DCOne-002

**Inclusion criteria**

Main Inclusion Criteria:
1. Confirmed diagnosis of AML according to WHO2016 criteria, including cytological, molecular and cytogenetic criteria (except acute pro-myelocytic leukaemia/APL).
2. In CR1 (first complete remission) or CRi (incomplete blood count recovery) documented by bone marrow examination up to one month before vaccination; CR defined as less than 5% blasts in normo-cellular bone marrow, ANC >1\*E9/L, platelet count >100\*E9/L, no evidence of extramedullary disease. Patients in CRi (patients with <5% blasts but with incomplete blood count recovery) should have platelets >50 E9/L.
3. MRD as defined by multicolour flow cytometry (MFC) at a value of > 0.1%, or detection of specific molecular abnormalities such as NPM1 mutation.
4. Patients that are in CR1 or CRi. Patients not having undergone consolidation therapy must have been in CR1 for at least 1 month prior to enrolment.
5. Expected and willing to undergo all study procedures, including outpatient evaluations for clinical and immunological monitoring.
6. Male or female of ≥ 18 years of age.
7. Women of childbearing potential must be using anti-conceptive therapy or use two (2) barrier contraceptive methods (one by each partner and at least one of the barrier methods must include spermicide (unless spermicide is not approved in the country or region). See section 12.8 for birth control methods deemed acceptable for this study.
8. ECOG (WHO) performance status 0-2.
9. Willing and able to provide written informed consent for participation in the study

**Exclusion criteria**

Main Exclusion Criteria:
1. Acute Promyelocytic (APL; M3) type of AML.
2. Patients who have undergone or are scheduled for allogeneic stem cell transplantation.
3. History of previous allogeneic bone marrow or solid organ transplantation.
4. Uncontrolled or serious infections
5. Ongoing immunosuppressive therapy, other than short use of low dose steroids, i.e. equivalent to an average dose of ≤10mg of prednisone/day.
6. Chemotherapy and antineoplastic hormonal therapy within 28 days prior to the screening visits.
7. Active autoimmune disease.
8. Inadequate liver function (AST and ALT > 3 x ULN, serum bilirubin >3 x ULN).
9. Other active Malignancies within the last 5 years, except for adequately treated carcinoma in situ of the cervix or squamous carcinoma of the skin or adequately controlled limited basal cell skin cancer.
10. Pregnant or lactating females.
11. Major surgical procedure (including open biopsy) within 28 days prior to the first study treatment, or anticipation of the need for major surgery during the course of the study treatment.
12. Uncontrolled hypertension (systolic > 150 mm Hg and/or diastolic > 100 mm Hg) or clinically significant (i.e. active) cardiovascular disease.
13. Evidence of any other medical conditions (such as psychiatric illness, physical examination or laboratory findings) that may interfere with the planned treatment, affect patient compliance or place the patient at high risk from treatment-related complications.
14. Known HIV, Hepatitis B and/or Hepatitis C infections.
15. History of hypersensitivity to the investigational medicinal product or to any excipient present in the pharmaceutical form of the investigational medicinal product.