ASX/Media Release

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Botanix provides update on development activities

- **Botanix has completed its review of the BTX 1204 program study data, in the context of its broader dermatology platform, as well as current economic and clinical trial conduct conditions**
- **Increased focus will now be devoted to its antimicrobial platform, with the dermatology platform continuing to progress in a cost effective, but clinically constrained manner**
- **Significant reduction in operational costs and overhead has been implemented with a view to ensuring that cash reserves support planned programs**
- **Despite these challenges, multiple near-term milestones, solid cash backing and the increasing interest in antimicrobials for secondary infections, will drive next phase of growth for Botanix**

Philadelphia PA and Sydney Australia, 16 April 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") today provided an update on its dermatology and antimicrobial platforms. The dermatology platform consists of development programs for acne (BTX 1503), atopic dermatitis (BTX 1204), psoriasis (BTX 1308) and rosacea (BTX 1702). The antimicrobial platform consists of development programs for the prevention of post-surgical infections (BTX 1801) and other development programs for bacterial infections.

BTX 1204 study review

The Botanix team and extended key opinion leader group has completed its review of the recently reported BTX 1204 Phase 2 study top line results in patients with moderate atopic dermatitis ("1204 Study") that did not meet its primary endpoint. While the secondary endpoints provided patients with a small improvement in the Signs of AD, a reduction in BSA affected by AD, and a reduction in itch when compared to patients receiving vehicle, those differences were not statistically significant.

The review confirmed that while BTX 1204 was safe and well-tolerated, the active arm did not provide a statistically significant improvement in the signs and symptoms of atopic dermatitis, in patients with moderate disease. Further subgroup analysis of the primary and secondary endpoints did not identify any noteworthy trends or differences from the original outcomes, to provide confidence to move forward with BTX 1204 at this time.

Prioritisation of Platforms and Development Resources

In light of the BTX 1204 Study results, the current Covid-19 related restrictions and the prevailing economic climate, Botanix has undertaken a review of its dermatology and antimicrobial platforms to prioritise resources in the next 24 months, with a view to:

- maximising return on development dollars invested in continuing programs;
- preserving the value of its existing investment in its dermatology platform;
- increasing the potential to license or partner its development assets across both platforms;
- reducing costs and overheads where appropriate to reflect the new prioritisation of programs; and
- ensuring its cash reserves are sufficient to execute its planned development programs and provide a runway of at least 24 months of funding for the Company.

Botanix will be focusing its development resources primarily on its antimicrobial platform and the progression of its first clinical program for BTX 1801, while continuing to progress key assets from the dermatology platform in a clinically constrained manner. The lockdown of Western Australia's border and travel restrictions across Australia and New Zealand has restricted the flow of clinical trial material, the ability of Botanix staff to travel to sites to initiate and monitor clinical studies and the ability for subjects to enroll in clinical studies. These unprecedented travel restrictions have greatly influenced the Company's near-term plans to conduct clinical studies.

As a consequence, Botanix plans the following with respect to each of the assets in the dermatology and antimicrobial platforms:

- **BTX 1503 (acne):** the end of Phase 2 meeting will proceed as planned to gain guidance from the FDA as to the path required to support an NDA submission. Subject to any disruptions caused by the current Covid-19 situation, this meeting is targeted for the end of this quarter. Following that meeting, the Company will review the feedback from FDA and decide how to progress the development of BTX 1503;
- **BTX 1204 (atopic dermatitis)**: clinical development will be suspended;
- **BTX 1702 (rosacea):** clinical development on hold until recruitment may begin again with an expectation of enrolling the study in a timely and consistent fashion;
- **BTX 1308 (psoriasis):** clinical development will be suspended;
- **BTX 1801 (antimicrobial):** proceeding and will be re-focused to be conducted wholly within Western Australia, and will resume recruitment as travel requirements within Western Australian regions are eased; and
- **Permetrex™:** opportunities and partnerships will continue to be sought, both for the development of new products that can be rapidly brought to market for dermatology or antimicrobial applications.

Development resources and reduction in costs

Consistent with the prioritization of programs, Botanix has implemented a number of cost reduction measures aimed at reducing cash burn and extending the cash runway to ensure funding for its value creating activities. These measures include reducing staff and consultant headcount and reducing directors' fees, which will provide a cost saving of ~70% of headcount and Board costs on an annualised basis.

Most of the staff reductions have been made in our US commercial and development teams, to reflect the refocusing of activities in the coming months. All Board members have agreed to a reduction in base fees of 25% for a 12-month period, with the balance of director contract terms remaining the same.

The increased workload arising from the headcount reduction, will be assumed by our executive directors to ensure continuity and the ability to scale back up, as milestones are achieved in our development programs. The Board has agreed to issue options to remaining directors and staff, in consideration for this additional workload, to reflect the reduction in compensation and to retain key resources. Option grants to Directors will be made under the Company's existing employee securities incentive plan and will be subject to shareholder approval, at a general meeting to be called. A summary of the planned option grants is set out below:

- Vince Ippolito – 17,994,914 options
- Michael Thurn – 11,186,028 options
- Bill Bosch – 4,863,490 options
- Stewart Washer – 4,863,490 options

Options will be priced at a 34% premium to the 7-day VWAP up to and including 15 April 2020, vesting after 12 months and exercisable within 24 months of grant.

As at 31 December 2019, the Company held A$27.2m cash, not including the ~A$7.6m R&D tax refund received in January 2020. A further R&D tax incentive claim for a refund of ~A$5m to ~A$7m is expected to be lodged in respect of R&D activities for the year ended 30 June 2020. Botanix's cash reserve is expected to be more than sufficient to fund the planned BTX 1801 (antimicrobial) and BTX 1702 (rosacea) programs and support Company costs over the coming 24 months.

Increasing interest in bacterial infections

Antibiotic resistance is a significant global challenge in the context of public health, with the UN forecasting that drug resistant diseases could cause 10 million deaths each year by 2050 and result in an annual economic loss of US$100 trillion if new solutions are not found.[1] Some of the most troublesome resistance forming bacteria worldwide include *Staphylococcus aureus* (*'Staph'*) and Methicillin-resistant *Staphylococcus aureus* (*'MRSA'* or 'Golden Staph'). *Staph* and *MRSA* are the leading cause of Surgical Site Infections[2] and approximately 80% of SSIs are caused by the patient infecting themselves from their own nose. Antibiotics used for nasal decolonisation (e.g. Bactroban™ also known as *mupirocin*) have seen a significant increase in the development of resistance, with some hospitals recording resistance rates as high as 95% restricting its use[Error! Bookmark not defined.].

This is the first market opportunity that Botanix is targeting with its BTX 1801 synthetic cannabinoid clinical program. Botanix is also actively exploring opportunities for its synthetic cannabidiol and its

1 No Time to Wait: Securing the future from drug-resistant infections. Report to the Secretary-General of the United Nations (2019) available at https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1

2 Decolonization to Reduce Post discharge Infection Risk among MRSA Carriers, Huan et al Feb 14 2019, N Engl J Med 2019; 380:638-650

cannabinoid analog assets in other secondary infections and across different of routes of administration, as well as assessing additional opportunities to expand its pipeline of therapeutics that are responsive to both pandemic associated and resistant bacterial threats. The increasing interest and availability of non-dilutive funding for therapeutics that treat bacterial infections, provides a unique opportunity for Botanix.

Botanix President and Executive Chairman Vince Ippolito, said: "The Company is extremely grateful to our team for the work that they have done to build Botanix to where it is today."

"As we chart a new course forward in these uncertain times, today we need to focus our expenditures and programs on activities that are highly meaningful to patients and that will create value for shareholders."

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 has two separate cannabinoid development platforms, dermatology and antimicrobial products, both of which leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly synthetic cannabidiol. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases.

The Company is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabinoids with first enrolment for BTX 1801 Phase 2a study for the prevention of surgical site infections expected in CY2020. For the dermatology platform, preparations are also well advanced for an end of Phase 2 meeting with the FDA for its BTX 1503 acne program and the Company plans to progress its Phase 1b rosacea study in the near future.

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

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