**MHRA Guidance on the use of Real-World Data in Clinical Studies for Regulatory Decision-Making Supports Albert Labs' Licensing Pathway**

***Accelerating access to psychedelic-based medicines for patients with urgent and unmet needs.***

**VANCOUVER, BC, Jan. 4, 2022 /CNW/ -** On the 17th December 2021 the UK's Medicines and Healthcare products Regulatory Agency (MHRA) produced guidance acknowledging and setting out the criteria for the use of Real World Data and Evidence in regulatory decision making. This guidance is consistent with Albert Labs' strategy, one of the first psychedelic drug development companies to use a Real World Evidence (RWE) approach for regulatory approval.

Albert Labs is pursuing the RWE pathway in the licensing of their natural psilocybin medicine which has been endorsed by leading hospital centers in the UK. This expedited pathway offered by the UK regulatory system will accelerate access to treatment, benefiting patients, not only in the UK but the rest of Europe, Canada, and the US.

" We embrace this regulatory guidance particularly in the investigation of psilocybin-assisted psychotherapy. Albert Labs consider that carefully designed pragmatic trials that implement a progressive use of Real World Evidence, will greatly advance the understanding of the safety, effectiveness, impact, and optimal clinical use of this new therapy." said Dr. Malcolm Barratt-Johnson, the Chief Medical Officer of Albert Labs.

The guidance emphasizes that a study or studies considered under this guidance need to be of the same standard as would be expected from a traditional Randomized Control Trial (RCT). The guidance further states that well-designed and conducted prospective RCTs provide a high level of evidence irrespective of the categorization of the data source.

" Our approach, in the investigation of psilocybin-assisted therapy, has been designed to reduce risk, improve outcomes, and importantly to speed up access to those patients who will benefit from this therapy. We believe Real World Evidence will play a vital role in helping safeguard the development of this promising mental health treatment." added Dr. Malcolm Barratt-Johnson.

Albert Labs, is following the MHRA's guidance and taking the necessary regulatory and scientific steps required for authorization of a new treatment using an RWE approach. The trials are focused on early access to treatment. Albert Labs expects to treat patients suffering from cancer-related distress in the first half of 2022 with this focused approach and accelerated product development and licensing pathway.

ON BEHALF OF THE BOARD OF DIRECTORS

**Albert Labs Inc.**

**Dr. Michael Raymont**

**Chief Executive Officer & Chairman**

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