

#### **ASX/Media Release**

#### 4 March 2020

#### **Botanix Cowen conference and additional BTX 1503 data analysis**

Boston MA and Sydney, Australia, 4 March 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce that President and Executive Chairman, Vince Ippolito and the Botanix team will be presenting the Company's progress at the Cowen Healthcare conference in Boston, US. The updated Botanix investor presentation is attached to this release.

The Company will provide an update on the progress of the key clinical programs, including preparation for the BTX 1204 Phase 2 atopic dermatitis study data expected in 1Q CY2020, BTX 1503 end of phase 2 meeting with the FDA scheduled for 2Q CY2020, and the BTX 1702 Phase 1b rosacea study currently underway.

The investor presentation also contains a summary of the additional data analysis of the Phase 2 BTX 1503 acne study, which supports the Company's selection of the 5% once daily dose of BTX 1503 for the planned Phase 3 program. The additional data analysis using the secondary endpoint of total lesion reduction shows that BTX 1503 5% once-a-day is statistically significant over vehicle (p=0.033) across the entire study. Reduction in total lesions (i.e. inflammatory and non-inflammatory) is a clinically meaningful measurement that dermatologists use to assess the effectiveness of a medication in reducing both types of lesions.

Cowen and Company is hosting the 40<sup>th</sup> Annual Health Care Conference, held between 2 to 4 March 2020 in Boston, US. The conference features company presentations, thematic panel discussions, workshops and one-on-one discussions. The conference is expected to attract attendees from more than 325 public and private healthcare companies and investors globally.

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'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<sup>TM</sup>) for direct skin delivery of active pharmaceuticals in all skin diseases.



The Company has announced data from its Phase 2 acne patient study and is preparing for the end of Phase 2 meeting with the FDA. A Phase 2 patient study in atopic dermatitis is now fully recruited with data planned for 1Q CY2020 and its new Phase 1b rosacea study recently received ethics approval. The Company has also successfully completed a mechanism of action study for synthetic cannabidiol in skin disease, with positive 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 1Q CY2020.

To learn more please visit: <a href="https://www.botanixpharma.com/">https://www.botanixpharma.com/</a>

#### For more information, please contact:

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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 is 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.



# Botanix Pharmaceuticals

Cowen Healthcare Conference

**March 2020** 



### World class team

#### Global team with proven experience and an unrivalled track record



**Vince Ippolito** 

**President and Executive Chairman** 



COO of Anacor and Medicis with 17 years at Novartis

More than 30 years experience in pharma with 20+ years within dermatology



**Dr Michael Thurn** 

**COO** and Board Director



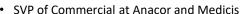
Operations + Regulatory

- Extensive start up life sciences experience in dermatology
- Previous MD of Spinifex Pharmaceutical, which sold to Novartis for A\$700m



**Howie McKibbon** 





 More than 20 years dermatology and pharma commercial experience



**Matt Callahan** 

**Founder and Board Director** 





Developed 4 products through FDA approval and launch Serial founder and ex-investment director of 2 venture capital firms in life sciences



**Dr Stephane Levy** 

**Chief Medical Officer** 



Medical + Clinical

- Ex-CMO of Almirall US operations and VP Clinical with Sanofi and Novartis
- · Broad commercial and clinical development experience



**Ric Peterson** 

**Chief Financial Officer** 



Finance + Strategy

- · Former CFO of Sienna, Novan and Medicis
- Unrivalled dermatology experience across multiple companies for more than 30 years



Jack Lawler

**VP Development** 



Development + Clinical

- 20 years clinical trial and development experience
- Most recently VP at Egalet Corporation and Director at Viropharma (Shire)



**Dr Joyce Rico** 

**Strategic Advisor** 



Medical, Research & Development

- Recent CMO for Novan Pharmaceuticals
- Prior experience as a Board Member for the Society of Investigative Dermatology, VP, Medical Affairs at Astellas and dermatology faculty at Duke, NYU and Northwestern



Dr Judith Plon

**VP Regulatory Affairs** 



Regulatory

- 30 years regulatory experience with multiple FDA approved dermatology products
- Ex-AVP Global Regulatory Affairs at Sanofi



## **Botanix overview**

Botanix is a clinical stage synthetic cannabinoid company, focused on developing topical products for the treatment of skin diseases and bacterial infections



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 atopic dermatitis data and new rosacea and bacterial infection clinical studies



## Advanced dermatology pipeline with near term milestones

Combination of clinical, safety and mechanism of action data from recent Botanix studies provide support for ongoing clinical programs, including near term completion of Phase 2 AD study

	Product	Indication	Ph 1	Ph 1b	Ph 2	Ph 3	Status
	BTX 1503 Gel	Moderate to severe acne					Preparing for FDA end of Phase 2 meeting
Synthetic CBD with	BTX 1204 Solution	Moderate atopic dermatitis					Study data 1Q CY2020
Permetrex™ topical technology	BTX 1702 Solution	Rosacea					Phase 1b study commenced 1Q CY2020
	BTX 1801 Ointment	Antimicrobial					Preparing for Phase 2 study
	BTX 1308 Ointment	Psoriasis					Successful MOA <sup>1</sup> study

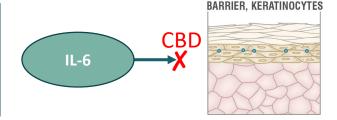


# Topical CBD is well suited to treat skin disease and infections

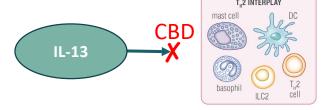
Botanix has generated strong scientific support for synthetic CBD's anti-inflammatory and immune modulation mechanisms of actions, combined with newly identified antimicrobial effects<sup>1</sup>

#### **CBD** anti-inflammatory / immune modulating effects

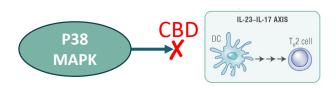
CBD inhibits a key cytokine which affects skin barrier disfunction



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



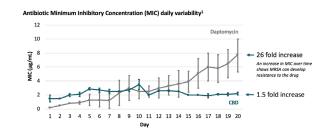
#### **CBD** antimicrobial effects

CBD is active against all tested gram +ve bacteria

Antibiotic	S. aureus all isolates (μg/mL)		MRSA¹ (μg/mL)		MSSA² (μg/mL)		
	MIC <sub>50</sub>	MIC <sub>90</sub>	Range	MIC <sub>50</sub>	MIC <sub>90</sub>	MIC <sub>50</sub>	MIC <sub>90</sub>
Cannabidiol			0.25 - 8		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



% viable cells						
83.65%	82.94%	67.87%	10.41%	1.45%		
	w t	7.7				



1. Botanix data on file, see slides 13, 14, 15, 19, and 20 of this deck for further data and previous BTX 1801 releases

# Permetrex™ - proprietary novel skin delivery technology

Makes new types of topical products<sup>1</sup> that deliver very high doses of drug into the layers of the skin without using permeation enhancers, preservatives, or irritating levels of alcohol / petrol derivatives

## **Initial application**

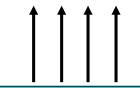
CBD drug is incorporated in Permetrex™ formulation which spreads easily over skin surface

**Epidermis** 

Dermis

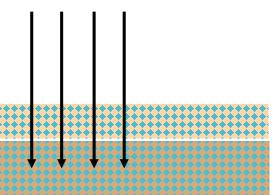
## **Evaporation of solvent**

Volatile majority of the formulation evaporates - leaving a minority of highly concentrated drug solution on the skin surface



#### **Delivery into the skin**

The rapid change in concentration of the drug as a result of evaporation, drives CBD quickly into the skin and is designed not to leave excess excipients on the surface







# Intellectual property portfolio

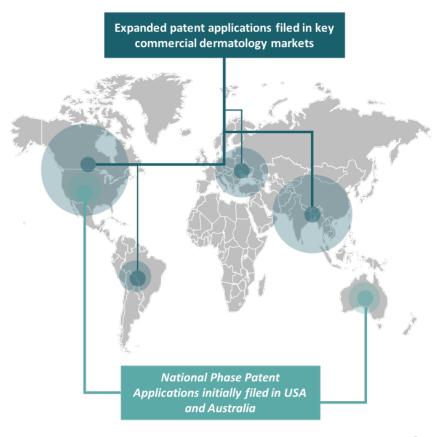
Multiple patents filed in key jurisdictions covering each indication, the Permetrex<sup>™</sup> technology and the broader potential of CBD in different skin diseases

#### **Patents**

- Botanix currently has 12 patent families pending that cover the:
  - Combination of Permetrex<sup>TM</sup> plus CBD, as a unique composition of matter filing for each formulation used in each disease (PCT/AU2018/050117, PCT/AU2018/050045, PCT/AU2018/050044, PCT/AU2018/050047)
  - Specific doses of CBD that are effective (from Botanix clinical data) to treat each disease

(PCT/AU2019/050050, PCT/AU2019/050051, PCT/AU2019/050052)

- Novel use of CBD (as well as CBD plus Permetrex<sup>TM</sup> and other excipients) to treat resistant bacteria and to disrupt biofilms (PCT/AU2018/051233, AU2018902331, PCT/AU2019/050626)
- Novel use of CBD to target IL-6 and P38 MAPK and related cell stress pathways in selected diseases (AU2019902123)
- Patent protection targeted at key geographic regions with large and viable dermatology markets (US, Europe, Japan, Australia, New Zealand, Korea, Singapore, China, Brazil etc)
- Patent filings undertaken in 2016-2019, so significant patent life remaining for commercialisation



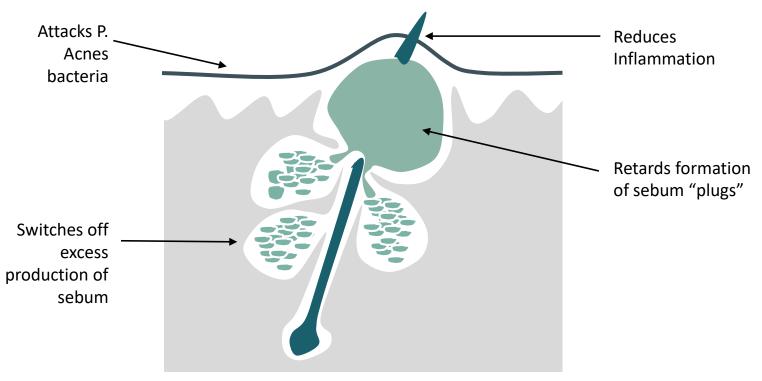




## BTX 1503 – moderate to severe acne

BTX 1503 is a safe and well tolerated topical treatment that potentially addresses all of the 4 causes of acne

## BTX 1503 potentially addresses 4 key acne pathologies 1



#### CBD has been shown in studies to...

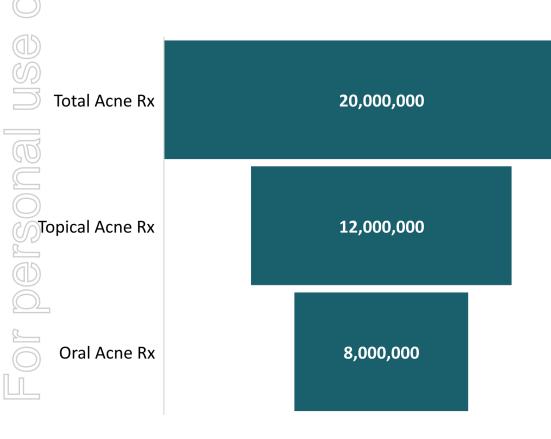
- Exert anti-inflammatory effects<sup>2</sup> and to suppress sebocyte proliferation<sup>3</sup>
- 2 Have <u>potent anti-microbial</u> activity against gram-positive bacteria<sup>4</sup>
- Inhibit human keratinocyte proliferation, through a non CB1/CB2 mediated mechanism<sup>5</sup>
- 1. Rocha & Bagatin Acne Vulgaris: an Inflammatory Disease Even Before the Onset of Clinical Lesions (2014). Inflammation and Allergy Drug Targets June 13(3)
- 2. Based on BTX 1308 Phase 1b study and BTX 1503 Phase 1b study BOT data on file
- 3. Olah et al. J Clin Invest. 2014:124(9):3713-3724
- 4. Based on BTX 1801 data University of Queensland and Charles River BOT data on file
- 5. Wilkinson & Williamson. J Derm Sci. 2007;45:87-92



## Sizable acne market with a clear unmet medical need

Competitive products with tolerability and safety concerns, as well as antimicrobial resistance challenges, have generated significant annual sales

#### Acne prescription market



#### Top brands at peak sales

Rank	Brands	Peak gross sales	US peak prescriptions
1	SOLODYN Minocycline	~\$1bn	1,295,346
2	DORYX FRANCHISE Doxycycline	~\$900m	983,368
3	EPIDUO FRANCHISE Adapalene+BPO	~\$700m	1,208,376
4	ACZONE FRANCHISE Dapsone	~\$300m	896,102

Source: IQVIA NPA



## BTX 1503: Phase 2 study

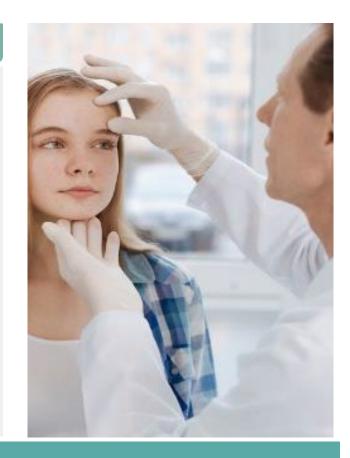
12-week randomised, double-blind, vehicle controlled study to evaluate the safety and efficacy of BTX 1503 in patients with moderate to severe acne

#### Design

- 5 dose groups: 368 subjects
  - High Dose twice a day: 92 subjects
  - High Dose once a day: 92 subjects
  - Low Dose once a day: 92 subjects
  - Vehicle/Control: 92 subjects
- 35 US and Australian dermatology sites
- Children (> 12 years) and adults
- Moderate to severe acne patients
- Treatment Period 12 weeks

#### **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





Study completed in 4Q CY2019



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## BTX 1503: Phase 2 top line data

While statistical significance was not reached for the primary endpoint due to the very high vehicle response from the USA sites, solid efficacy and safety results show BTX 1503 5% once-a-day (QD) dose is the best treatment to take forward



BTX 1503 is safe and effective

All doses of BTX 1503 were very safe – no serious adverse events or treatment related discontinuations in BTX 1503 5% once-a-day (QD) group, while achieving positive effects on acne lesion reductions



BTX 1503 once a day is the dose

BTX 1503 as a once daily application had the best performance, which from a patient compliance and commercial perspective, is the ideal dosing regime



**Clinical response** 

A strong and consistent impact on inflammatory lesions was seen with an even greater effect on non-inflammatory lesions



Positive efficacy and Australian data is statistically significant

Overall efficacy outcome is positive and Australian sites showed clear separation from vehicle of BTX 1503 5% QD



USA only vehicle response

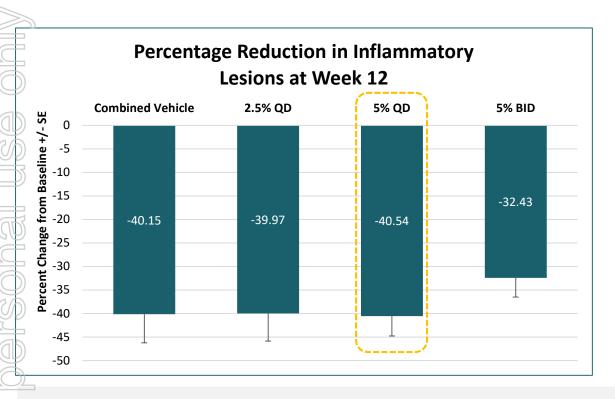
Patients in the USA that received vehicle had an unusually high vehicle response which skewed the overall primary endpoint

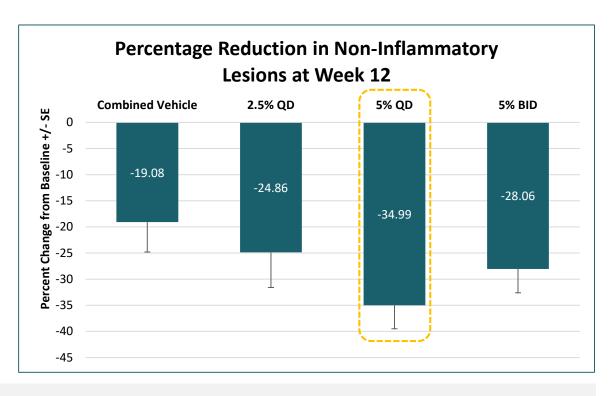
botanix

Source: BTX 1503 Phase 2 Study Results released 22 October 2019

# **Secondary endpoints - Inflammatory and Non-Inflammatory Lesions**

BTX 1503 5% once-a-day (QD) was the best performing active dose for reduction in total lesions





- BTX 1503 5% QD effect on inflammatory lesions was in line with target product profile at 12 weeks
- Vehicle response from USA sites was significantly greater than seen in Australia (see next slide for geographic break out)
- Percentage reduction in inflammatory and non-inflammatory lesions in line with leading topical acne prescription products

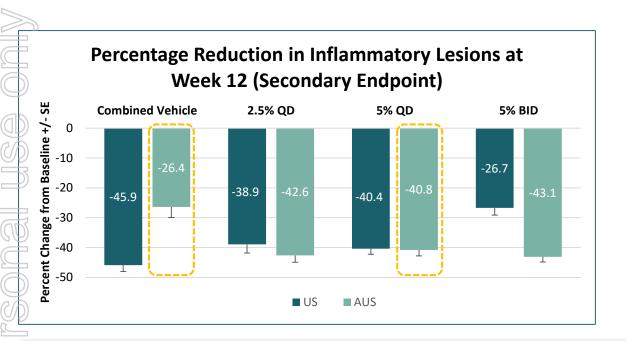
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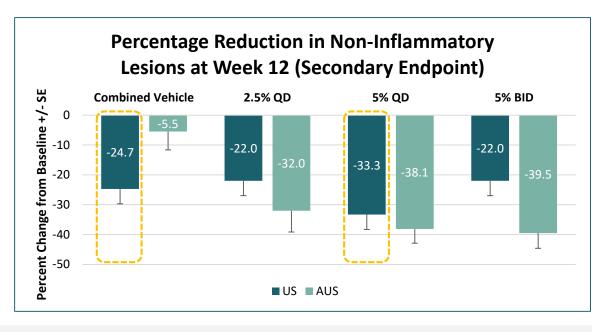
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Source: BTX 1503 Phase 2 Study Results released 22 October 2019 – Botanix data on file

# Secondary endpoints by geography

Australian data highlights the efficacy and separation expected from vehicle





- Australian clinical sites showed statistically significant improvements in reduction in inflammatory lesions with BTX 1503 BID 43.1% reduction (p<0.05) with BTX 1503 QD showing a 40.8% reduction
- Non-inflammatory lesions were reduced in Australia and the USA following treatment with BTX 1503 with the Australian BTX 1503 5% QD group showing a 38.1% reduction vs a 5.5% reduction for Vehicle (p<0.002)
- Vehicle group response in USA was almost two to four times the response seen in Australia

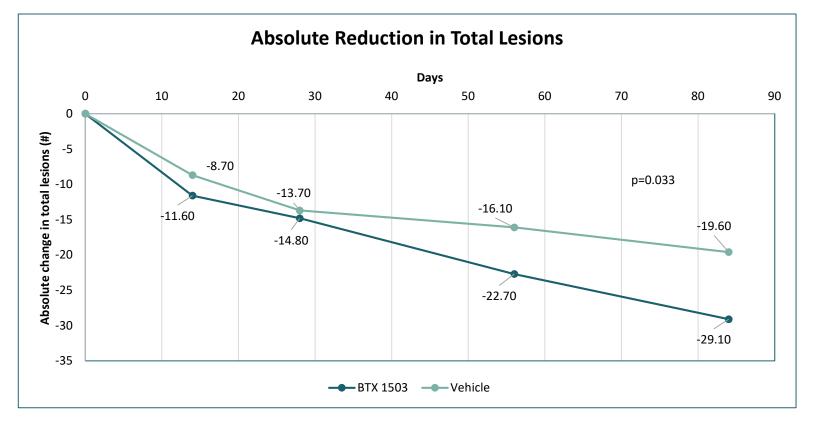
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Source: BTX 1503 Phase 2 Study Results released 22 October 2019 – Botanix data on file

## Clinically meaningful results: BTX 1503 5% QD versus vehicle

Additional analysis from the Phase 2 study showed BTX 1503 5% once-a-day showed statistical significance in overall lesion reduction versus vehicle (p=0.033)



Additional analysis on the **reduction in <u>total</u> lesions** (i.e. both inflammatory <u>and</u> non-inflammatory) for BTX 1503 5% **shows that BTX 1503 5% is statistically significant over vehicle (p=0.033).** Reduction in total lesions is a clinically meaningful endpoint that dermatologists use to assess the effectiveness of a medication.

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Source: BTX 1503 Phase 2 Study Results released 22 October 2019 – Botanix data on file

Dersonal

## Acne next steps

Overall efficacy and safety combined with statistical significance of Australian data provide confidence to proceed with end of Phase 2 FDA meeting and preparation for Phase 3 clinical studies

#### Outcomes support and expand on Phase 1b results

- Overall safety and efficacy is positive and Australian data shows strong separation from vehicle and excellent safety profile
- Non-inflammatory lesion reduction performance exceeds expectations across geographies and is essential to overall disease resolution

#### Phase 2 patient population reflects Phase 3 study design requirements

- Approximately half of patients included in the Phase 2 study were under 18 years old which have traditionally been the lowest responders in acne studies
- Endpoints in this Phase 2 study already mirror those required in Phase 3 studies for approval

#### Safety and efficacy data with once a day dose reflects optimal patient compliance and commercial target product profile

- Exceptionally clean safety profile positions BTX 1503 on top of comparative products
- Efficacy in inflammatory and non-inflammatory lesion reduction in-line with target product profile

#### End of Phase 2 meeting with FDA to be scheduled - targeting 2Q CY2020

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Source: BTX 1503 Phase 2 Study Results released 22 October 2019 – Botanix data on file

For personal

BTX 1204 – atopic dermatitis

BTX 1702 – papulopustular rosacea



## BTX 1204: CBD mechanism of action in atopic dermatitis

Ideal therapy that addresses multiple factors of disease pathology

CBD inhibits itch

Suppresses itch by interacting with VR / TRPV-1 receptors present on mast cells and keratinocytes<sup>3</sup>

> Bacteria Immune Response

Barrier

Disfunction

**Pruritis** 

**CBD** repairs barrier dysfunction

Inhibits <u>p38 MAP Kinase</u> activation and <u>IL-6</u> production in keratinocytes which interrupts the signaling process to dendritic cells and Th2 helper cells<sup>1,2</sup>

CBD is potent antibiotic against *S. aureus* bacteria

Reduces *S. aureus* and *MRSA* colonisation responsible for triggering skin inflammation and secondary skin infections<sup>4</sup>

CBD modulates the immune system

Inhibits Th17 (IL-17) and Th2 responses (<u>IL-13</u>) responses limiting the release of proinflammatory cytokines (TNF $\alpha$ , IL-1, <u>IL-6</u>, IL-8, and IL-12)<sup>1,5</sup>

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<sup>1.</sup> BTX 1308 Phase 1b clinical study – BOT data on file

<sup>2.</sup> Tan et al. Mol Med Rep 2017:16((6) 8883-8867

<sup>3.</sup> Eagelston et al. Dermatol Onlin J. 2018 Jun 15;24 (6)

<sup>4.</sup> Based on University of Queensland testing – BOT data on file

<sup>5.</sup> Petrosino et al. J Pharmacol Exp Ther. 2018 Jun;365(3):652-663

# Atopic dermatitis market projected to be ~US\$25B in 2027

BTX 1204 is being developed to address the need for a safe, non-steroid option for chronic use with multiple mechanisms of action including anti-inflammatory, anti-microbial and immune modulation

#### One of the most common skin diseases<sup>1</sup>

- Characterised by flare-ups of itch, red / inflamed rash and excessive dryness or scaling
- Affects 20-25m Americans<sup>2,3</sup> of which 90% are mild to moderate<sup>4,5</sup>
- ~85% of cases present by the age of 5 years<sup>6</sup>

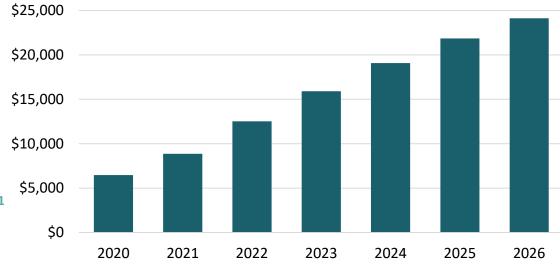
#### Large unmet need across the atopic dermatitis population<sup>7</sup>

- Limited options for safe and effective treatment of chronic disease
- Biologics are reserved for the severe population (~10% patients)

#### Pediatric population particularly needs tolerable steroid free alternative1

- Safety concerns with chronic use of high potency steroids
- Topical Calcineurin Inhibitors (Protopic / Elidel) have a boxed warning
- Current non-steroidal options have been reported to have tolerability concerns
- 1. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al Guidelines of care for the management of atopic dermatitis, Section 1 diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol 2014 Feb: 70(2):338-51.
- 2. Hanfin, J.M. et al. Dermatitis, 2007, 82(2): 82-91
- 3. Silverberg, J.I. & Hanifin, J.M. J Allergy Clin Immunol, 2013, 132(5): 1132-1138
- 4. Silverberg, J.I. & Simpson, E.L. Dermatitis, 2014, 25(3): 107-114
- 5. Barbarot et al. Allergy, 2018, 73:1284-1293
- 6. https://www.aad.org/media/stats-numbers
- 7. Global Data. Pharmapoint Atopic Dermatitis Nov 2015
- 8. Decision Resources Group

# Projected atopic dermatitis market by revenue (US\$M)<sup>8</sup> (includes 44m topical corticosteroids prescriptions in the US)



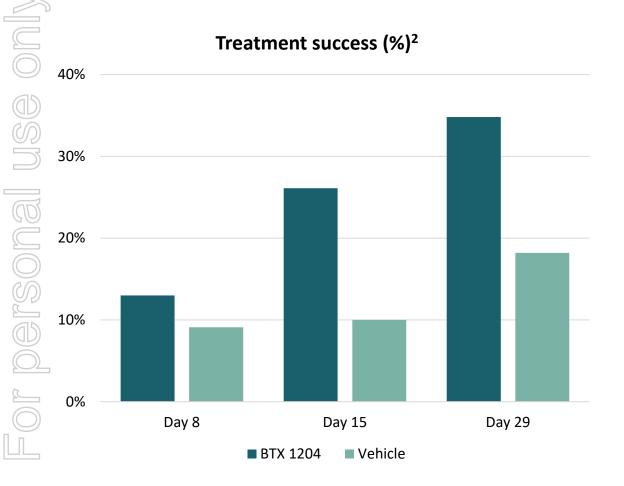






# BTX 1204 Phase 1b study results support efficacy and safety potential

BTX 1204 was twice as effective as vehicle (with efficacy still increasing at study completion) and displayed a substantial improvement in the study endpoints (key signs of atopic dermatitis)<sup>1</sup>



#### Efficacy still increasing at 4 week timepoint (n=36)

- 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**

- Safe and well tolerated with no SAE's
- BTX 1204 profile may allow extended dosing which remains a key challenge with most available therapies

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. Signs of AD score and Investigators Static Global Assessment (ISGA) score on target lesion. Treatment success based on greater than, or equal to, a 4 point improvement



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# BTX 1204: atopic dermatitis - Phase 2 fully recruited

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

### **Study Design**

- 2 dose groups: ~200 subjects
- − BTX 1204: ~100 subjects
- Vehicle/Control: ~100 subjects
- ~25 US and Australian and NZ dermatology sites
- Children (> 12 years) and adults
- Moderate AD patients
- Treatment period of 12 weeks

#### **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
  - % body surface area (BSA) affected by AD
  - Time to achieve IGA success

#### Safety

Adverse events and local tolerability

On track to report top line data in 1Q CY2020



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## BTX 1702: impact of papulopustular rosacea

Papulopustular rosacea is a chronic skin disease characterised by redness (inflammation) and acne-like break-outs<sup>1</sup>

#### **≅**16m Americans affected by rosacea<sup>2</sup>

Affects 5.5% of the world-wide population<sup>3</sup>

85% of patients are over 30 years old<sup>4</sup>

Most common in middle aged women with light skin<sup>5</sup>

Side effects associated current options affect treatment preferences, satisfaction, and QOL<sup>6</sup>

## **Collearly identified unmet medical need**<sup>2</sup>

Market is projected to grow to \$2.6bn by 2025<sup>7</sup>

5m prescriptions in the US alone<sup>8</sup>

#### Very high emotional and psychological impact<sup>2</sup>

1. Blount BW, Pelletier AL. Am Fam Physician. 2002;66:435-440.

2. National Rosacea Society. www.rosacea.org

3. Gether L, et al. Br J Dermatol. 2018;179:282-289

4. Aimee Two, et al, JAAD, Volume 72, Issue 5, May 2015

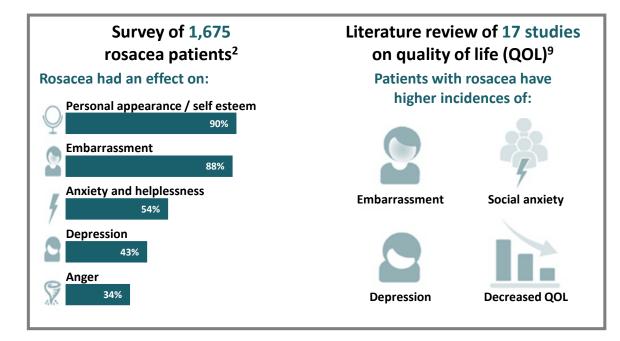
5. Mayo Clinic. www.mayoclinic.org

6. Todd Williamson, et al. Am Drug Benefits, 2018 Apr; 11(2): 97–106

7. Grandview Research. www.grandview research.com

8. Symphony Health Solutions, PHAST

9. Moustafa F. J Am Acad Dermatol. 2014;71:973-980.









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## BTX 1702 Phase 1b study design

6 week randomised, double-blind, vehicle-controlled study to evaluate the safety and tolerability of BTX 1702 in patients with papulopustular rosacea

### **Study Design**

- 4 dose groups: ~120 patients
- BTX 1702 Formulation A twice daily: 30 patients
- BTX 1702 Formulation B twice daily: 30 patients
- Vehicle A twice daily: 30 patients
- Vehicle B twice daily: 30 patients
- Approx 6 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 and 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 underway 1Q CY2020



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## **Near term milestones**

Key near term milestones combine clinical and other meaningful study endpoints providing solid news flow through CY2020

Event	Timing
BTX 1204 atopic dermatitis study data	1Q CY2020
BTX 1503 end of Phase 2 meeting with FDA	2Q CY2020
BTX 1801 Qualified Infectious Disease Product designation	2Q CY2020
BTX 1702 rosacea study completion	3Q CY2020
Cash Position	
End Dec 2019 (does not include R&D tax concession receipt of ~\$7m in Jan)	A\$27m

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## Inflammation + bacterial infection are important to most skin diseases<sup>1</sup>

Newly announced data provide scientific support for synthetic CBD's mechanism of action (MOA), which is highly relevant to all Botanix pipeline products

#### Acne



Relevance	CBD mechanism of action	Relevance
✓	Kills relevant bacteria (P. Acnes and Staph/MRSA) <sup>2</sup>	✓
✓	Anti-inflammatory effect <sup>3</sup>	✓
	Immune modulating <sup>3</sup>	✓
✓	Skin barrier protectant <sup>3</sup>	✓
✓	Safe and non-irritating <sup>4</sup>	✓

#### **Atopic dermatitis**



#### Recent Phase 2 acne data supports synthetic cannabidiol MOA

- 1. Dainichi et al 2014 JDS Vol 76 Iss 2 81-86
- 2. Based on BTX1801 data (University of Queensland and Charles River testing) BOT data on file
- 3. Based on BTX 1308 Phase 1b biopsy data BOT data on file
- 4. Based on 3 Phase 1b studies for BTX1503, 1204 and 1308 respectively BOT data on file



## **Disclaimer and notices**

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 is 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.

Release authorised by
Vince Ippolito
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