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## INTERIM ANALYSIS OF A WT-1 AND PRAME 'FAST-DC' VACCINE SHOWS SAFETY AS ACTIVE IMMUNOTHERAPY FOR THE PREVENTION OF AML RELAPSE

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Contributions



Abstract

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### Background

Patients with acute myeloid leukemia (AML), not eligible for allogeneic hematopoietic stem cell transplantation (HSCT), have a significant risk of disease relapse due to lack of long-term disease control.

### Aims

To investigate the possibility of relapse prevention after initial chemotherapy, a safety and feasibility Phase I/II trial (NCT02405338) is currently being conducted using dendritic cells (DCs), generated with a rapid production protocol of 3 to 4 days. The manufacture uses RNA electroporation encoding the full-length protein antigens PRAME (Preferentially expressed antigen in Melanoma) and WT-1 (Wilm's Tumor-1 Antigen) as well as a cocktail containing a TLR-7/8 agonist for maturation. Data presented here reflect results of an interim analysis at the 1 year follow up time point, while vaccination continues until all patients reach the end of the trial at a follow up of 2 years.

### Methods

A total of 20 subjects (median age 59, range 24 to 73) with AML (risk groups good, intermediate, poor: 13, 5, 2), in morphologic complete remission or complete remission with incomplete hematologic recovery after induction or consolidation therapy, not eligible for allogeneic HSCT, were entered in the trial. Subjects had to be positive for WT-1 with or without positivity for PRAME. DC vaccinations were carried out monthly, with a higher frequency within the first 6 weeks. AML diagnoses were established with a median of 9.8 months before the first vaccination (range 4.5 to 17.5 months), and the last chemotherapy infusion was performed at a median of 6.9 months (range 2 to 14.8 months).

### Results

The manufacture of the DC vaccine in these chemotherapy-pretreated subjects was feasible for all 20 patients and aliquots of 5 to 10 x 10<sup>6</sup> cells were used per vaccination. The vaccinations were well tolerated with no serious adverse events (SAEs) related to the treatment. The most common adverse events (AEs) were injection site related, accounting for 35% of all AEs and were mild in nature (Grade 1). A total of 3 grade 3 adverse events, unlikely or not related to the treatment, were recorded: one Herpes zoster infection, one upper respiratory tract infection and 3 decreases in platelet counts. All three platelet count decreases were due to relapses of the leukemia.

After a 12-months treatment period, the overall survival was 89% (18 of 20 patients, 95% confidence interval: 61 to 97%) and the progression free survival was 60% (12 of 20 patients, 95% confidence interval: 36 to 78%). Most relapses, 5 out of 8, occurred within the first 80 days after the start of the vaccination, out of which the 2 deaths were in patients with relapses on days 45 and 64, which could point to a starting relapse upon entering the study.

## Conclusion

In summary, at a follow up time of 1 year, DC vaccination against WT-1 and PRAME appears to be safe and feasible for use in the prevention of AML relapse.

**Session topic:** 25. Gene therapy, cellular immunotherapy and vaccination - Clinical

**Keyword(s):** AML, Immunotherapy

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