

# A Phase I Trial of Intravenous *Viscum album* Mali in Solid Tumor Patients and the Clinical Case that Inspired the Trial

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## **Introduction:**

*Viscum album*, commonly known as mistletoe, contains several biologically active substances including lectins, viscotoxins, oligo- and polysaccharides, peptides, amino acids, and flavonoids. Individual cases, trials, and systematic reviews of Helixor demonstrate improvements in quality of life, the tolerability of conventional tumor therapy, survival and tumor response. A recent trial demonstrated the safety of Helixor P in doses up to 2000mg intravenously once weekly.

## **Methods:**

In the proposed Phase I trial, inspired by an individual case of colon cancer that combined conventional and complementary therapy, we will seek to determine the safety and toxicity profile as well as the maximum tolerated dose of Helixor® M in patients with advanced solid tumors who have received at least one line of systemic therapy for metastatic disease. This phase I study will evaluate up to 8 dose levels of Helixor®M as a single agent: 150 mg, 300 mg, 600 mg, 900 mg, 1200 mg, 1500 mg, 1800 mg, and 2000 mg. Drug will be given intravenously over 3 hours dosed 3 times a week. Patients will have blood draws every 4 weeks for correlates and disease monitoring. Imaging for RECIST response will be done every 8 weeks or as clinically indicated.

## **Results:**

In a standard 3+3 phase I trial design, we are continuing to enroll patients to increasing dose cohorts as designed starting with 150mg to 2000mg. We continue to monitor blood and imaging markers of their disease. In addition we continue to monitor their quality of life while on trial. We will also report on exploratory correlates including germline mutations that may correlate with response. In addition we will look at immunological markers including changes in cytokine production by peripheral blood mononuclear cells (PBMC) as indicated by interleukin 2 [IL-2], interleukin 6 [IL-6], interleukin 8 [IL-8], interleukin 12 [IL-12], and interferon- gamma [IFN- $\gamma$ ].

## **Conclusion:**

Once we complete the safety assessment, we hope to expand to test mistletoe in combination with chemotherapy.