Clinical Trial of Kanglaite Injection in Patients with Non-small Cell Lung Cancer (NSCLC) in Russia

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KLT injection is natural preparation, made by extracting the effective components from seeds of coix, adding natural emulsion agent to form microparticle emulsion.

According of Chinese date, in 214 pts. with metastatic NSCLC KLT produced an objective response rate (CR+PR) of 12%. We performed the phase II study to determine the activity and toxicity of KLT in inoperable stage pts. with NSCLC.

Method: 13 previously untreated pts. with morphologically confirmed NSCLC (4-adenocarcinoma and 9 pts - squamous cells cancer) were enrolled in this trial. KLT 200ml was administered as 90 min i.v. infusion daily on days 1-21 and 29-49.

Patients characteristic: male 9/female 4; median age - 57.4; ECOG PS: 0-1, 1-8, 2-4; stage UFA” -1, III”B” -5, IV -7.

Results: 13 pts. were assessable for toxicity and 12 pts. for response.

Efficacy: SD 50% (including MR (effect<50%) in 3 pts.); PD -6 pts. (50%). KLT demonstrated useful actions on human immune system: increasing in 8/11 CD38, CD 50 and IgG; in 7/11 CD 3, CD 4, HLA-DR, CD 5; in 6/11 CD 7, CD 95, CD4/CD8, NK-activity; IN 5/11 CD25, CD45RA, IgA, IgM. Elevation of CD 95 and CD 50 is most important and may improve results of second line chemotherapy CD95 (FAS) plays key roles in the initiation of apoptotic pathway CD 50 (adhesion molecules - cadherins). Tolerance has been excellent. Adverse events were mild: transient elevation of hepatic enzymes ALT -3(23%), AST -2( 15.3%).