ASX/Media Release

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Emerald set to benefit from interim TGA decision to down schedule CBD

- **Interim decision from Australia's Therapeutic Goods Administration (TGA) would require producers of "low dose" CBD products to present clinical evidence of safety and efficacy in order to register those products with the Australian Register of Therapeutic Goods (ARTG)**
- **TGA recommendation would allow "low dose" CBD products on the ARTG to become available to patients through pharmacies for approved indications only**
- **TGA recommendation highlights the need for independent, high-quality clinical evidence to support individual evaluations of quality, safety and effectiveness for cannabinoid medicines**
- **Emerald ideally positioned to support the market need for independent and dose-specific clinical evidence with its unique and growing real-world evidence data platform**

Emerald Clinics Limited (ASX: EMD) ('Emerald' or 'the Company'), a Real-World Evidence company that develops remote patient monitoring technologies underpinned by a clinical services model, has welcomed an interim decision from Australia's Therapeutic Goods Administration (TGA) that recommends "low dose" cannabidiol, or CBD, become a Schedule 3 medicine on the Australian Register of Therapeutic Goods (ARTG).

The interim ruling outlined the process for "low dose" CBD to be registered as a Schedule 3 medicine at the 60mg/day limit. Registration of "low dose CBD" would require a full submission to the TGA and high quality clinical evidence to support safety and effectiveness.

The TGA interim decision could allow patients to purchase "low dose" CBD as a Pharmacist Only or over-the-counter medication for specific indications. Advertising to consumers would not be permitted, and higher doses of CBD and other cannabinoid medicines would still require a prescription from a medical practitioner.

Emerald's strategy of generating high quality clinical evidence on the safety and efficacy of new treatments, including CBD, makes it well positioned to benefit from the changes announced by the TGA.

Emerald's CEO Dr Michael Winlo said: "Regulators play an important role ensuring medicines are safe and effective before they are available to patients which is why they require independent and high quality clinical evidence to support their recommendations.

"Emerald exists to generate product-specific real-world evidence packages and insights that can support regulators, like the TGA and others involved in these decisions around the globe, together with developers of CBD and other new treatments. We are encouraged by this meaningful commitment to bring evidence-based, innovative therapies to patients."

The TGA will undertake a second consultation period with a closing deadline of 13 October 2020 and expects to make a final decision on 1 February 2021.

Release authorised by: Dr Michael Winlo, CEO and Managing Director

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About Emerald Clinics Limited

Emerald Clinics Limited (ACN 625 085 734) is an Australian incorporated company focussed on generating Real-World Evidence using its network of specialist medical clinics and purpose-built, remote patient monitoring software and technology. The Emerald model provides care while also co-creating high quality and ethically sourced clinical data from informed and consenting patients. Emerald's evidence is used to accelerate the development of new treatments and models of care. Emerald customers pay for deidentified data, clinical trials and consulting services or monitor their workforce.

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 results 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 its product candidates. In addition, the forward-looking statements included in this press release represents 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.