Phase II Trial of a Personalized Vaccine for Advanced HCC

Introduction

The trial is evaluating a novel therapeutic vaccine to treat advanced hepatocellular carcinoma (HCC) treated with the most common treatments including sorafenib. The trial aims to improve clinical outcomes for patients beyond the best current standard of care. The trial is ongoing, and interim data from an initial phase I study has been reported. The trial is designed to evaluate the safety and efficacy of the vaccine in the treatment of advanced HCC.

Endpoints

The primary endpoint of the trial is to determine the safety and tolerability of the vaccine. Secondary endpoints include the evaluation of the vaccine's efficacy in terms of disease control and overall survival. The trial is being conducted in multiple centers across different countries.

Methods

The trial is a randomized, double-blind, placebo-controlled study. Patients are randomly assigned to receive either the vaccine or placebo in a 2:1 ratio. The vaccine consists of a personalized cocktail of tumor neoantigens and HSP, as well as checkpoint molecules and other immunomodulatory agents.

Results

The trial has enrolled a total of 120 patients, with 80 receiving the vaccine and 40 receiving placebo. The trial is currently in its second phase, with patients being followed up for a minimum of 12 months. Interim data from the first phase of the trial has shown promising results, with the vaccine demonstrating a high degree of safety and a tolerable side effect profile.

Conclusion

The trial is expected to provide important insights into the efficacy and safety of personalized vaccines in the treatment of advanced HCC. Further analysis of the trial data is ongoing, and results are expected to be made available in the near future.