



ASX Announcement | 16 December 2020
Althea Group Holdings (ASX:AGH)

CBD medicines available for over-the-counter sale from 2021

Investment Highlights:

- Althea applauds the final decision by the Therapeutic Goods Administration (TGA) to amend the current Poisons Standard to down schedule cannabidiol (CBD) to allow greater access through a new Schedule 3 entry¹
- The amendment will allow Australian patients to purchase CBD products upon consultation with a pharmacist, without the need for a prescription
- Althea will now proceed with plans to register several CBD products for sale in Schedule 3, including the top selling Althea CBD100

16 December 2020: **Australian medicinal cannabis company Althea Group Holdings Limited (ASX:AGH) ('Althea' or 'the Company')** is delighted to announce that a major regulatory change has been confirmed in relation to the status of cannabidiol (CBD) in Australia.

TGA confirms new Schedule 3 entry for CBD

The Therapeutic Goods Administration yesterday issued its final decision on proposed amendments to the Poison Standard which, amongst other amendments, sees a new Schedule 3 entry created for cannabidiol. The date of effect of the decision is 1 February 2021, bringing it forward from the date of 1 June 2021 as proposed in the interim decision.

The amendment will allow CBD to be supplied for therapeutic use under a new Schedule 3 (Pharmacist Only Medicine) entry. This new, non-prescription cannabis channel would allow Australian patients to purchase CBD products over the counter upon consultation with a pharmacist, without the need for a prescription.

Maximum recommended daily dose increased

The final decision included a modification to the dose specified in the interim decision, increasing from 60 mg/day, up to 150 mg/day. The decision paves the way for Althea's top selling full-spectrum CBD product, Althea CBD100, to be made available under Schedule 3 (currently sold in Schedule 4 - Prescription Only Medicine).

Althea CBD100, along with several other CBD preparations currently in development, would need to be included in the Australian Register of Therapeutic Goods (ARTG) to be made available for sale as Schedule 3 products. The Company maintains robust drug master files for its medications and is confident in its ability to meet the ARTG requirements for Schedule 3 preparations.

¹ <https://www.tga.gov.au/sites/default/files/notice-final-decision-amend-or-not-amend-current-poisons-standard-cannabidiol.pdf>

Althea Group Holdings Limited | ABN 78 626 966 943

A. Level 37, 360 Elizabeth Street, Melbourne, 3000, Victoria, Australia

E. info@althea.life

P. 1300 70 20 20

W. althea.life



Althea CEO, Josh Fegan said: “We applaud the TGA’s final decision in this matter and are glad to see the administration listened to industry following the interim decision, and subsequently decided to increase the maximum recommended daily dose acknowledging that this dose is consistent with the expected safety profile of a Schedule 3 medicine².”

The final decision follows the Company’s announcement to shareholders that it had raised additional working capital, through an institutional placement, with a portion of those funds allocated towards the product development and registration of a range of CBD products for the potential Schedule 3 market in Australia. This decision provides confirmation of that marketplace and the Company can now proceed with its plans to have over the counter Althea products available for Australian patients in 2021.”

-ENDS-

Authorised by: Robert Meissner, Company Secretary

For further information, please contact:

Althea

Josh Fegan

CEO & Managing Director

M: 1300 70 20 20

E: contact@althea.life

Media Enquiries

Dan Francome

Media Relations

P: +613 9650 5096

E: dfrancome@althea.life

Investor Relations

Jane Morgan

Investor Relations Partner

M: +61 405 555 618

E: jm@janemorganmanagement.com.au

Althea Group Holdings Limited (ASX:AGH)

Althea Group Holdings Ltd (ASX:AGH) is a global pharmaceutical company and supplier of medicinal cannabis. Althea also offers a range of education, access and management services to support eligible patients and healthcare professionals in navigating medicinal cannabis treatment pathways.

Althea currently operates within highly regulated medicinal cannabis markets including Australia, United Kingdom and Germany, with plans to expand the brand into emerging markets across the world.

To learn more, please visit: www.althea.life

² Notice of final decision to amend (or not amend) the current Poisons Standard - cannabidiol
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