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4-Week Repeated Dose Rat GLP Toxicity Study of Oncolytic ECHO-7 virus Rigvir Administered Intramuscularly with a 4-week Recovery Period

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The oncolytic ECHO-7 virus Rigvir was registered in Latvia in 2004 and later in Georgia, Armenia and Uzbekistan. No severe adverse events have been observed. The aim of this 4-week repeated dose good laboratory practice (GLP) toxicity study was to determine the potential toxicity and reversibility of any findings after a 4-week treatment-free period to meet regulatory requirements. Han Wistar rats were randomly assigned to control and Rigvir (2*106, 1*107 and 2*107 TCID50) groups. Intramuscular administration was on days 1-3, 8-10, 15-17, 22-24. Clinical signs, average food intake, body weights, ophthalmology, clinical pathology parameters, bioanalysis, gross necropsy, organ weights, biodistribution and histopathology were evaluated. There were no unscheduled deaths, adverse clinical signs, no changes in body weight, body weight gain, food intake, ophthalmoscopy, clinical pathology, urine volume or composition, or organ weights. Slightly higher numbers of eosinophils in Rigvir-treated animals returned to normal after recovery. Rigvir was biodistributed to the spleen. Low incidence of inflammatory cell infiltration at administration sites and increased lymphoid cellularity at the regional (inguinal and popliteal) lymph nodes were observed; after recovery, only those in popliteal lymph nodes remained. Therefore, it is concluded that the 4-week Rigvir (2*107 TCID50) administration was well tolerated in rats. The no observed adverse effect level (NOAEL) was the highest dose tested, 2*107 TCID50.

Keywords: ECHO-7 Virus, Oncolytic Virus, Rigvir, Virotherapy, Preclinical

Biography:

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