ASX/Media Release

14 December 2018

Botanix presents at International Cannabinoid Summit

Key highlights

- Botanix presented at the International Cannabinoid Derived Pharmaceuticals Summit, Boston
- Shared podium with speakers from GW Pharmaceuticals, RespireRx Pharmaceuticals and other leading clinical stage cannabinoid companies
- Presented on Botanix's skin disease development programs as well as the novel regulatory strategy adopted by the Company to move from project initiation to Phase 2 within 24 months
- The conference highlighted that there is a growing interest in cannabinoid therapeutics as the next wave of investment focus

Boston and Sydney Australia, 14th December 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce that its Founder and Executive Director, Matt Callahan, presented at the International Cannabinoid Derived Pharmaceuticals Summit in Boston. Mr Callahan's presentation is attached to this release.

The International Cannabinoid Derived Pharmaceuticals Summit is an emerging industry and academic conference focused on profiling the leading companies developing cannabinoids through clinical development. The Summit gathers together industry leaders and academic researchers who are at the forefront of cannabinoid drug development. Botanix shared the podium with the Head of Research at GW Pharmaceuticals (who recently received the first FDA approval for an oral cannabidiol product for a form of epilepsy) and the Senior Vice President of RespireRx Pharmaceuticals (who are developing a cannabinoid analog for sleep apnoea), amongst other companies.

Matt Callahan, Founder and Executive Director of Botanix said: "The Summit was a fantastic opportunity to showcase the breadth and depth of our skin disease focused clinical programs. It is clear that outside GW Pharmaceuticals' recently approved Epidiolex product, Botanix has the most mature pipeline of any other cannabinoid company featured at the Summit. Our rapid development approach has distinguished us from our peers, many of whom have been in development for 5-15 years and are only now starting human studies for the first time."

Mr Callahan's presentation provided an update on the progress of Botanix's late stage clinical programs, BTX 1503 for acne and BTX 1204 for atopic dermatitis, as well the ongoing patient study for BTX 1308 for psoriasis. The presentation also highlighted the novel development strategy that has been employed by Botanix that has allowed its clinical programs to move rapidly from early formulation development to Phase 2 studies within 24 months, while successfully navigating US FDA and DEA regulatory requirements.

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 completed its first acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 study in June 2018 with completion expected in mid-2019. The BTX 1204 Phase 1b atopic dermatitis patient study concluded in June 2018 and a Phase 2 study is due to commence in December 2018. The BTX 1308 Phase 1b psoriasis patient study commenced in September 2018.

For more information on Botanix, please visit www.botanixpharma.com

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Clinical Trials – USA and Australia

International Cannabinoid Derived Pharmaceuticals Summit

December 2018

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RESTORING HEALTHY SKIN

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Overview

1. Botanix clinical programs
2. Speed – idea to Phase 2 within 24 months
3. Why Australia?
4. DEA and FDA
5. Key takeaways

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Botanix snapshot

Botanix is a global **dermatology company** delivering **synthetic cannabinoids topically for the treatment of skin diseases**

Dermatology focused	Advanced clinical programs targeting multi-billion dollar prescription markets for **acne, atopic dermatitis and psoriasis**
De-risked drug active	Products use a synthetic form of cannabidiol with a proven safety profile – **increases 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 technology, **Permetrex™ - enhances delivery of cannabidiol into the skin** compared to traditional formulation approaches
Experienced team	US based leadership team with **20+ FDA approvals** between them and extensive dermatology industry experience

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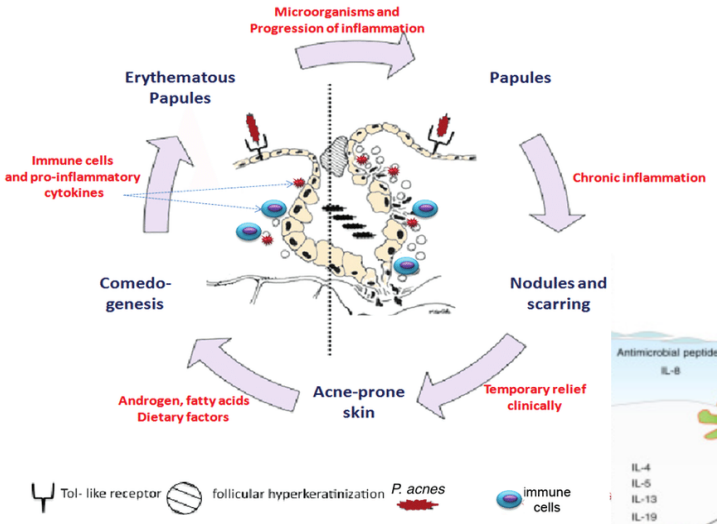
CBD in Skin Disease – Understanding the MOA

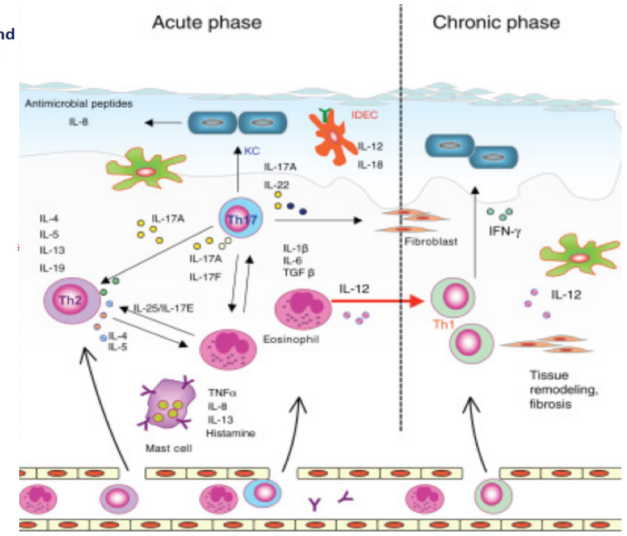
In addition to the anti-microbial activity, CBD acts on numerous skin disease relevant pathways and targets

Not simply "there are CB1/CB2 receptors are in skin"



Acne

Atopic Dermatitis



CBD has been shown to…

- Have **anti-inflammatory effects on human sebocytes** and to **suppress sebocyte proliferation**[2]
- **Have potent anti-microbial** activity against gram-positive bacteria[3]
- **Inhibit human keratinocyte proliferation,** through a non CB1/CB2 mechanism[4]
- **Inhibits Th17 responses (IL17),** anti-inflammatory effect[5, 6]
- **Attenuates Th2 responses (IL4/IL13),** anti-inflammatory effect[7, 8,9]

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. Olah et al. *J Clin Invest*. 2014:124(9):3713-3724; 3. Appendino et al. *J Natl Prod*. 2008;71:1427-1430; 4. Wilkinson & Williamson. *J Derm Sci*. 2007;45:87-92. 5. Harvey et al. *Cytokine*. 2014;65:236-244; 6. Kaplan et al. Biochem Pharmacol. 2008;76(6):726-737; 7. Gaffal et al. *Exp Derm*. 2014;23;401-406; 8. Kim et al. *Int J Derm*. 2015;54:e410-e408; 9. Lee et al. *Mol Med*. 2016;22:136-146.

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Clinical programs

Phase 2 acne and atopic dermatitis programs supported by exciting development pipeline, with Permetrex™ collaborations to augment revenue and news flow

Product candidate		Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Next milestones
Synthetic cannabidiol	BTX 1503	Moderate to severe acne	→	→	→	→	Phase 2 clinical study
	BTX 1204	Atopic dermatitis	→	→	→	→	Phase 2 clinical study
	BTX 1308	Psoriasis	→	→	→		Phase 1b patient study
	BTX 1801	Antimicrobial	→				Pre-clinical
Permetrex™ programs	Internal/ external	Various		Collaborations →			Ongoing Service fees and potential licenses

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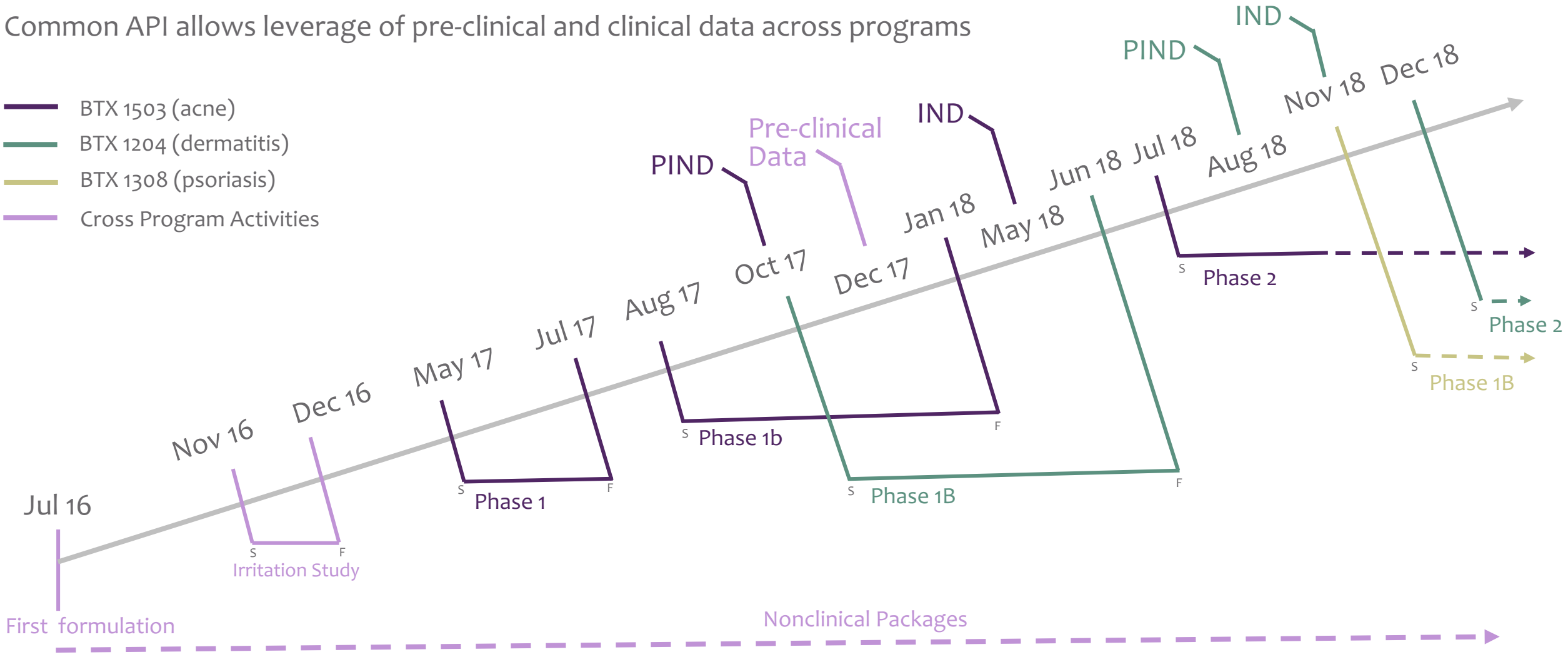
Moving fast with multiple programs

Common API allows leverage of pre-clinical and clinical data across programs



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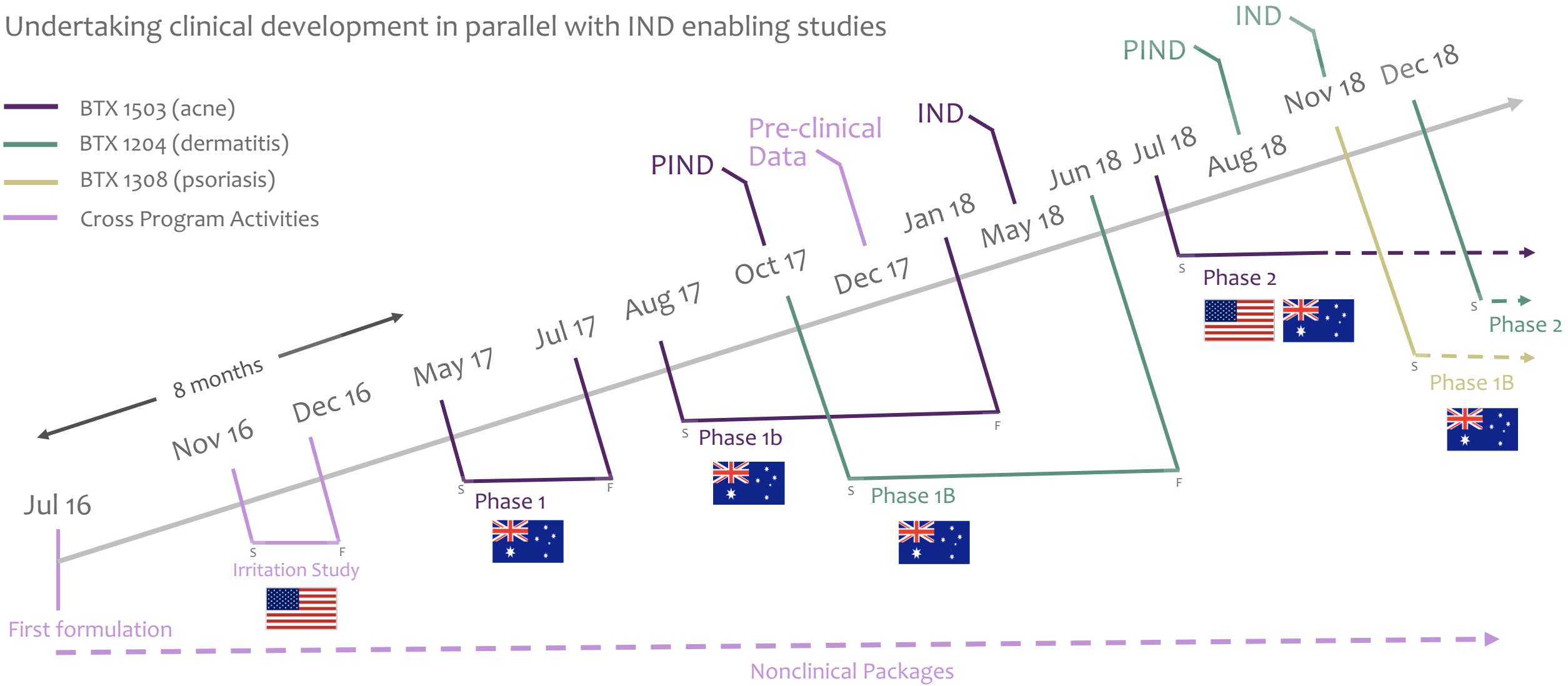
Arbitraging regulatory systems

Undertaking clinical development in parallel with IND enabling studies



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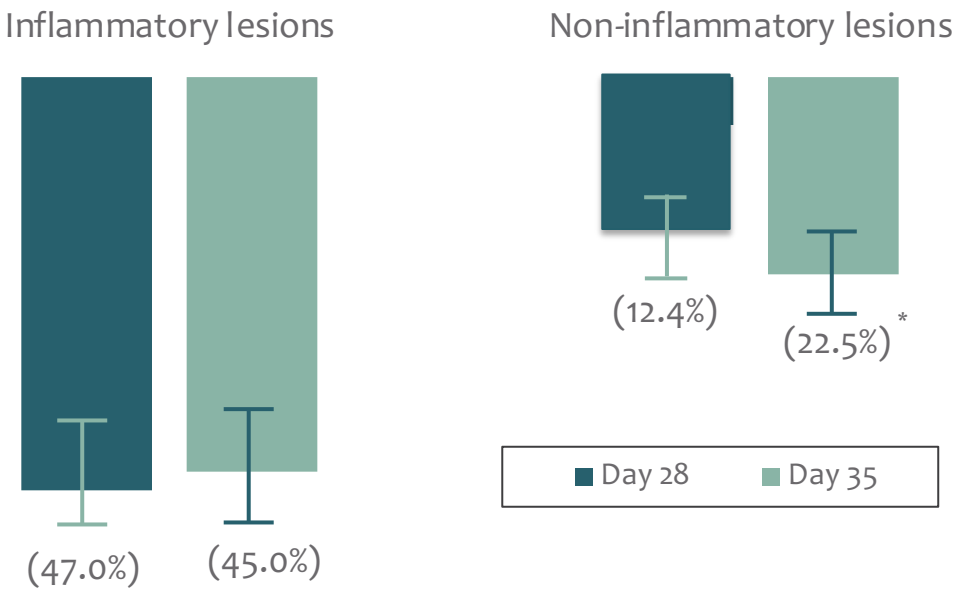
Efficiently generating POC data

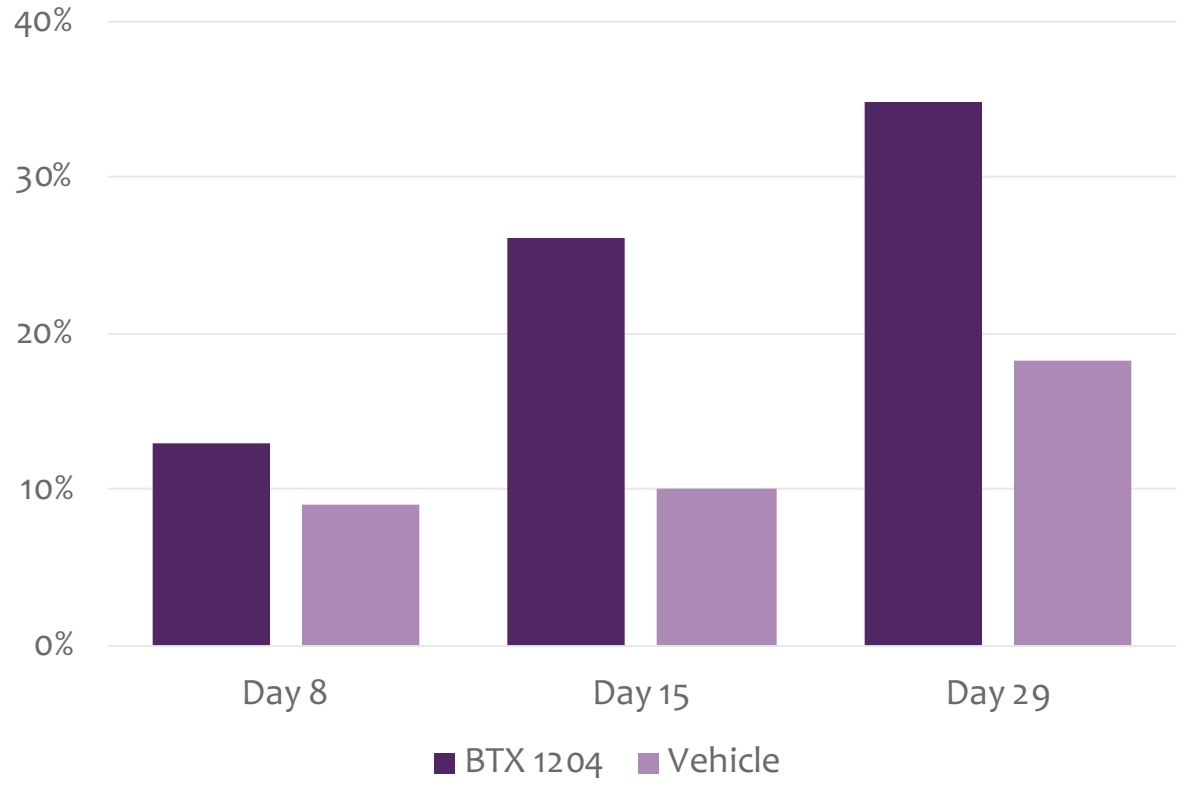
Consider doing shorter duration or "killer experiment" studies first to generate POC data within tox coverage

Acne - Lesion Count Reduction (%) [1]



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

Atopic Dermatitis - Treatment Success (%)[2]



1. Botanix data on file. 4 week single armed study in moderate to severe patients. Lesion count reduction based on average inflammatory lesion reduction at 4 weeks.

2. Botanix data on file. 4 week controlled study in mild to moderate AD patients. Results indicated substantial reduction in key signs of AD. Treatment success defined as a greater than, or equal to, a 4 point improvement in the signs and symptoms of AD

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Translating into IND Studies – Phase 2 study overview

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: ~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
- 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

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

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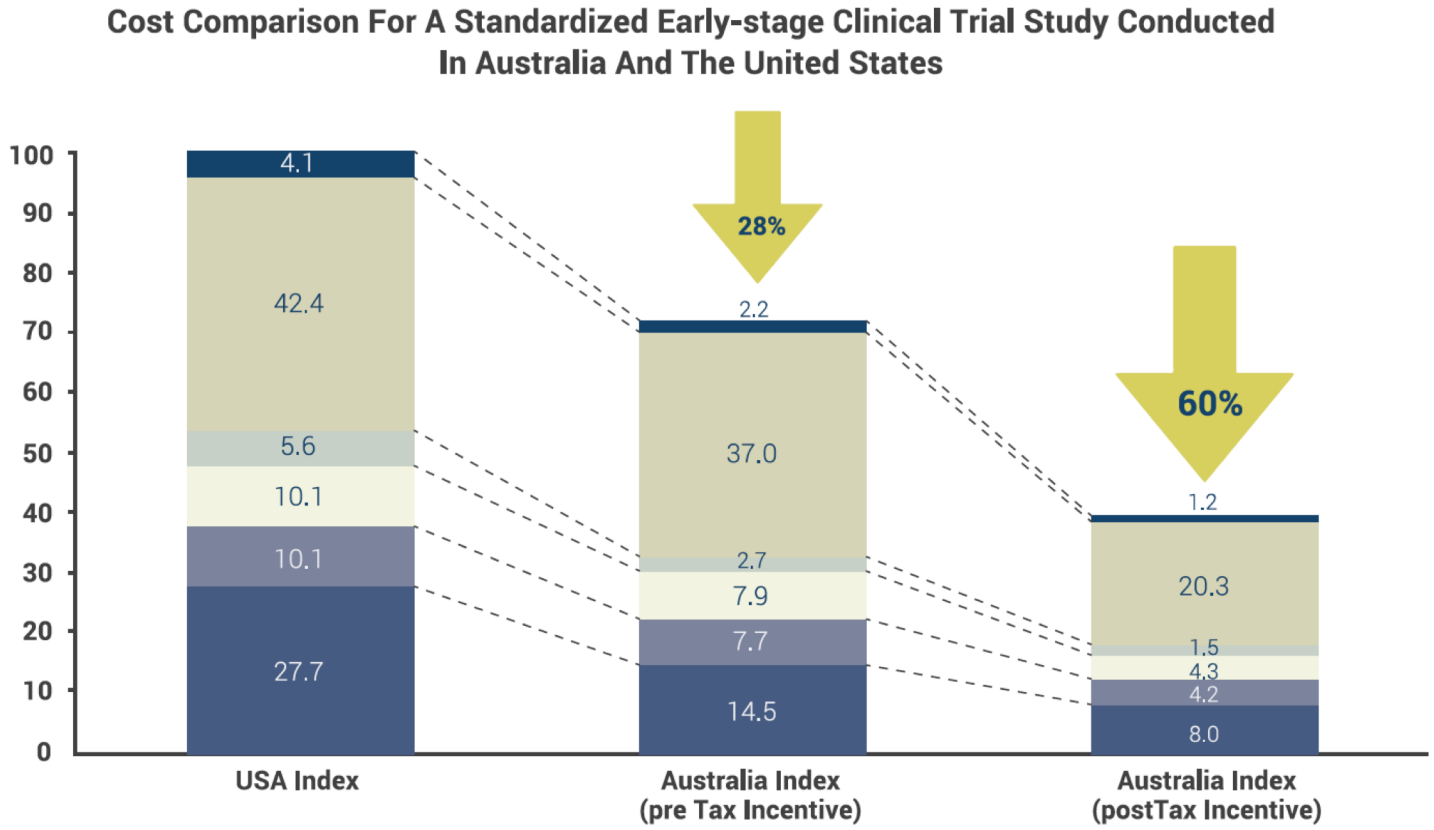
Australia benefit 1 - COST

The cost of conducting early stage studies in Australia is usually ½ to 1/3rd cheaper than the US with no quality differences



Currency conversion rate: AUD1 = USD0.9 0.72

Source: Cost comparison for Phase 1 clinical trial in the US and Australia. Novotech cost comparison case study. 2016.

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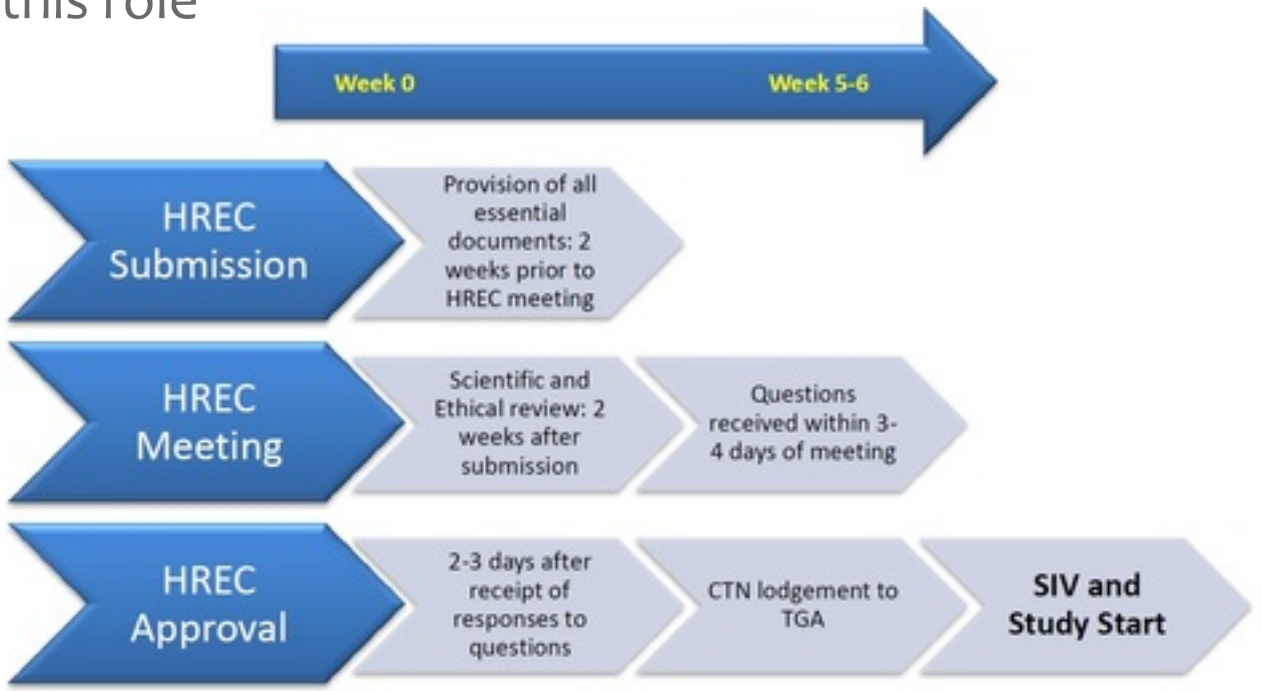
Australia benefit 2 – FAST and NO DEA

TGA is essentially a registry and HREC is the key body that reviews and regulates studies

- **No IND required for clinical trials** – less pre-clinical
- **Full GMP** material is **not mandated** for Phase I
- **TGA does not review the CTN** – HREC assumes this role
- **No DEA equivalent** - importing is not onerous

Sponsors to gain critical Go/No Go information on their product before allocating resources to longer term and costly pre-clinical and other IND enabling activities



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Australia benefit 3 – R&D TAX CREDIT*

Who doesn't like cash back on every R&D purchase?

43.5%

* What you get back as a cash return as a % of R&D spend at the end of each financial year…

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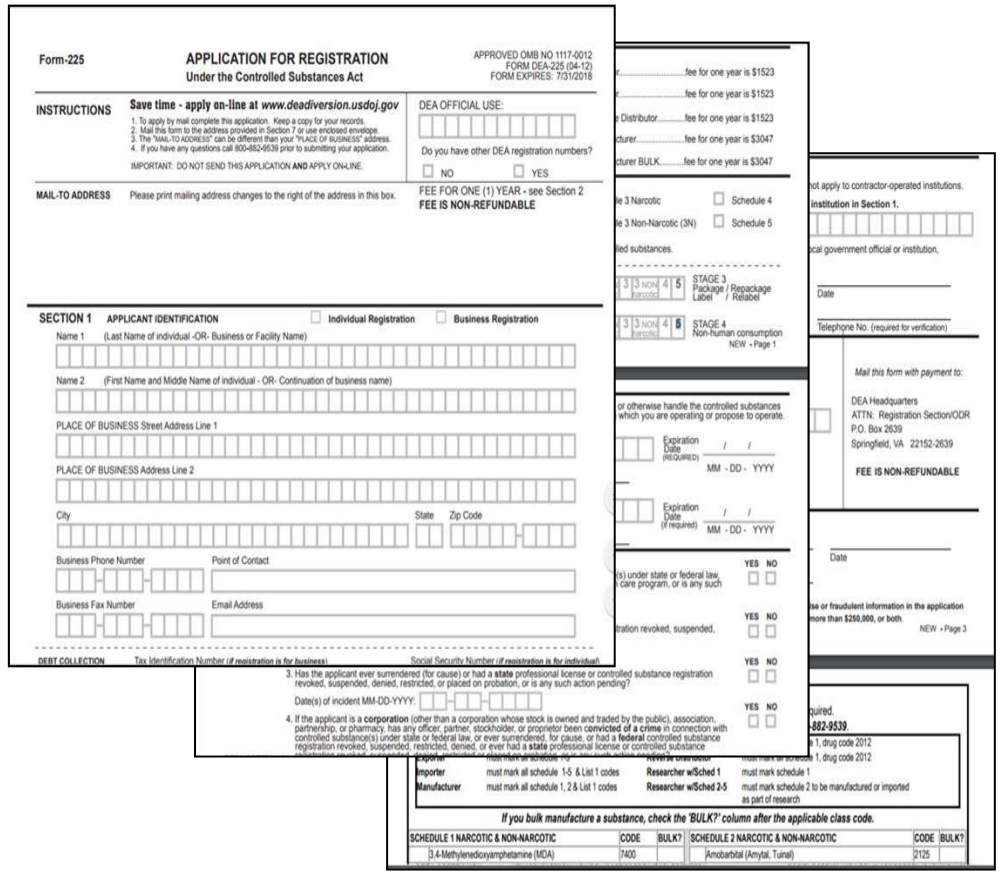
USA – Dealing with DEA

DEA regulates the manufacture, transport and study of cannabinoids – stay on their good side…

- Cannabinoids are Schedule 1 substances and are subject to DEA regulation
- DEA approval of protocols is required to conduct any studies – all pre-clinical or clinical studies
- DEA approval is also required to ship materials across US State lines or internationally
- Companies and facilities that handle, study or test cannabinoids need to be licensed (with the appropriate type of license)
- Manufacturing API and final drug product are all governed by quotas – don't assume you can buy enough or make enough to run pre-clinical or clinical studies



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USA – Dealing with FDA and DEA

DEA is a separate and additional requirement for conducting studies in the USA – timelines are not specified and the requirements vary by State

- DEA approval for a clinical study happens AFTER the IND is filed
- DEA has no timeline within which they have to review the protocol
- Clinical studies require a Federal DEA license and may also need a State license
- Licensing requirements vary by State:
  - some States require licenses - some don't
  - some States require protocol specific licenses - some don't
  - while the "requirements" are the same – interpretation may differ
- Modifications to the protocol require updates to both DEA and FDA

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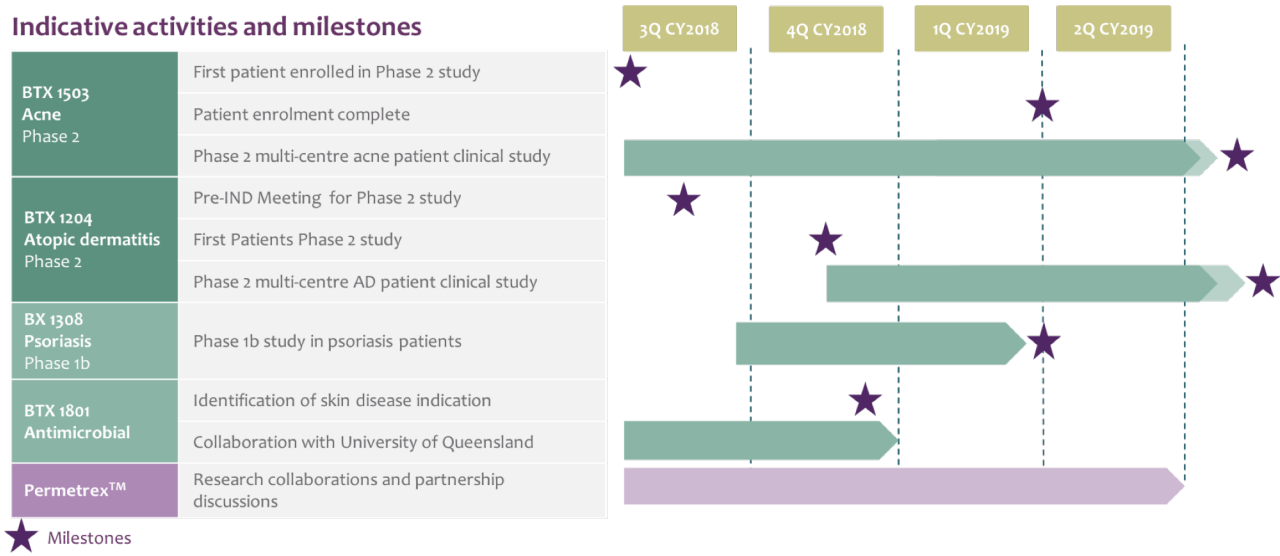
Key takeaways

Think creatively about how to generate data in parallel with a view to getting into Phase 2 ASAP

- Leverage Australia's regulatory system to get into humans quickly
- Conduct pre-clinical studies in parallel to clinical program
- Think about how to generate human POC data quicker and more simply
- Flip to IND after generation of POC human data and you have pre-clinical data in hand
- Make sure you obtain DEA approvals for all studies (pre-clinical and clinical)
- Undertake DEA clinical site preparation and registrations as early as possible
- Ensure you reserve time for DEA approval after you have an open IND



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