



ZOOM LUD01-003

Indication	Melanoma patients (stage III-IV)																																	
Title	Vaccination of patients with stage III or IV malignant melanoma with short and long peptides, Montanide, and CpG-7909/PF-3512676																																	
Protocol ID	LUD01-003																																	
Phase	Phase I																																	
Sponsor	Ludwig Institute for Cancer Research																																	
Local Principal Investigator	Prof. Olivier Michielin																																	
Primary Objective	<p>Primary objectives:</p> <ul style="list-style-type: none"> • To determine whether a peptide specific CD8 and CD4 T cell response can be induced by vaccination with melanoma antigen peptides (Melan-A analog EAA and ELA, NY-ESO-1b, NY-ESO-1lp and MAGE-A10) ± CpG-7909 / PF-3512676 ± IL-2 • To assess the safety of vaccination. 																																	
Inclusion/exclusion criteria	<p>Inclusion criteria include the following :</p> <ul style="list-style-type: none"> ○ Histologically confirmed stage III or IV melanoma ○ If patient is HLA-A2 negative, tumor must express NY-ESO-1 only, if patient is HLA-A2 positive, tumor must express Melan-A and at least one of the following tumor antigens MAGE-A10, NY-ESO-1 and LAGE-1. ○ Expected survival of at least 5 months ○ Full recovery from surgery ○ Karnofsky scale performance status of 70% or more. ○ Age > 18 years. ○ Able to give written informed consent ○ The following laboratory results: <table style="width: 100%; border: none;"> <tr> <td style="padding-left: 40px;">Hemoglobin</td> <td style="padding-left: 20px;">≥ 100g/L</td> <td></td> </tr> <tr> <td style="padding-left: 40px;">Neutrophil count</td> <td style="padding-left: 20px;">≥ 1.5 x 10⁹/L</td> <td></td> </tr> <tr> <td style="padding-left: 40px;">Lymphocyte count</td> <td style="padding-left: 20px;">≥ 0.5 x 10⁹/L</td> <td></td> </tr> <tr> <td style="padding-left: 40px;">Platelet count</td> <td style="padding-left: 20px;">≥ 100 x 10⁹/L</td> <td></td> </tr> <tr> <td style="padding-left: 40px;">Serum creatinine</td> <td style="padding-left: 20px;">≤ 2 mg/dL</td> <td style="padding-left: 20px;">(0.18mmol/L)</td> </tr> <tr> <td style="padding-left: 40px;">Calculated clearance</td> <td style="padding-left: 20px;">> 60 ml/min</td> <td></td> </tr> <tr> <td style="padding-left: 40px;">Serum bilirubin</td> <td style="padding-left: 20px;">≤ 2mg/dL</td> <td style="padding-left: 20px;">(0.034mmol/L)</td> </tr> <tr> <td style="padding-left: 40px;">Granulocyte count</td> <td style="padding-left: 20px;">> 2.5x10⁹/L</td> <td></td> </tr> <tr> <td style="padding-left: 40px;">ASAT, ALAT</td> <td style="padding-left: 20px;">< 2.5 x upper limit of normal</td> <td></td> </tr> <tr> <td style="padding-left: 40px;">aPTT</td> <td style="padding-left: 20px;">21-33 sec</td> <td></td> </tr> <tr> <td style="padding-left: 40px;">TP</td> <td style="padding-left: 20px;">≥ 80%</td> <td></td> </tr> </table>	Hemoglobin	≥ 100g/L		Neutrophil count	≥ 1.5 x 10 ⁹ /L		Lymphocyte count	≥ 0.5 x 10 ⁹ /L		Platelet count	≥ 100 x 10 ⁹ /L		Serum creatinine	≤ 2 mg/dL	(0.18mmol/L)	Calculated clearance	> 60 ml/min		Serum bilirubin	≤ 2mg/dL	(0.034mmol/L)	Granulocyte count	> 2.5x10 ⁹ /L		ASAT, ALAT	< 2.5 x upper limit of normal		aPTT	21-33 sec		TP	≥ 80%	
Hemoglobin	≥ 100g/L																																	
Neutrophil count	≥ 1.5 x 10 ⁹ /L																																	
Lymphocyte count	≥ 0.5 x 10 ⁹ /L																																	
Platelet count	≥ 100 x 10 ⁹ /L																																	
Serum creatinine	≤ 2 mg/dL	(0.18mmol/L)																																
Calculated clearance	> 60 ml/min																																	
Serum bilirubin	≤ 2mg/dL	(0.034mmol/L)																																
Granulocyte count	> 2.5x10 ⁹ /L																																	
ASAT, ALAT	< 2.5 x upper limit of normal																																	
aPTT	21-33 sec																																	
TP	≥ 80%																																	

	<p>Exclusion criteria include the following:</p> <ul style="list-style-type: none">○ Clinically significant heart disease (NYHA Class III or IV).○ Other serious illnesses, e.g., serious infections requiring antibiotics, bleeding disorders or uncontrolled peptic ulcer, or seizure or central nervous system disorders.○ History of immunodeficiency disease or autoimmune disease.○ Metastatic disease to the central nervous system, unless treated and stable.○ Known HIV positivity.○ Known seropositivity for hepatitis B surface antigen.○ Chemotherapy, radiation therapy, or immunotherapy within 4 weeks before study entry (6 weeks for nitrosoureas)○ Concomitant treatment with steroids, antihistamine drugs. Topical or inhalation steroids are permitted.○ Participation in any other clinical trial involving another investigational agent within 4 weeks prior to enrollment.○ Pregnancy or lactation.○ Women of childbearing potential not using a medically acceptable means of contraception.○ Psychiatric or addictive disorders that may compromise the ability to give informed consent.○ Lack of availability of the patient for immunological and clinical follow-up assessment.○ Coagulation or bleeding disorders.○ Metastatic disease to the central nervous system, unless treated and stable
--	---

<http://clinicaltrials.gov/ct2/show/NCT00112242?term=cpg+melanoma&rank=4>