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
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

<table>
<thead>
<tr>
<th>Product candidate</th>
<th>Indication</th>
<th>Pre-Clin</th>
<th>Ph 1</th>
<th>Ph 1b</th>
<th>Ph 2</th>
<th>Next milestones</th>
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</thead>
<tbody>
<tr>
<td>BTX 1503</td>
<td>Moderate to Severe Acne</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Phase 2 clinical trial underway Data available mid-2019</td>
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<tr>
<td>BTX 1204</td>
<td>Atopic Dermatitis</td>
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<td></td>
<td></td>
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<td>Phase 2 clinical trial pending IND Prep 3Q CY2018</td>
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<td>BTX 1308</td>
<td>Psoriasis</td>
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<td></td>
<td></td>
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<td>Phase 1b patient study pending Ethics approval 3Q CY2018</td>
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<td>BTX 1801</td>
<td>Antimicrobial</td>
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<td>Phase 1b patient study Following pre-clin work 4Q CY2018</td>
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Permetrex™ programs

<table>
<thead>
<tr>
<th>Internal/External</th>
<th>Various</th>
<th>Collaborations</th>
<th>Ongoing</th>
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Synthetic form of natural product extract – cannabidiol
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
- 17 Multiple Sclerosis
- 15 Pain
- 9 Schizophrenia
- 6 Cancer
- 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.

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

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.
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 \(\frac{1}{4}\) to \(\frac{1}{2}\) the concentration of alternative formulations.

Cannabidiol (CBD) percentage delivery (%)\(^1\)

<table>
<thead>
<tr>
<th>% of applied dose delivered</th>
<th>Epidermis</th>
<th>Dermis</th>
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<tbody>
<tr>
<td>% concentration of CBD in formulation</td>
<td>10% CBD formulation</td>
<td>20% CBD formulation</td>
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<tr>
<td>10% CBD formulation</td>
<td>10% CBD formulation</td>
<td>20% CBD formulation</td>
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</tbody>
</table>
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

**Ideal profile:**
- Efficacy similar to mid-potency steroids
- Safety profile that allows long term use

**Perceived Efficacy**

- More Favorable
  - Monoclonal antibodies
  - High-potency topical steroids
  - Mid-potency topical steroids

- Less Favorable
  - Topical calcineurin inhibitors

**Perceived Safety**

- More Favorable
  - Low-potency topical steroids

- Less Favorable

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“I still have a lot of patients that complain about itch and rash persisting” - Pediatrician

“The potent medications have too many side effects” - GP
**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

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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.

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

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
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 Success**

- Treatment success defined as a greater than, or equal to, a 4 point improvement in the signs and symptoms of AD.
- Based on improvement in average score ratings from baseline to Day 29.

**Substantial reduction in the key signs of AD**

- **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.

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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)
**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

<table>
<thead>
<tr>
<th><strong>Design</strong></th>
<th><strong>Endpoints</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• 2 dose groups: ~200 subjects</td>
<td></td>
</tr>
<tr>
<td>– BTX 1204: ~100 subjects</td>
<td></td>
</tr>
<tr>
<td>– Vehicle/Control: ~100 subjects</td>
<td></td>
</tr>
<tr>
<td>• ~25 US and Australian dermatology sites</td>
<td></td>
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<tr>
<td>• Adolescents and Adults</td>
<td></td>
</tr>
<tr>
<td>• Moderate AD patients</td>
<td></td>
</tr>
<tr>
<td>• Primary endpoint:</td>
<td></td>
</tr>
<tr>
<td>– 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</td>
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<tr>
<td>• Secondary endpoints:</td>
<td></td>
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<tr>
<td>– change from Baseline in the Signs of AD</td>
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<tr>
<td>– Eczema Area Severity Index (EASI) Score</td>
<td></td>
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<tr>
<td>– % body surface area (BSA) affected by AD</td>
<td></td>
</tr>
<tr>
<td>– time to achieve IGA success</td>
<td></td>
</tr>
<tr>
<td>• Safety</td>
<td></td>
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<tr>
<td>– adverse events and local tolerability</td>
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</table>

**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)

<table>
<thead>
<tr>
<th>Milestones</th>
<th>3Q 2018</th>
<th>4Q 2018</th>
<th>1Q 2019</th>
<th>2Q 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1b atopic dermatitis patient data</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Pre- IND meeting for FDA regulated Phase 2 trial</td>
<td></td>
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<td></td>
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<tr>
<td>Phase 2 first patients enrolled</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US and Australian sites activated</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Patient enrolment complete</td>
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</table>
BTX 1503: acne – MOA for acne

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

- Attacks *P. Acnes* bacteria
- Switches off excess production of sebum
- Reduces Inflammation
- Retards formation of sebum “plugs”

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 (%)

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>Day 28</th>
<th>Day 35</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory lesions</td>
<td>47.0%</td>
<td>45.0%</td>
</tr>
<tr>
<td>Non-inflammatory</td>
<td>5.4%</td>
<td>22.5%</td>
</tr>
</tbody>
</table>

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

### Comparison of other FDA approved products

<table>
<thead>
<tr>
<th>Product</th>
<th>Owner</th>
<th>Lesion count reduction (%)¹</th>
<th>2016 annual revenue²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epiduo®</td>
<td>Galderma</td>
<td>~42%</td>
<td>US$494m</td>
</tr>
<tr>
<td>Aczone®</td>
<td>Allergan</td>
<td>~38%</td>
<td>US$456m</td>
</tr>
<tr>
<td>BTX 1503</td>
<td>Botanix</td>
<td>~47%</td>
<td>-</td>
</tr>
</tbody>
</table>

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

**Aczone®**
- 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

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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**

<table>
<thead>
<tr>
<th>2Q 2018</th>
<th>3Q 2018</th>
<th>4Q 2018</th>
<th>1Q 2019</th>
<th>2Q 2019</th>
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**Trial duration**
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

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)**

- **Ethics approvals for Phase 1b study**
  - 3Q 2018
- **Phase 1b patient study**
  - 4Q 2018
- **Data announcement**
  - 1Q 2019
- **Phase 1b patient study**
  - 2Q 2019

- 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


Fall Clinical presentation – October 2018
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

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)
5. Outlook
### Key catalysts

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

#### Indicative activities and milestones

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

- 3Q CY2018: First patient enrolled in Phase 2 trial
- 4Q CY2018: Patient Enrolment Complete
- 1Q CY2019: Phase 2 multi-centre acne patient clinical trial
- 2Q CY2019: Pre-IND Meeting for Phase 2 Trial
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