

## ASX/Media Release

7 June 2018

### **BTX 1204 atopic dermatitis study results presentation**

**Philadelphia PA and Sydney Australia, 7 June 2018:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “The Company”) is pleased to release a presentation containing supplementary information on the BTX 1204 atopic dermatitis Phase 1b study results.

#### **Key highlights**

- **Study data indicated BTX 1204 was twice as effective over the vehicle with substantial improvement in the key signs of atopic dermatitis**
- **BTX 1204’s efficacy still increasing at the 4-week timepoint, suggesting a longer treatment period enables BTX 1204 to potentially exceed industry performance**
- **Achieved clear separation from vehicle, with BTX 1204 showing superiority over vehicle at an early stage of the treatment period**
- **BTX 1204 demonstrated an excellent safety profile allowing for extended dosing, which remains a key challenge for other available therapies**

**Botanix Executive Director Matt Callahan said:** “We are extremely pleased with the results of our BTX 1204 atopic dermatitis study after a relatively short treatment period of just 4-weeks. There is potential for BTX 1204 to exceed the performance of other products over a longer treatment period, given efficacy was still increasing at the end of the treatment period along with the excellent safety profile demonstrated by BTX 1204. Further, the substantial reduction in key signs of atopic dermatitis, provides us with the confidence that the unmet needs of itch and underlying inflammation can be addressed.”

#### **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 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 successfully completed its first patient studies with its lead product, BTX 1503 for the treatment of acne, in January 2018 and is now preparing for a 360 patient with BTX 1503, a Phase 2 study commencing mid-2018 with completion expected in mid-2019. The Phase 1b BTX 1204 atopic dermatitis patient study concluded in June 2018. A further Phase 1b BTX 1308 psoriasis patient study is also scheduled to commence in 3Q CY2018.

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

**For more information, please contact:**

**General enquiries**

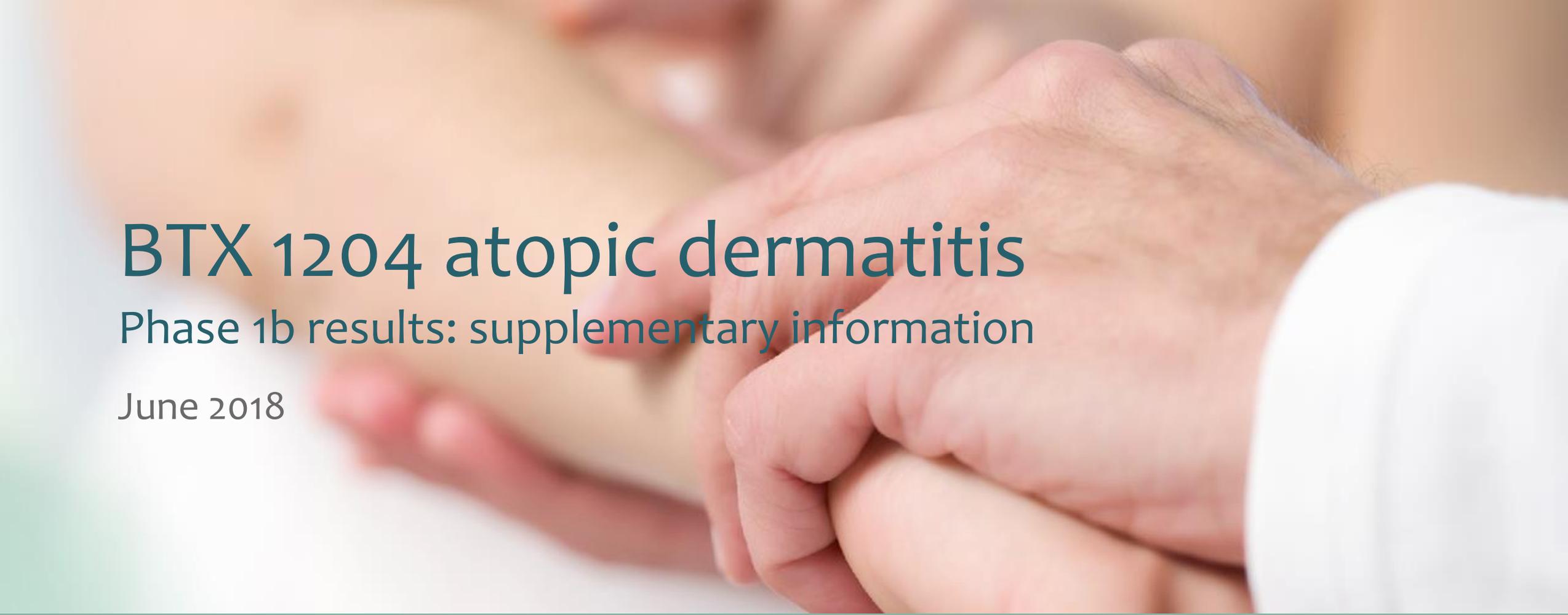
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# BTX 1204 atopic dermatitis

Phase 1b results: supplementary information

June 2018

# Company investment highlights

Botanix is an emerging global dermatology company with 2 advanced clinical programs and a strong pipeline



## Dermatology Focused

Targeting **multi-billion dollar prescription markets for acne** (with no new products approved in the last 20 years) and **atopic dermatitis** (US\$7bn market)



## Clinical Stage

**Successful clinical data** from atopic dermatitis and acne patient studies shows industry leading performance, after only 4 weeks of treatment (with no apparent plateau in efficacy)



## Novel Approach

Products use a synthetic form of a widely studied natural product, **greatly enhances the probability of clinical and regulatory success**



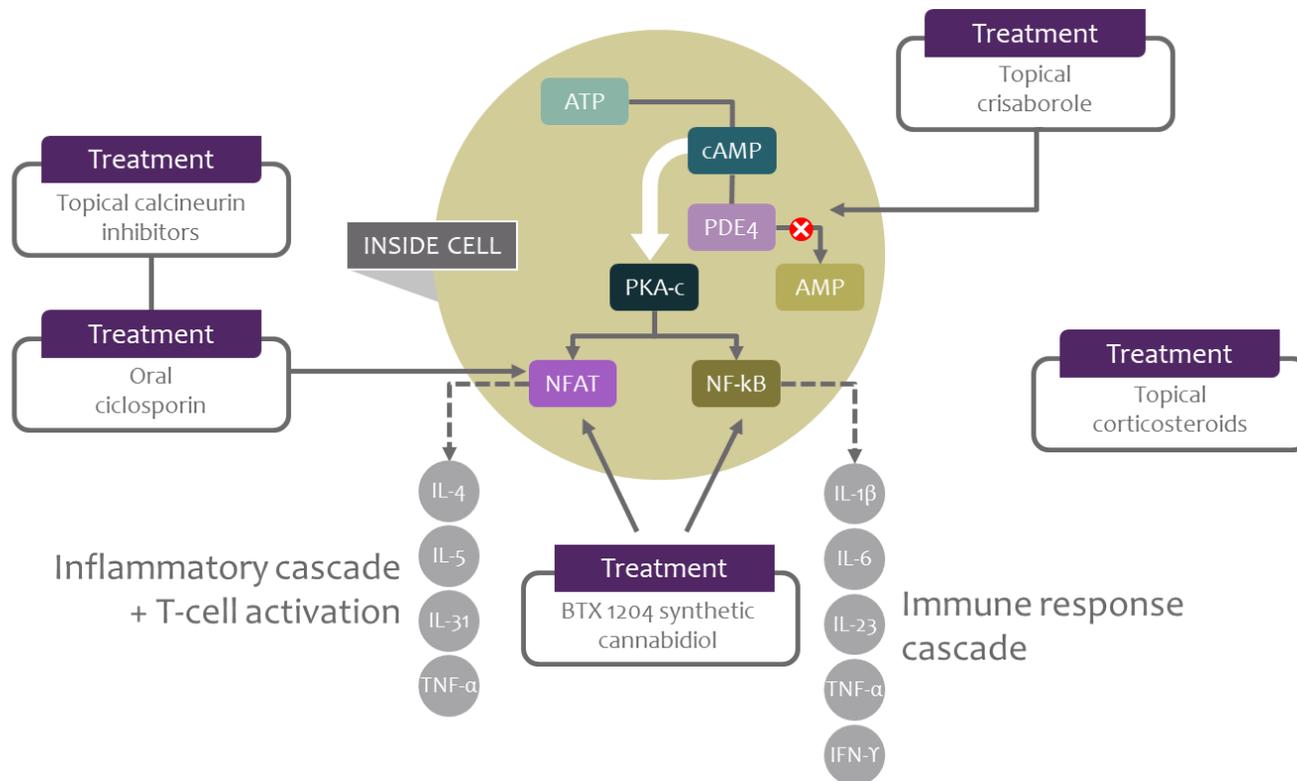
## Experienced Team

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

# Atopic dermatitis disease overview

Atopic dermatitis (AD) is a chronically relapsing skin disorder with an immunologic basis, but for which environmental factors (allergens, stress, food and skin flora) all play a part

## Disease pathology and common treatments



- The exact cause of AD is unknown, but likely a combination of genetic and environmental factors
- AD can begin later in life, but 60% of patients develop the condition in the first year of life, and 90% develop it prior to 5 years of age
- **Commonly reported symptoms of AD are:**
  - Itch
  - Eczematous lesions
  - Xerosis (dry skin)
  - Lichenification (thickening of the skin)

# BTX 1204 Phase 1b atopic dermatitis patient study

Successful 4-week, double-blind, vehicle controlled patient study concluded in June 2018

## Design

- 37 subjects 18 years and older:
  - 25 on BTX 1204 / 12 vehicle
  - 32 patients completed the study
- 4 Australian dermatology sites
- At least 1 lesion (25 to 200 cm<sup>2</sup>), on the trunk upper or lower extremities
- Signs of AD score  $\geq 6$  and  $\leq 12$
- Investigator's Static Global Assessment (ISGA) of mild (2) or moderate (3)

## Endpoints

- Primary endpoints:
  - Safety
  - Adverse effects (AEs), labs, local tolerability and signs of AD
- Exploratory endpoints:
  - ISGA
  - Target lesion size

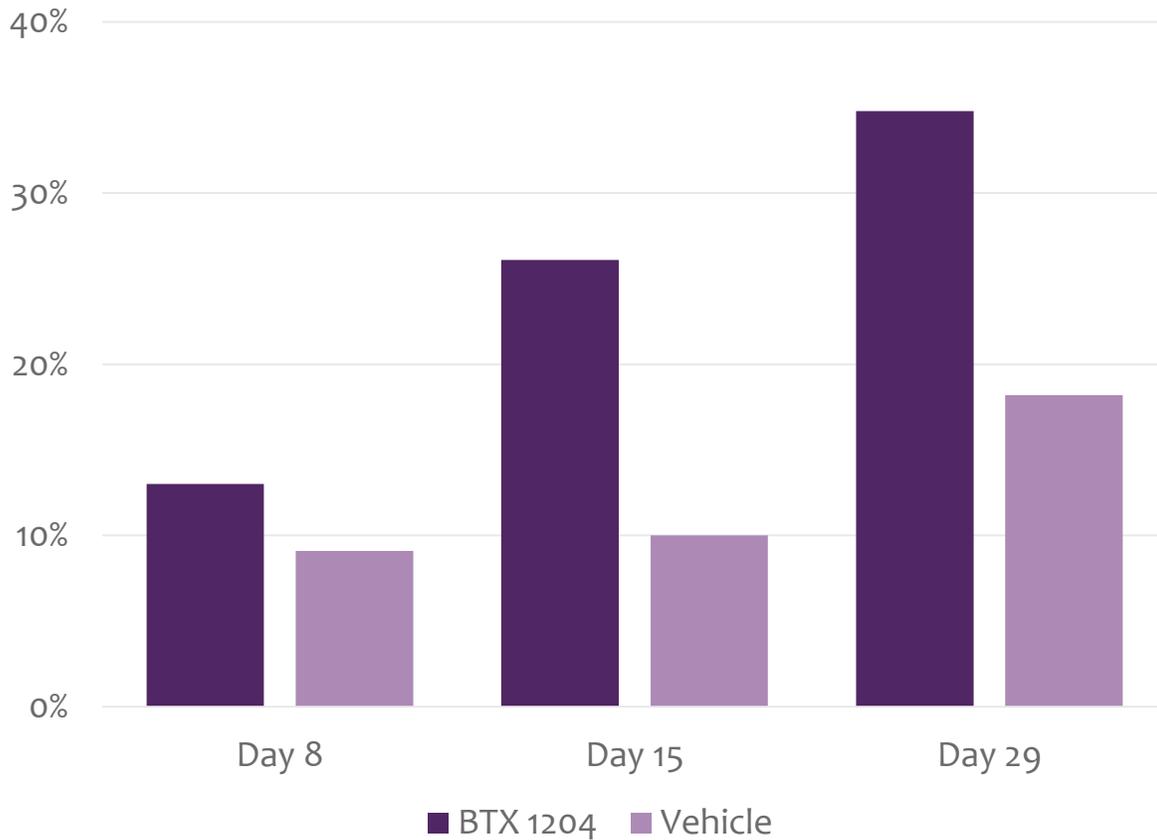


First vehicle (placebo) controlled study for a Botanix product

# BTX 1204 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 (%)<sup>1</sup>



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

## 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

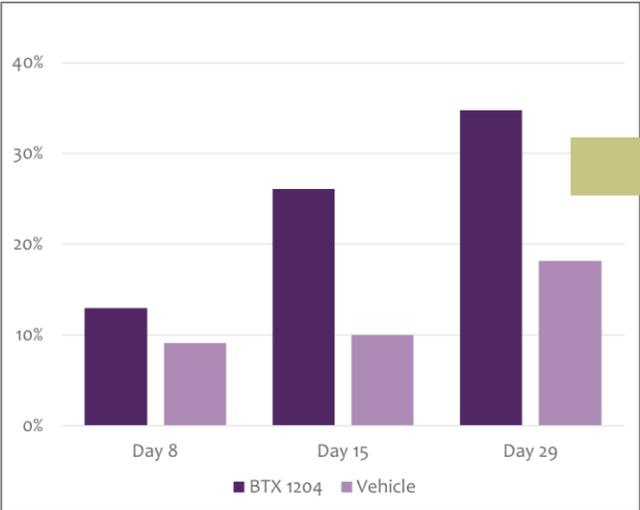
### Excellent safety profile

- Safety and tolerability established with no burning, stinging or application site serious adverse events
- BTX 1204 profile allows extended dosing which remains a key challenge with most available therapies

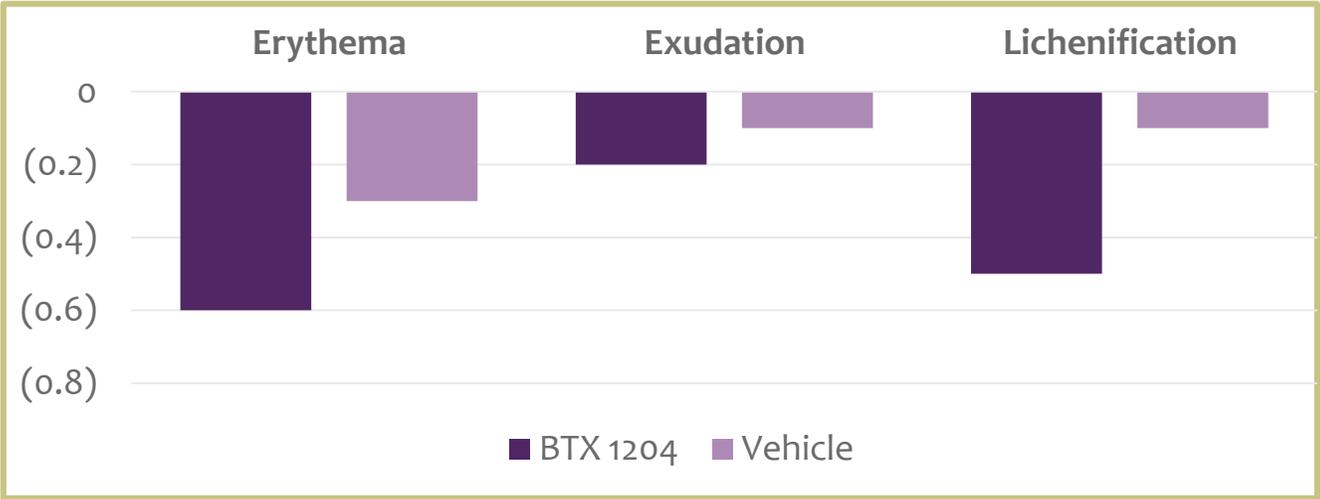
# BTX 1204 Phase 1b study results

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

Treatment Success<sup>1</sup>



Substantial reduction in the key signs of AD<sup>2</sup>



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

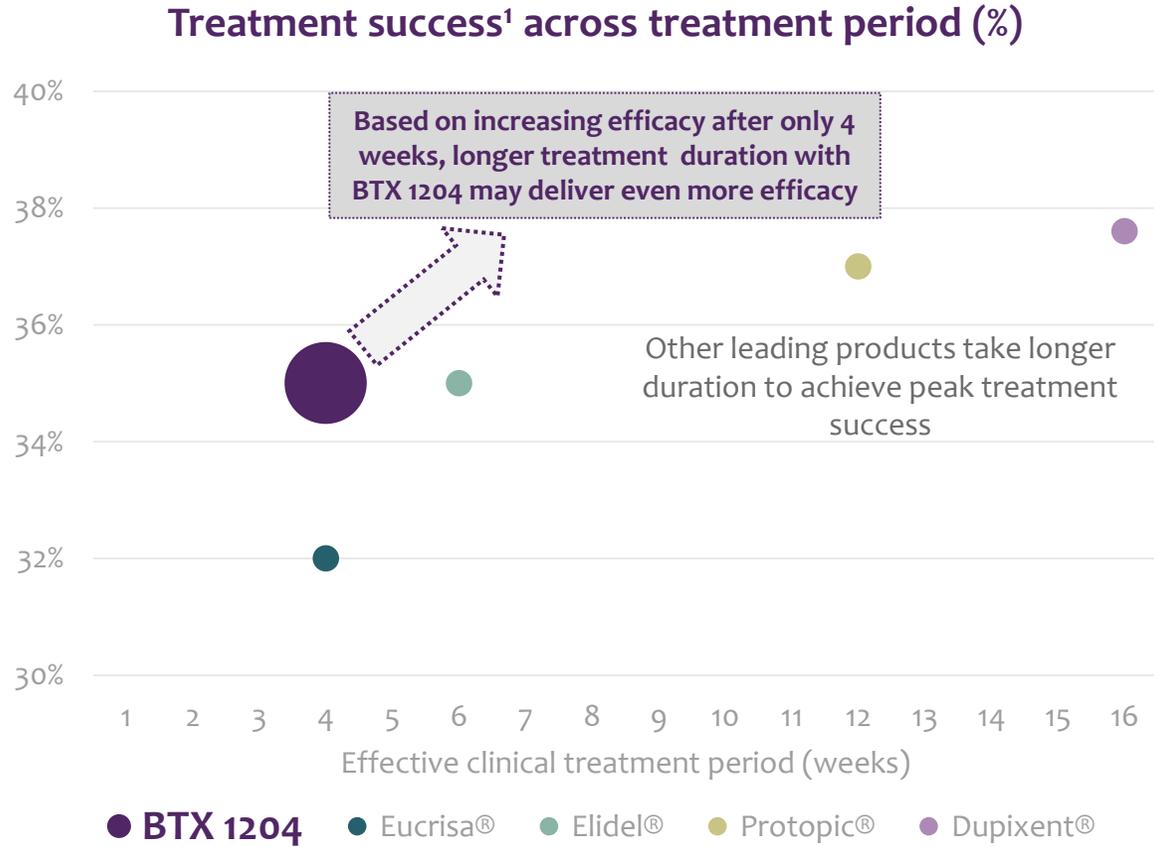
**Exudation:** ooze from lesion, associated with inflammation / infection

**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

# BTX 1204 study data in context

Study data highlights the potential for BTX 1204 to continue to increase in efficacy after 4 weeks compared to competitive products, without their attendant side effects



### Comparison with other FDA approved products

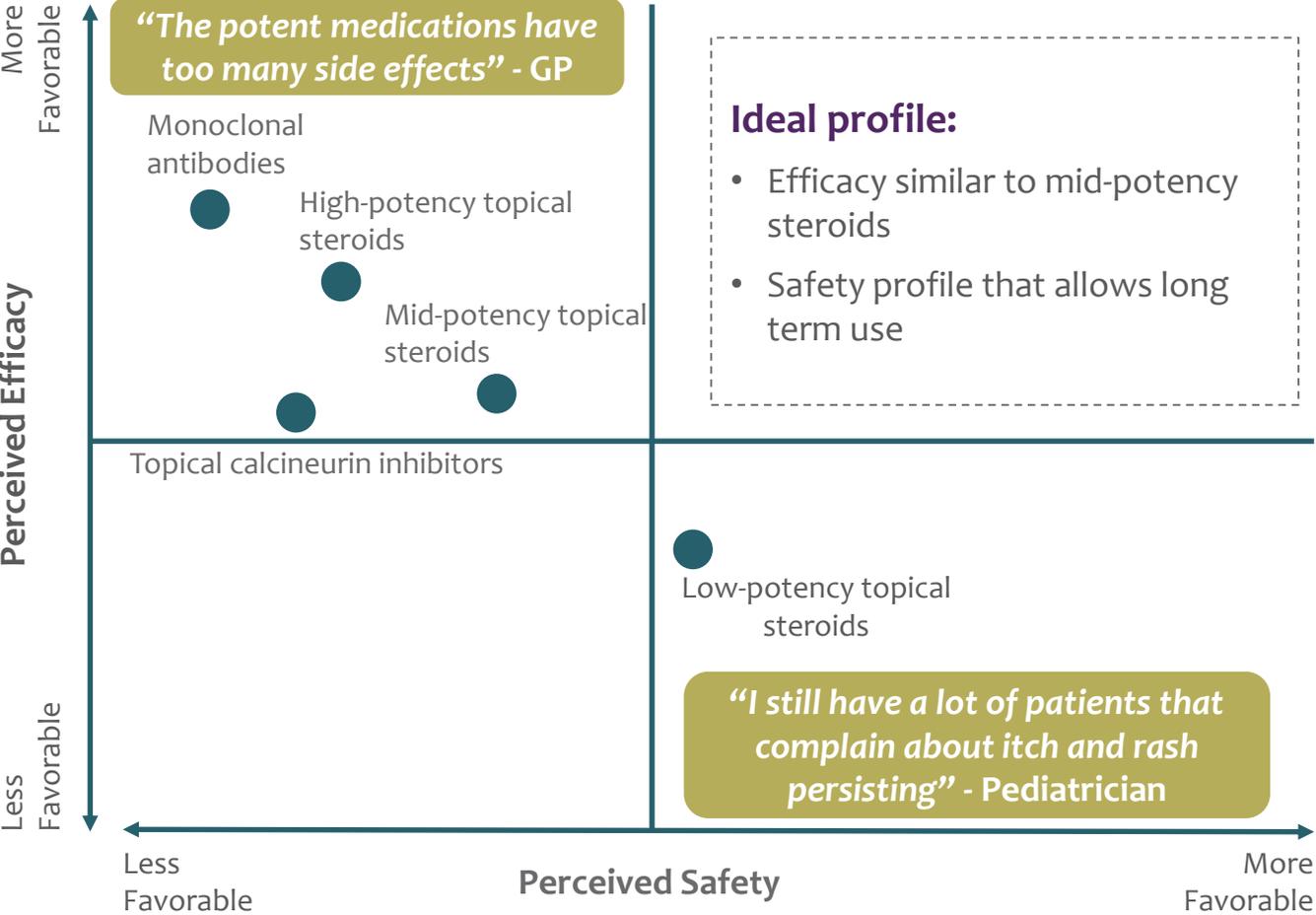
Product	Treatment success <sup>1</sup>	Treatment period	Peak sales p.a.	Comments
<b>BTX 1204</b>	35%	4 weeks (efficacy still increasing)	-	<ul style="list-style-type: none"> <li>✓ Positive effect on sign of AD signs related to itch</li> <li>✓ No irritation or concerning adverse event</li> </ul>
<b>Eucrisa®</b>	32%	4 weeks	TBA (launched in late 2017)	<ul style="list-style-type: none"> <li>✗ No effect on itch, 45% of patients experienced burning or stinging</li> </ul>
<b>Elidel®</b>	35%	6 weeks	~US\$350m	<ul style="list-style-type: none"> <li>✗ Infections and risk of lymphoma (long term risks)</li> </ul>
<b>Protopic®</b>	37%	12 weeks	~US\$175m	<ul style="list-style-type: none"> <li>✗ Infections and risk of lymphoma (long term risks)</li> </ul>
<b>Dupixent®</b>	37.6%	16 weeks	TBA (expected To be US\$2-4bn)	<ul style="list-style-type: none"> <li>✗ Lowers immune system, hypersensitivity, conjunctivitis and keratitis</li> </ul>

Source – Prescribing Information

1. Treatment success as defined by each product's Phase 3 clinical studies

# BTX 1204 positioning and opportunity post Phase 1b study data

Botanix is targeting efficacy improvements with much better safety profile than monoclonal antibodies (Dupixent<sup>®</sup>), TCI's (Protopic<sup>®</sup>) and high potency steroids, 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



# Proposed BTX 1204 Phase 2 study design

10-12 week randomised, double-blind, vehicle controlled study to evaluate the safety and efficacy of BTX 1204 in patients with moderate AD<sup>1</sup>

## Design

- 3 dose groups: ~270 subjects
  - High Dose twice a day: ~90 subjects
  - Low Dose once a day: ~90 subjects
  - Vehicle/Control: ~90 subjects
- ~25 US and Australian dermatology sites
- Children and adults
- Moderate AD patients

## Endpoints

- Primary endpoints:
  - Proportion of subjects with ISGA success defined as an ISGA score of “Clear” (0) or “Almost Clear” (1)
- Secondary endpoints:
  - The change from Baseline in the Signs of AD
  - The Eczema Area Severity Index (EASI) Score
  - Percent body surface area (BSA) affected by AD
  - The time to achieve ISGA success
- Safety
  - Adverse events and local tolerability

**FDA regulatory work already well advanced**

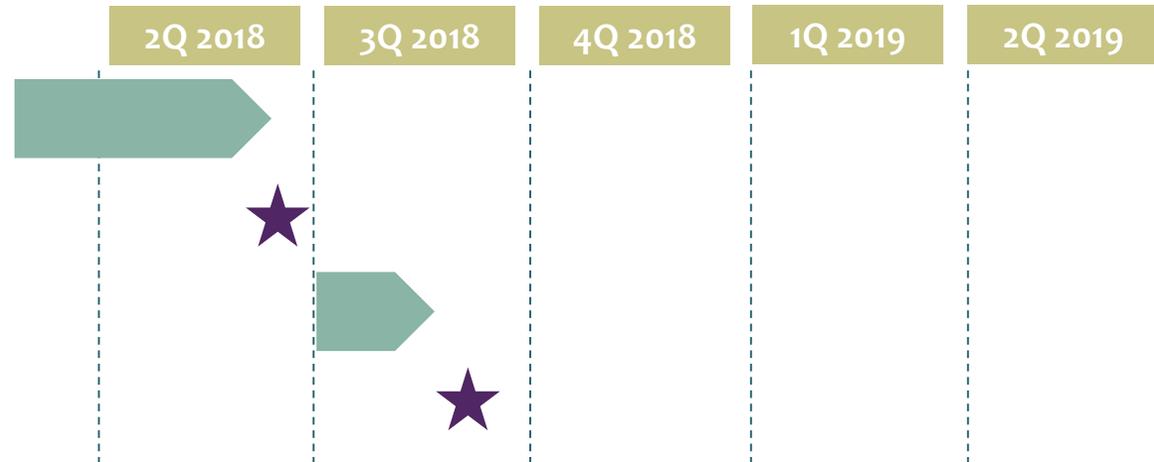
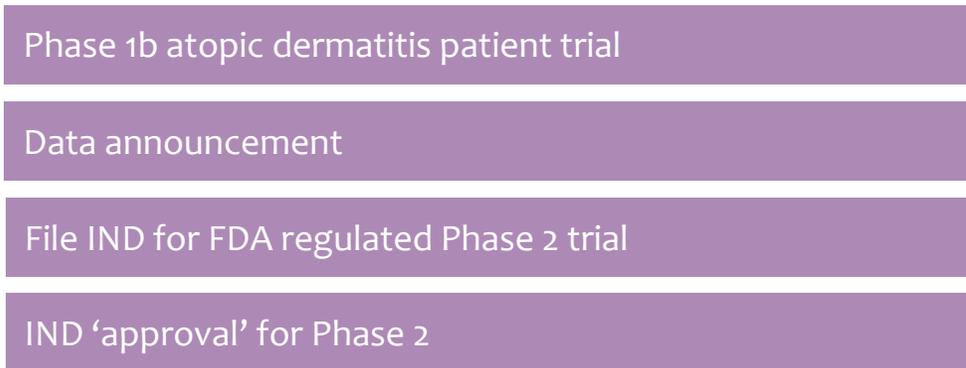
<sup>1</sup> Study design being finalised with key opinion leaders

# BTX 1204 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
- Preparation of FDA regulatory package for Phase 2 clinical trial approval well advanced
- Clinical trial duration likely similar to BTX 1503

## BTX 1204 indicative clinical timeline (CY)



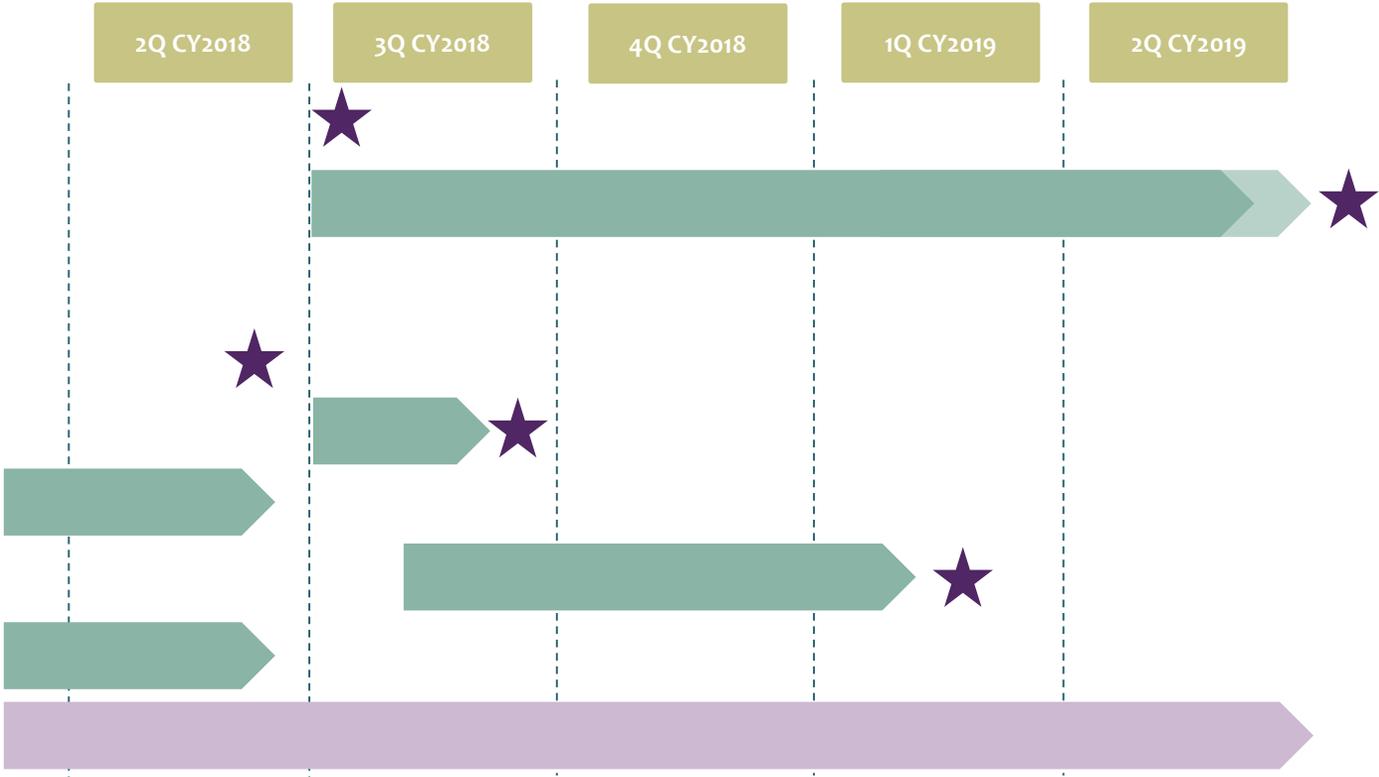
★ Milestones

# Company upcoming milestones

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

## Indicative activities and milestones

BTX 1503 Acne	First patient enrolled in Phase 2 trial
	Phase 2 multi-centre acne patient study
BTX 1204 Atopic Dermatitis	Phase 1b study in dermatitis patients
	Phase 1b study data announcement
	IND (FDA) submission for Phase 2 trial
BTX 1308 Psoriasis	Pre-clinical studies
	Phase 1b study in psoriasis patients
BTX 1801	Pre-clinical studies
Permetrex™	Research collaborations and partnership discussions



★ Milestones

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