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aGvHD

## Positive results for cannabidiol (CBD) for the prevention of acute graft-*versus*-host disease (GvHD)

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On August 19<sup>th</sup> 2019, it was announced that interim results from the phase II clinical study ([NCT03840512](https://clinicaltrials.gov/ct2/show/NCT03840512)) evaluating cannabidiol (CBD) for the prevention of acute graft-*versus*-host disease (GvHD) were significantly positive. As a result, enrollment into the high-dose cohort of the phase II trial will not commence, and instead, a phase III clinical registration study will be initiated. Furthermore, CBD has been granted orphan drug designation by both, the [U.S. Food and Drug Administration \(FDA\)](https://www.fda.gov) and [European Medicines Agency \(EMA\)](https://www.ema.europa.eu). Also, the FDA has recommended the application for both Breakthrough Therapy and Fast Track Designations for CBD for the prevention and treatment of acute GvHD.<sup>1</sup>

The phase II study evaluated the pharmacokinetic profile, safety, and efficacy of multiple doses of CBD in combination with standard prophylaxis (cyclosporine and methotrexate) for the prevention of acute GVHD (aGVHD) in patients following allogeneic hematopoietic stem cell transplantation (HSCT).<sup>3</sup>

### Phase II results after 180 days of observation:

- 1 of 12 patients in 75 mg cohort (8%) developed grade 2–4 acute GvHD, while no patients developed grades 3 or 4 acute GvHD
- No patients developed grades 2–4 acute GvHD in the medium-dose cohort (150mg dose of CBD)

### Principal elements of the phase III study design will include the following:

Phase III of the study will be a multicenter (Australia and Israel), double-blind placebo-controlled clinical trial. In this trial, 50 patients will be enrolled, 25 patients will be given a 150mg dose of CBD and 25 patients will be given placebo, twice daily.

### References

1. [Kalytera](https://www.kalytera.co/news/kalytera-to-conclude-phase-2-clinical-study-and-initiate-phase-3-study/). Kalytera to Conclude Phase 2 Clinical Study and Initiate Phase 3 Study <https://www.kalytera.co/news/kalytera-to-conclude-phase-2-clinical-study-and-initiate-phase-3-study/> [Accessed September 05 2019]
2. [GloboNewsWire](https://www.globenewswire.com/news-release/2019/08/19/1903469/0/en/Kalytera-to-Conclude-Phase-2-Clinical-Study-and-Initiate-Phase-3-Study.html). Kalytera to Conclude Phase 2 Clinical Study and Initiate Phase 3 Study. <https://www.globenewswire.com/news-release/2019/08/19/1903469/0/en/Kalytera-to-Conclude-Phase-2-Clinical-Study-and-Initiate-Phase-3-Study.html> [Accessed September 05 2019]
3. [ClinicalTrials.gov](https://www.clinicaltrials.gov/ct2/show/NCT03840512). An Open Label Study of Multiple Doses of Cannabidiol in the Prevention of Acute Graft-Versus-Host Disease (GVHD) NCT03840512. <https://www.clinicaltrials.gov/ct2/show/NCT03840512> [Accessed September 05 2019]

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