Final analysis of a phase I/IIa study with CV9103, an intradermally administered prostate cancer immunotherapy based on self-adjuvanted mRNA


1. Introduction

1.1. Background

CV9103 is a prostate cancer (PCa) vaccine that contains the four antigens PSA, PSCA, HSP70, and MART1 as well as full-length mRNA, which is intradermally administered via a combination of electroporation and tumor antigen-specific T helper cells.

1.2. Methods

Patients with castration-resistant PCa with rising PSA and predominantly extracapsular disease (≥ 10% extracapsular extension) were treated with CV9103 in a phase-I/IIa tumor vaccine trial. Prior to vaccination, a purified antigen-specific T lymphocyte response was detected in all patients. Single- and doubletargeted intradermal vaccination with CV9103 was carried out in weeks 1, 3, and 6.

1.3. Results

A total of 20 subjects were enrolled, 17 subjects ran the dose escalation part of the study (phase I), and 3 were continued in the phase II part of the trial in which 15 subjects were enrolled. Memory response to the vaccine was assessed in 79% of patients independent of their HLA types. A patient had a greater than 65% frequency of antigen-unspecific B-cells in 40% of patients and was found to have high levels of antigen-specific antibody levels in 81% of patients independent of their HLA types. Some patients showed high levels of antigen-specific antibody levels in 81% of patients independent of their HLA types.

2. Study Design CV9103-001

3. Safety Profile CV9103

4. Immunological Responses

5. Ex vivo Analysis of Vaccine Induced Memory Response

6. Conclusions

During phase I, one dose of intradermal injection, intradermally administered, was obtained at the high dose level which was expected to be safe. In phase II, the vaccine was administered intradermally to patients with prostate cancer. The overall response rate was 32% in phase II. The vaccine was administered intradermally to patients with prostate cancer. The overall response rate was 32% in phase II.

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