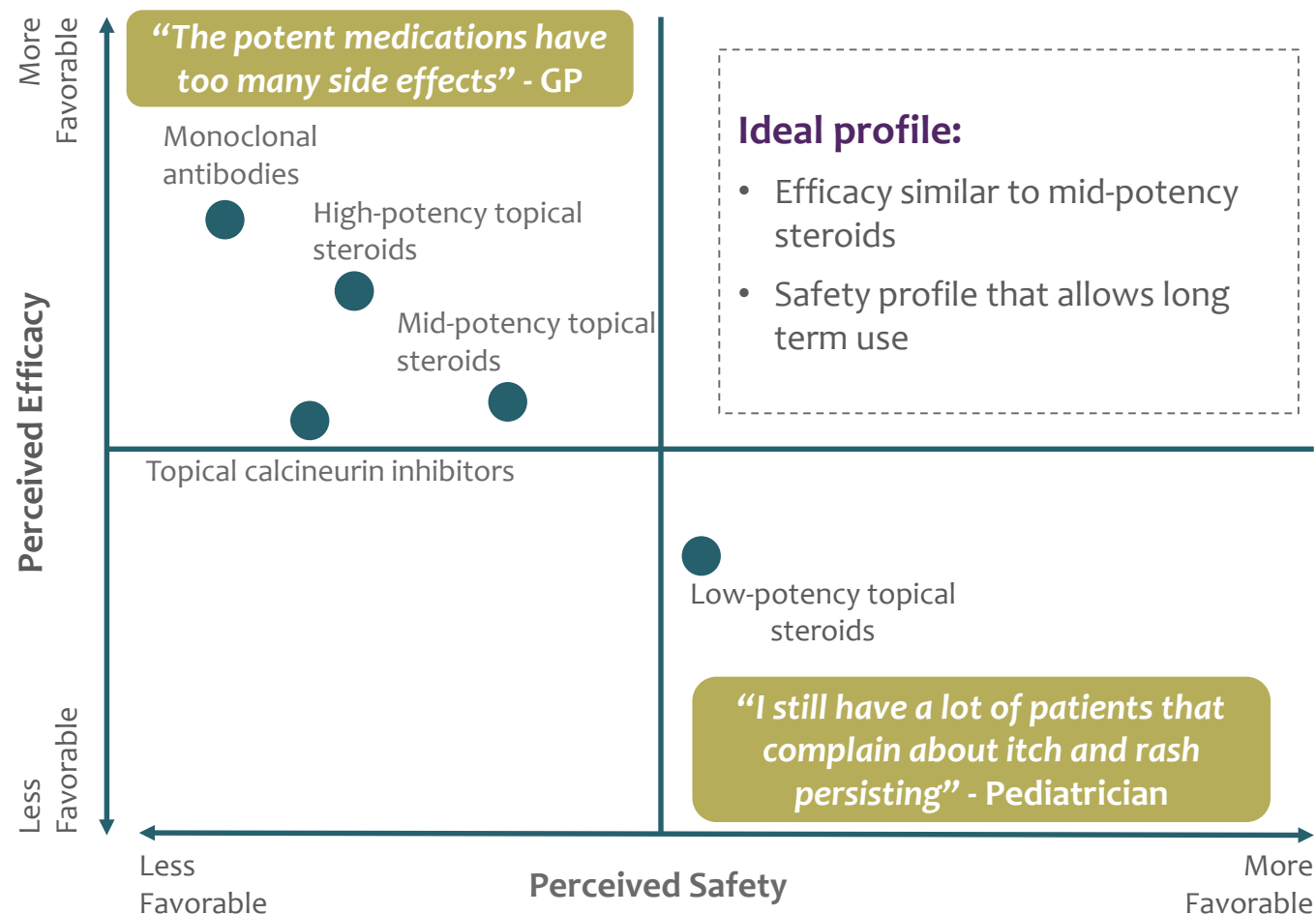


- Many existing AD treatments are targeted upstream of NFAT and NF-kB
- Cannabidiol also inhibits keratinocyte hyperproliferation

NFAT = Nuclear factor of activated T cell (NFAT) proteins
NF-kB = Nuclear factor kappa-light-chain-enhancer of activated B cells

BTX 1204: atopic dermatitis – positioning and opportunity

Botanix is targeting efficacy improvements with an improved safety profile, with new benefits in inflammation and itch reduction



BTX 1204 has shown potential to meet a number of unmet needs:

- ✓ Non-steroidal treatment option
- ✓ Potential impact of itch
- ✓ Improved safety profile and elimination of severe adverse side effects
- ✓ Ability to use long term (>12 weeks)
- ✓ Address underlying inflammation
- ✓ Correct skin barrier dysfunction
- ✓ Greater cost effectiveness

BTX 1204: atopic dermatitis – Phase 1b study design

Successful 4-week treatment period, double-blind, vehicle controlled patient study concluded in late May 2018

Design

- ~36 subjects 18 years and older (24 active / 12 vehicle)
- 4 Australian dermatology sites
- BTX 1204 solution BID applied topically
- At least 1 lesion (25 to 200 cm²), on the trunk upper or lower extremities
- Signs of AD score ≥ 6 and ≤ 12
- Investigator's Static Global Assessment (ISGA) of mild (2) or moderate (3)

Endpoints

- Primary endpoints:
 - safety – AEs, labs, local tolerability and signs of atopic dermatitis
- Exploratory endpoints:
 - ISGA
 - target lesion size

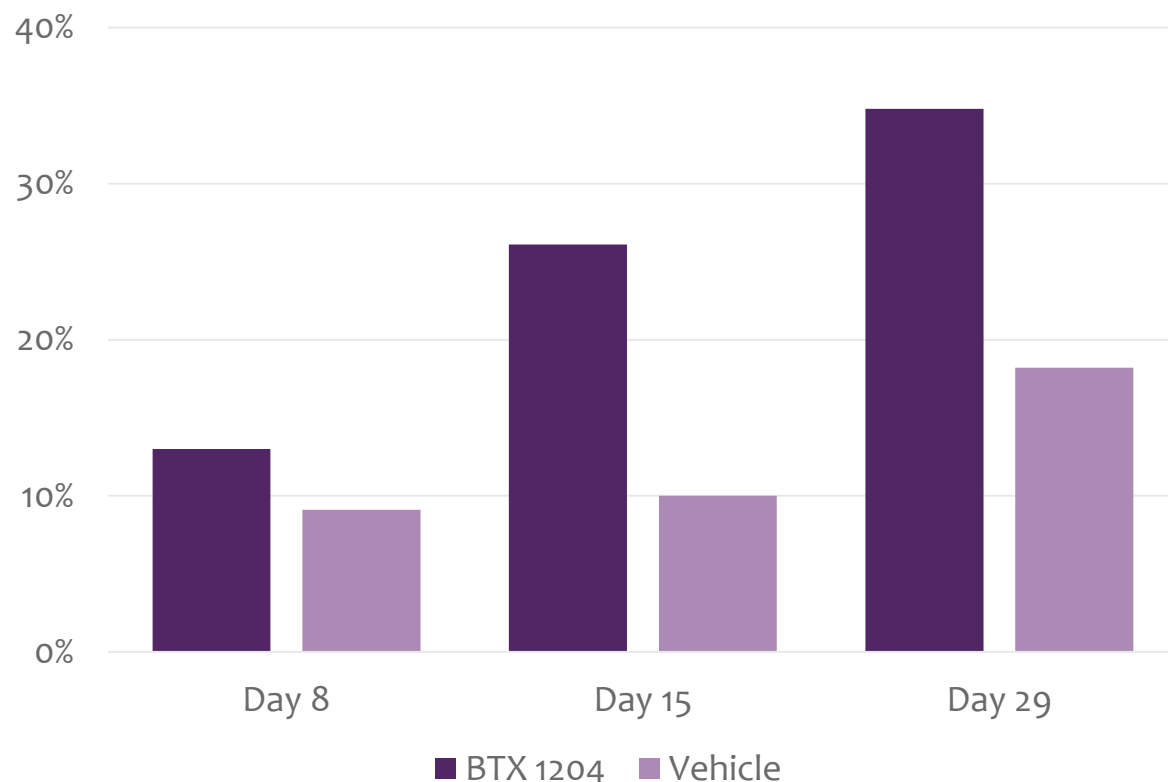


Study successfully completed in Q2 CY2018

BTX 1204: atopic dermatitis – Phase 1b study results

After only 4 weeks of treatment, study data indicated BTX 1204 was twice as effective over the vehicle (with efficacy still increasing) and substantial improvement in the key signs of AD observed

Treatment success (%)¹



Key takeaways

Efficacy still increasing at 4 week timepoint

- Achieved treatment success similar to many competitive topical products at the end of their peak treatment period
- Data suggests longer treatment period for BTX 1204 possible for increased efficacy, potentially to exceed industry performance

Clear separation from vehicle (placebo)

- Despite being a small study, BTX 1204 shows superiority over vehicle, starting at early time points
- First vehicle-controlled study for Botanix, which also supports potential for other pipeline products

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

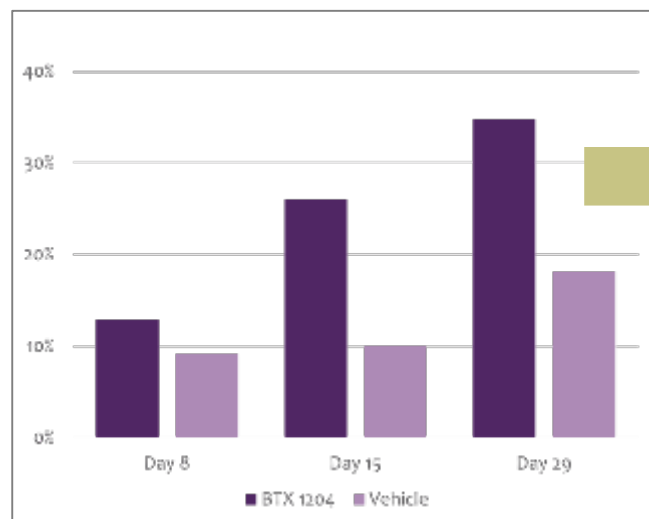
Notes: Results indicated substantial reduction in key signs of AD, providing confidence that unmet needs in AD can be addressed - more detailed results on slide 33

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

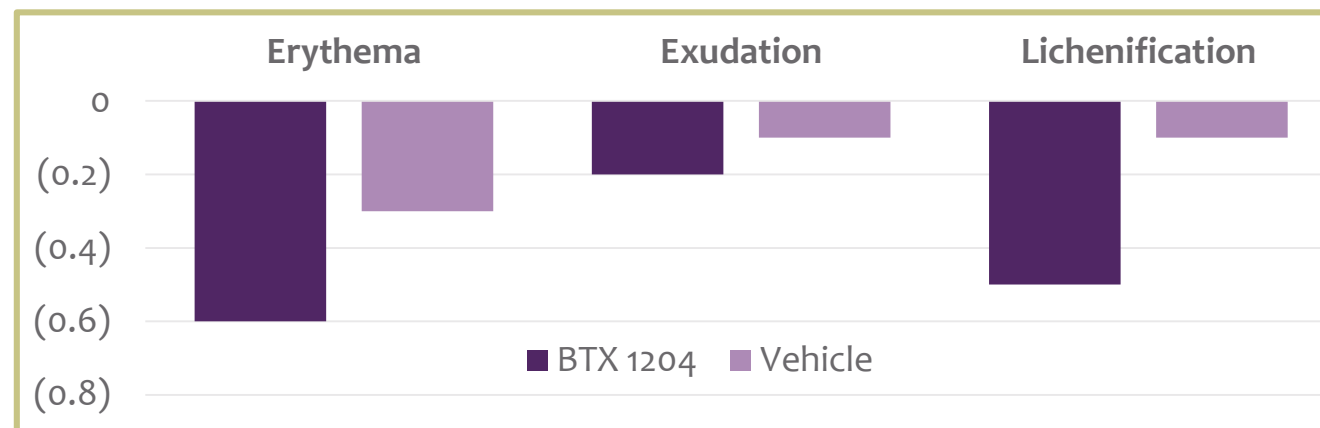
BTX 1204: atopic dermatitis – Phase 1b study results

Substantial reduction in key signs of AD, provides confidence that unmet needs in AD (itch / inflammation) can be addressed

Treatment Success¹



Substantial reduction in the key signs of AD²



Erythema: inflammation, common clinical manifestation of several skin diseases, including acne and rosacea

Exudation: ooze from lesion, associated with inflammation / infection

Lichenification: thickening of the skin in response to itching

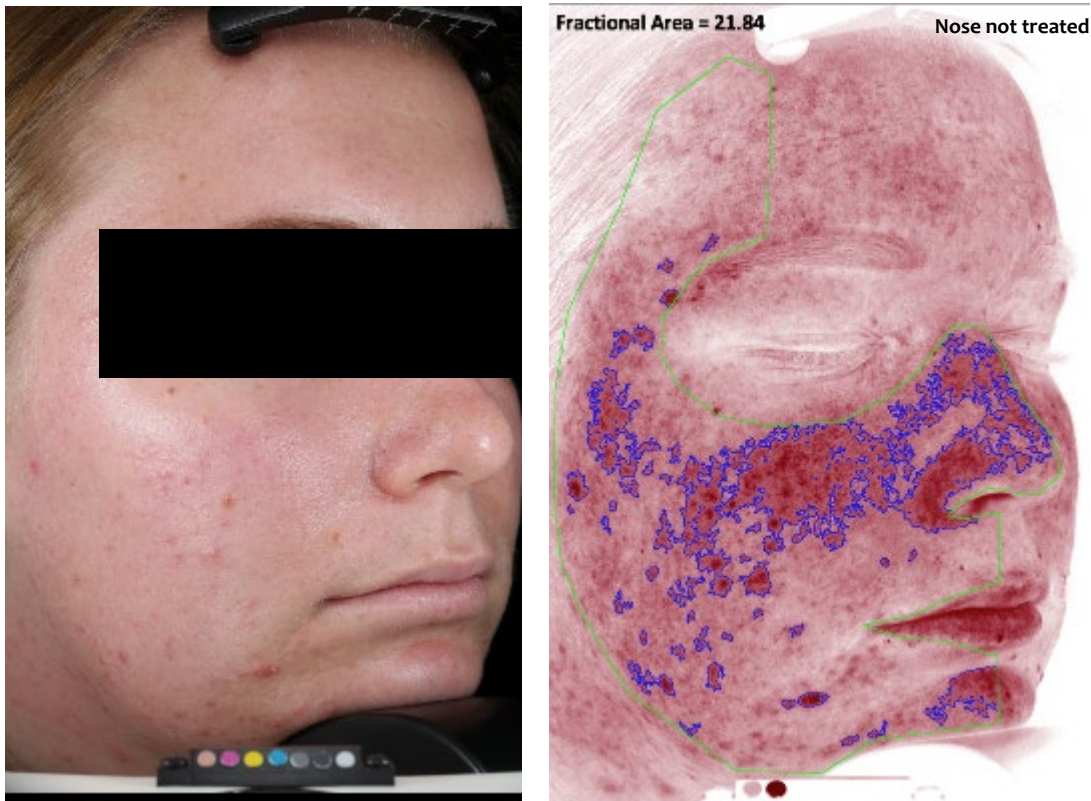
1. Treatment success defined as a greater than, or equal to, a 4 point improvement in the signs and symptoms of AD

2. Based on improvement in average score ratings from baseline to Day 29

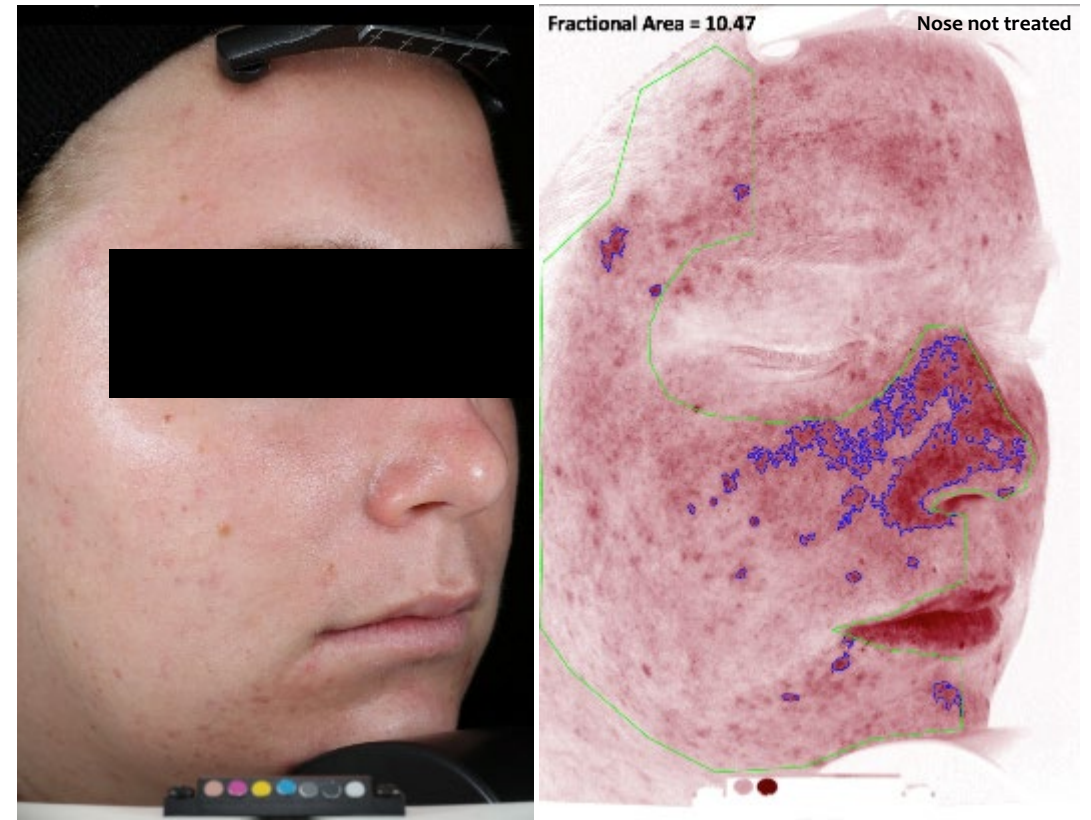
New data supporting anti-inflammatory effects of cannabidiol

Newly processed images from the Phase 1b acne patient study, demonstrate deep penetration of cannabidiol into the skin and a clear anti-inflammatory effect and improvement over the treatment course (4 weeks)

Baseline (0 days)



Visit 4 (28 days)



BTX 1204: atopic dermatitis – Phase 2 study design

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

Design

- 2 dose groups: ~200 subjects
 - BTX 1204: ~100 subjects
 - Vehicle/Control: ~100 subjects
- ~25 US and Australian dermatology sites
- Adolescents and Adults
- Moderate AD patients

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
 - Eczema Area Severity Index (EASI) Score
 - % body surface area (BSA) affected by AD
 - time to achieve IGA success
- Safety
 - adverse events and local tolerability

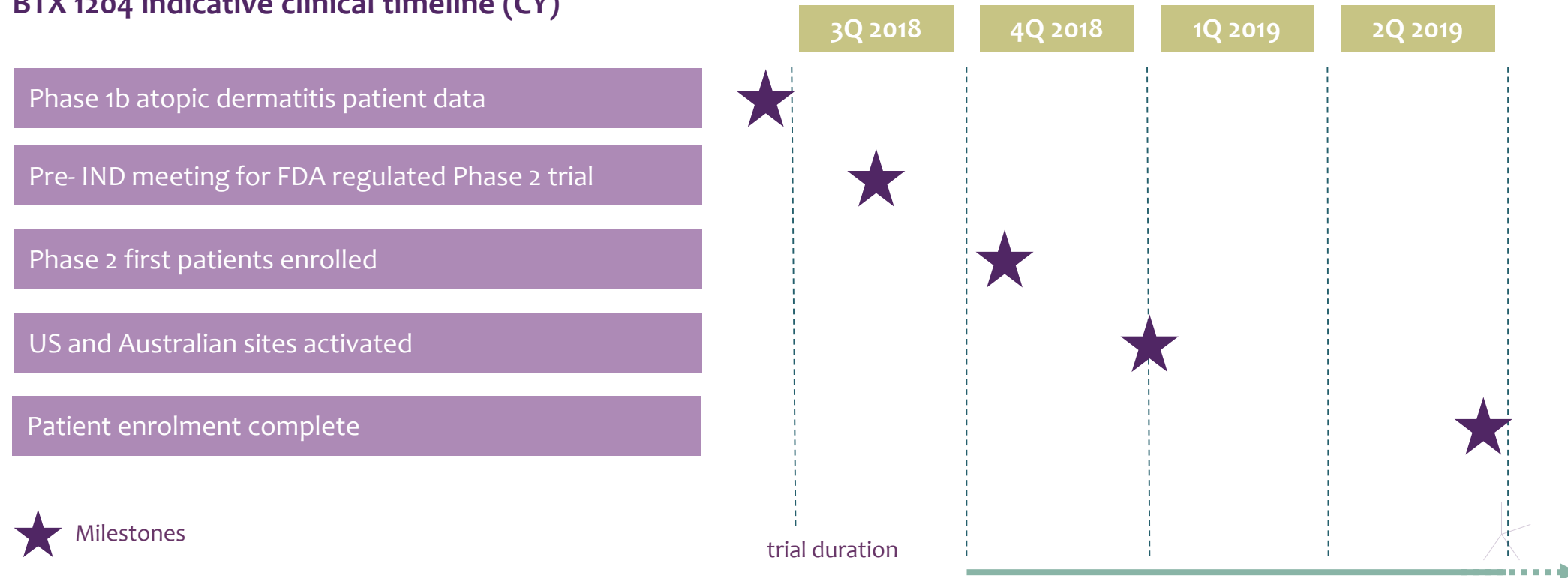
First patients in Q4 CY2018 – fully funded

BTX 1204: atopic dermatitis – next steps

Botanix is pursuing a rapid clinical development strategy to accelerate product commercialisation and timing to first revenues

- Development program leverages existing data from BTX 1503 acne studies, so regulatory and safety risk is lowered
- Common usage of DEA licensed dermatology clinics in USA from BTX 1503 acne Phase 2 trial reduces cost and start-up timing

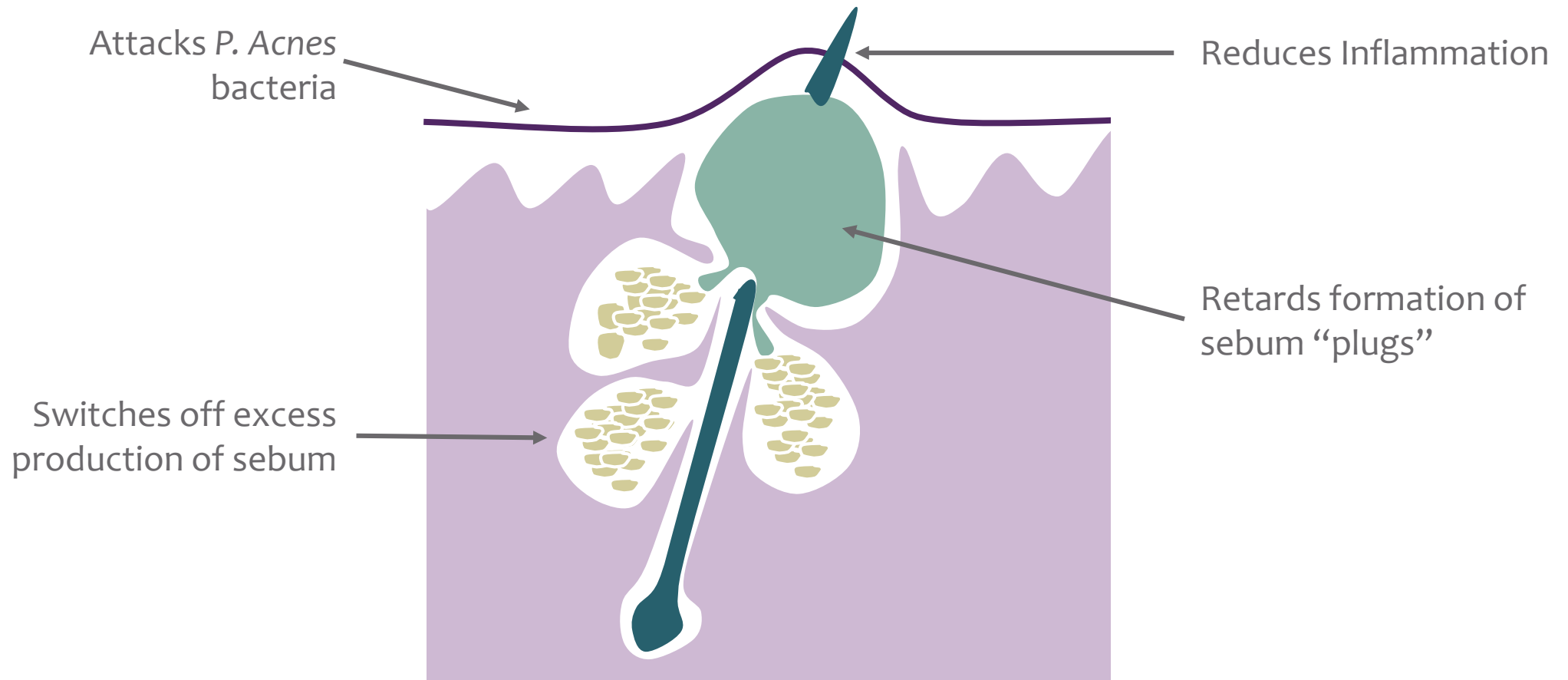
BTX 1204 indicative clinical timeline (CY)



★ Milestones

BTX 1503: acne – MOA for acne

BTX 1503 potentially address all 3 key pathologies of acne with a very safe side effect profile



Source: Cannabidiol exerts sebostatic and anti inflammatory effects on human sebocytes (2014). The Journal of Clinical Investigation

BTX 1503: acne – outperforms leading acne products

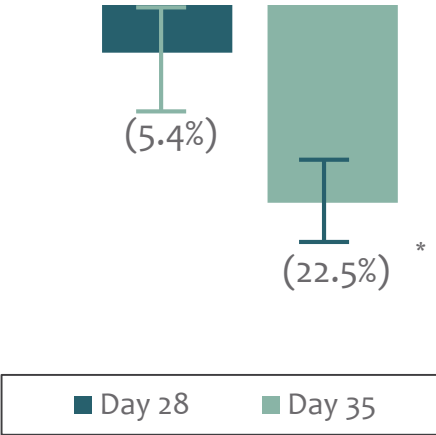
Study data resulted in a reduction in inflammatory lesions greater than any other FDA approved topical acne product after only 4 weeks

Lesion count reduction (%)

Inflammatory lesions






Non-inflammatory lesions



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

Comparison of other FDA approved products

Product	Owner	Lesion count reduction (%) ¹	2016 annual revenue ²
 Epiduo®	Galderma	~42%	US\$494m
 Aczone®	Allergan	~38%	US\$456m
 BTX 1503	Botanix	~47%	-

- Combination of two drugs – benzoyl peroxide and adapalene
- ✗ Common side effects include redness, skin peeling mild burning / stinging and dryness
- ✓ 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

1. Lesion count reduction based on average inflammatory lesion reduction at 4 weeks
2. Based on 2016 annual revenue in the US
3. Patient demographics: 21 year old female

BTX 1503: acne – Phase 2 study overview

12-week randomised, treatment-blinded, 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
- Moderate to severe acne patients

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

Commenced July 2018 (~12 months duration) – fully funded

BTX 1503: acne – next steps

Botanix is pursuing a rapid clinical development strategy to accelerate product commercialisation and timing to first revenues

- Phase 2 clinical trial started early 3Q CY2018 and will take approximately 12 months to complete
- Trial designed to deliver data that allows licensing and other corporate opportunities

BTX 1503 indicative clinical timeline (CY)

File IND for FDA regulated Phase 2 trial

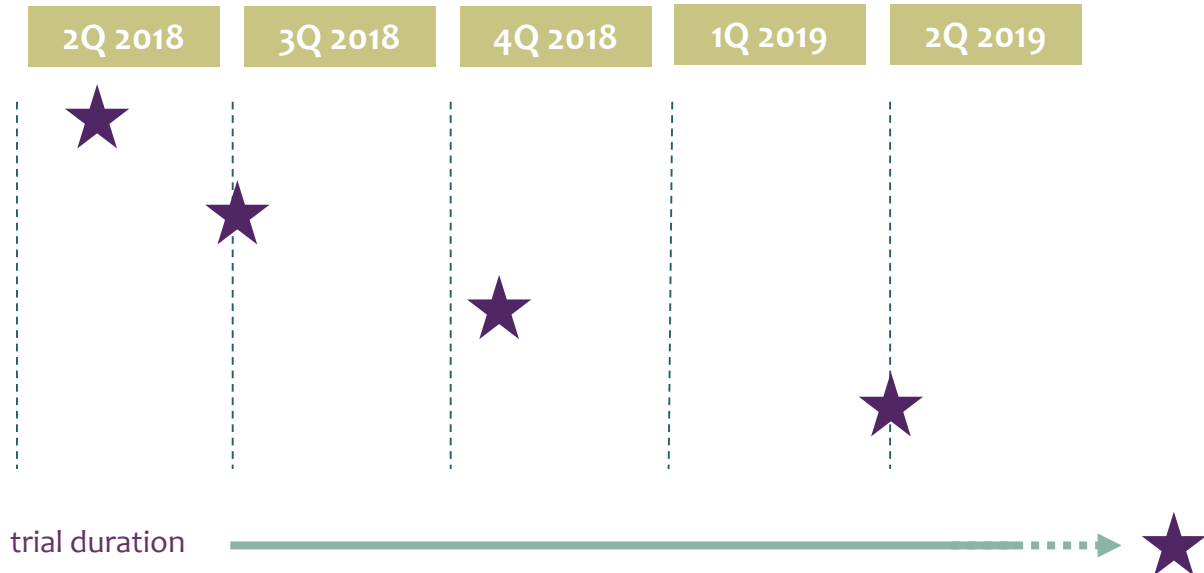
First patient enrolled in Phase 2 trial


US and Australian sites all activated

Patient enrolment complete



Milestones





4. Pipeline products

BTX 1308: psoriasis
BTX 1801: antimicrobial

BTX 1308: psoriasis – overview

Development pipeline also includes other synthetic cannabidiol and Permetrex™ enabled products targeting key dermatology markets

BTX 1308: psoriasis

- **Target market:** ~7.5m Americans have psoriasis (note: most have plaque psoriasis)
- **Market size:** estimated annual costs of injectable biologic treatments in the US is ~US\$20bn p.a.
- **Current issues:** biologic drugs are expensive and have serious side effect issues
- **Unmet needs:** safe and effective topical product for mild to moderate psoriasis



Psoriasis

Botanix is planning a Phase 1b study to commence in late 3Q CY2018



BTX 1308 leverages prior data from:

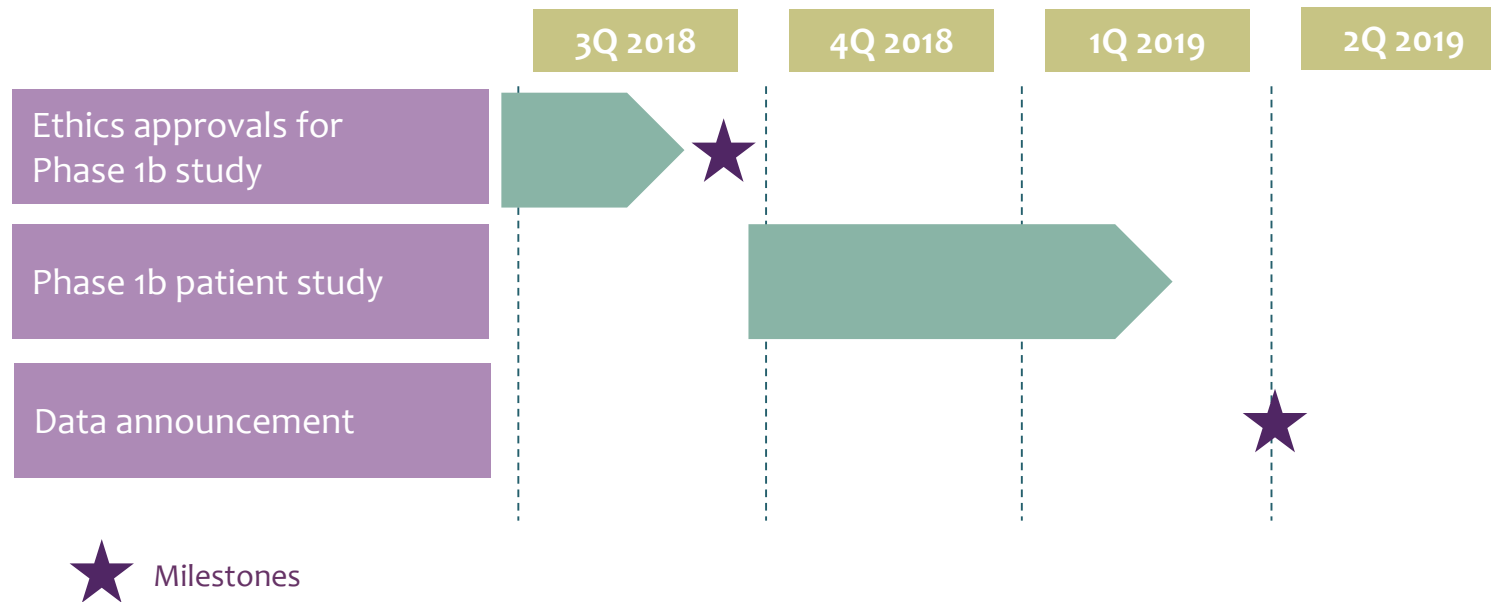
- ✓ BTX 1503 acne clinical program
- ✓ BTX 1204 AD clinical program
- ✓ Permetrex™ technology clinical studies

➡ No need to repeat early studies

BTX 1308: psoriasis – next steps

Botanix is preparing for a Phase 1b study to test BTX 1308 against placebo and another psoriasis drug in patients starting in late Q3 CY2018

BTX 1801 indicative development timeline (CY)

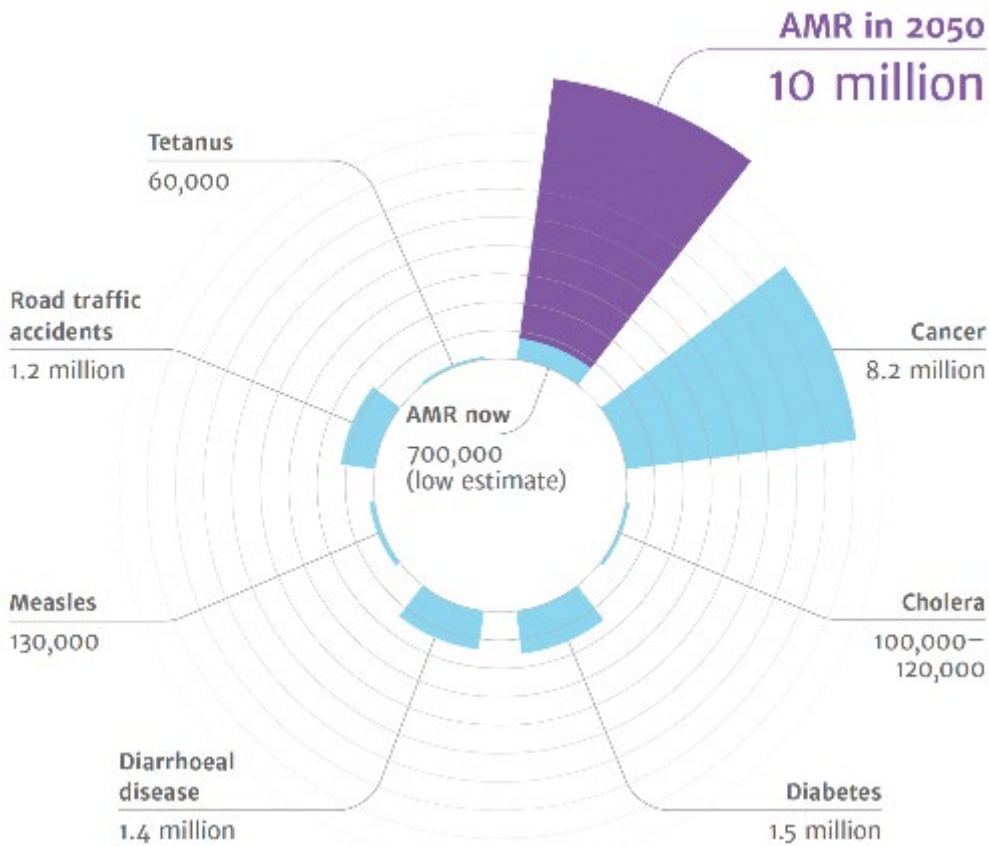


- Development program leverages existing data from BTX 1503 and BTX 1204 programs – no need to repeat early clinical studies and low regulatory risks
- Clinical studies are rapid and provide comparative data to demonstrate efficacy and safety benefits

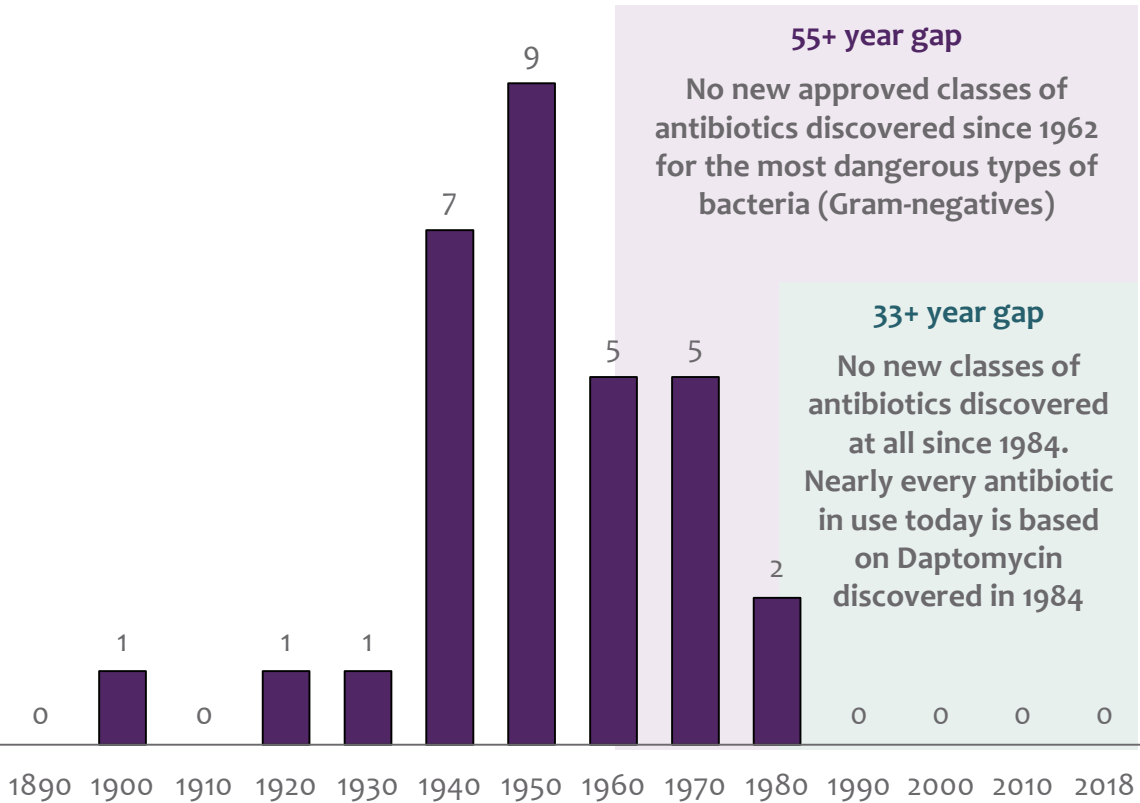
BTX 1801: antimicrobial – the problem of antimicrobial resistance

More than 700,000 people die as a result of antimicrobial resistance globally every year and estimates predict that by 2050, 10m lives p.a. will be at risk. However, no new classes of antibiotics have been approved in 33+ years

Deaths attributable to antimicrobial resistance (AMR)¹



Number of antibiotic classes discovered or patented²



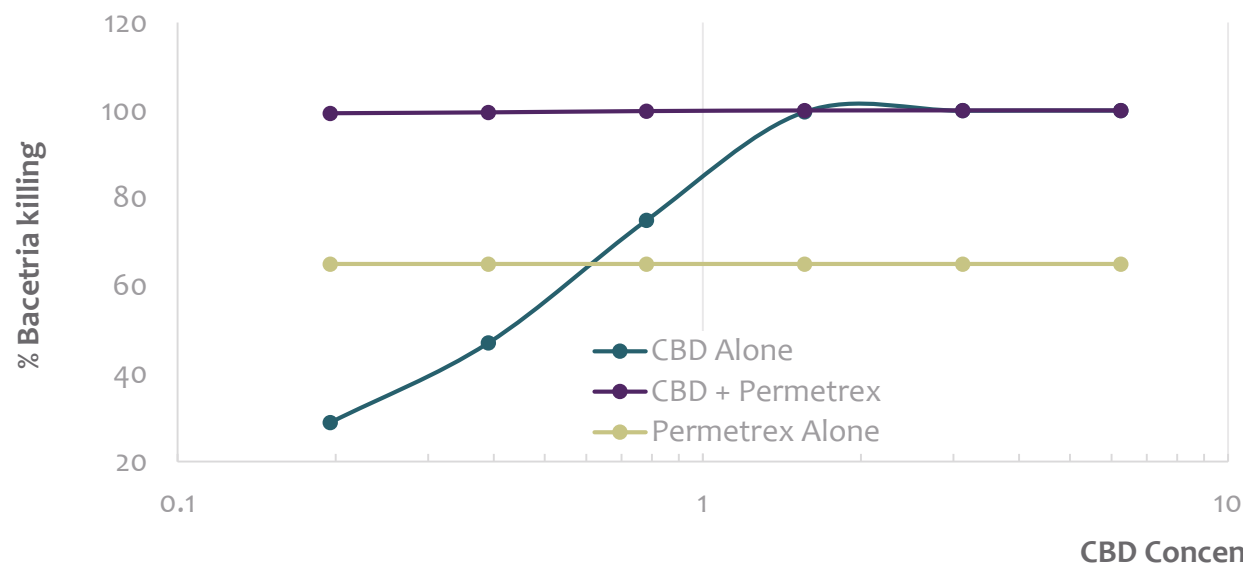
1. Tackling Drug Resistant Infections Globally Final Report and Recommendations (2016), The Review on Antimicrobial Resistance
2. Pew Charitable Trusts; Deak et al. Progress in the Fight Against Multidrug Resistant Bacteria; A Review of FDA Approved Antibiotics 2010-2015. 31 May 2016. DOI: 10.7326/M16-0291

BTX 1801: antimicrobial – Permetrex™ formulation of cannabidiol

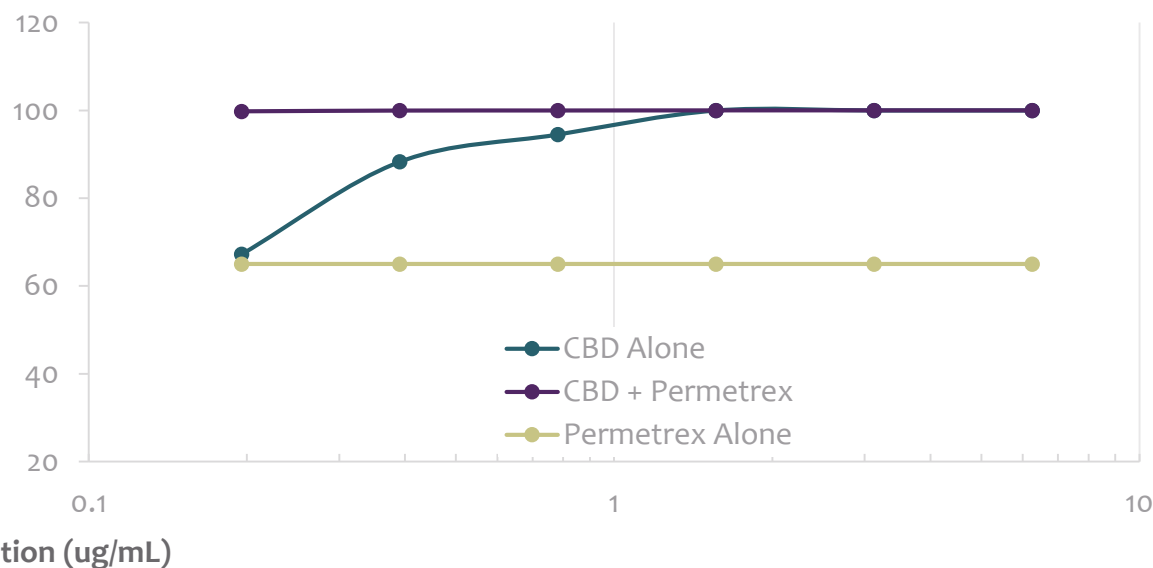
In two of the common antibiotic resistant bacteria strains, Permetrex™ significantly improves the killing power of cannabidiol, to achieve close to 100% bacteria killing effect (at low concentrations)

Summary of data

MRSA Bacteria I



MRSA Bacteria II

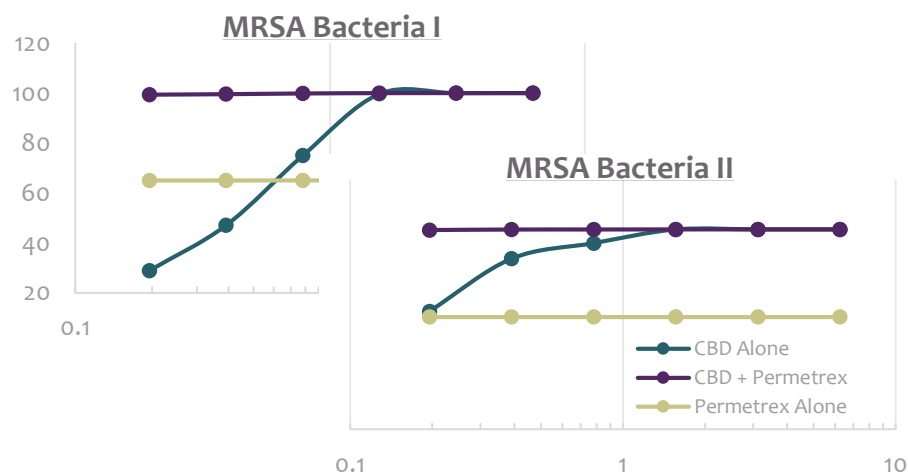


Combination of Permetrex™ and cannabidiol achieved high levels of bacteria killing (at low concentrations) by **allowing the active drug to permeate the biofilm / protective layer** often secreted by bacteria and **killing 99%+ bacteria to substantially reduce potential for resistance development**

BTX 1801: antimicrobial – results summary

BTX 1801 data demonstrates potential for a new antimicrobial to treat unmet needs in skin infections together with additional benefits seen in prior Botanix studies (e.g. reduction in inflammation)

Summary of data



The study results demonstrate that the delivery of cannabidiol with Permetrex™ can reduce the concentration of the active drug required to achieve the highest levels of bacterial killing

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
- ✓ Ability to use long term
- ✓ Anti-inflammatory and skin barrier improvement properties
- ✓ Suitable for treatment of children (due to low toxicity)
- ✓ Prevent early use of IV antibiotics (significant side effects)

Notes: See slide 40 for further information on results/ date



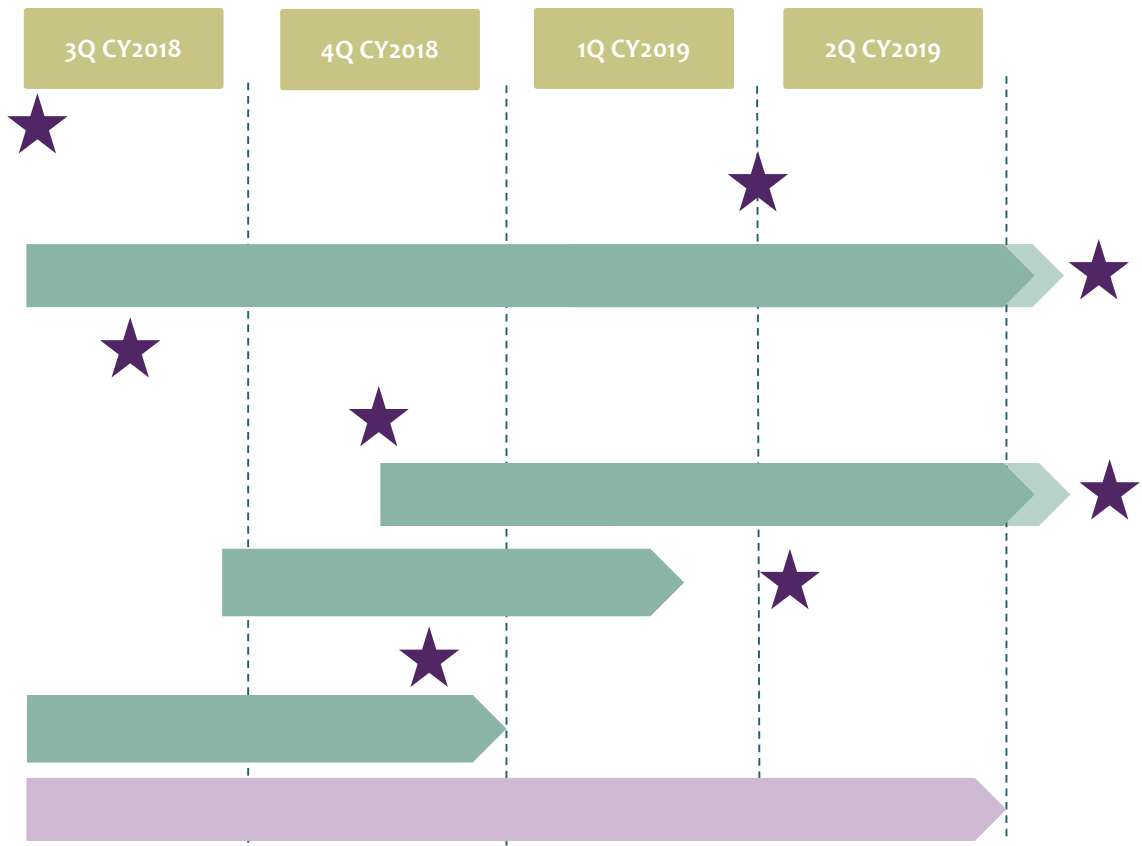
5. Outlook

Key catalysts

Significant clinical and operational milestones across multiple programs expected over the next 12 months

Indicative activities and milestones

Phase 2 BTX 1503 Acne	First patient enrolled in Phase 2 trial
	Patient Enrolment Complete
	Phase 2 multi-centre acne patient clinical trial
Phase 2 BTX 1204 Atopic Dermatitis	Pre-IND Meeting for Phase 2 Trial
	First Patients Phase 2 trial
	Phase 2 multi-centre AD patient clinical trial
BTX 1308 Psoriasis	Phase 1b study in psoriasis patients
BTX 1801 Antimicrobial	Identification of skin disease indication
	Collaboration with University of Queensland
Permetrex™	Research collaborations and partnership discussions



★ Milestones

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