



ZOOM sLAG-3

Indication	Melanoma patients stage II to IV, HLA A2+, Melan A+																																	
Title	Vaccination of melanoma patients (stage II-IV) with ImmuFact IMP321, tumor antigenic peptides and Montanide																																	
Protocol ID	sLAG-3																																	
Phase	Phase I/IIa																																	
Sponsor	CePO																																	
Local Principal Investigator	Prof. Olivier Michielin																																	
Primary Objective	<p>Primary objectives:</p> <ul style="list-style-type: none"> • To evaluate melanoma-antigen specific immune responses induced by this vaccination with tumor antigenic peptides derived from MAGE-A3 (MHC I and II), NY-ESO-1, Melan A and NA-17A with IMP321/LAG-3 as adjuvant/immunostimulant, formulated with Montanide, and • To assess the safety and tolerability of vaccination. 																																	
Inclusion/exclusion criteria	<p>Inclusion criteria include the following :</p> <ul style="list-style-type: none"> ○ Histologically confirmed stage II, III or IV melanoma patients ○ Tumor expression of Melan A antigen by reverse transcriptase and polymerase chain reaction (RT-PCR) analysis, preferably, or by immunohistochemistry. ○ HLA-A2 positive (serological or molecular typing of PBL). ○ Expected survival of at least three months ○ Karnofsky scale performance status of 70% or more. ○ Age > 18 years. ○ Able to give written informed consent ○ The following laboratory results: <table style="margin-left: 40px; border: none;"> <tr> <td>Hemoglobin</td> <td>≥ 100g/L</td> <td></td> </tr> <tr> <td>Neutrophil count</td> <td>≥ 1.5 x 10⁹/L</td> <td></td> </tr> <tr> <td>Lymphocyte count</td> <td>≥ 0.5 x 10⁹/L</td> <td></td> </tr> <tr> <td>Platelet count</td> <td>≥ 100 x 10⁹/L</td> <td></td> </tr> <tr> <td>Serum creatinine</td> <td>≤ 2 mg/dL</td> <td>(0.18mmol/L)</td> </tr> <tr> <td>Calculated clearance</td> <td>> 60 ml/min</td> <td></td> </tr> <tr> <td>Serum bilirubin</td> <td>≤ 2mg/dL</td> <td>(0.034mmol/L)</td> </tr> <tr> <td>Granulocyte count</td> <td>> 2.5x10⁹/L</td> <td></td> </tr> <tr> <td>ASAT, ALAT</td> <td>< 2.5 x upper limit of normal</td> <td></td> </tr> <tr> <td>aPTT</td> <td>within laboratory normal ranges</td> <td></td> </tr> <tr> <td>TP</td> <td>≥ 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	within laboratory normal ranges		TP	≥ 80%	
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	<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.○ 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.○ Kidney dysfunction with creatinine > 2 x the upper limit of the normal value.○ Reported strong (allergic) reactions to previous vaccination.
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<http://clinicaltrials.gov/ct2/show/NCT01308294?term=lag3&rank=1>