## Abstract

### Dosage regimen for administering a CD19xCD3 bispecific antibody

The present invention relates to a method for assessing (analyzing) the risk of potential adverse effects for a human patient mediated by the administration of a CD19xCD3 bispecific antibody to said patient comprising determining the ratio of B cells to T cells of said patient, wherein a ratio of about 1:5 or lower is indicative for a risk of potential adverse effects for said patient. Accordingly, the present invention relates a method (dosage regimen) for administering a CD19xCD3 bispecific antibody to a human patient having a B : T cell ratio of about 1:5 or lower, comprising (a) administering a first dose of said antibody for a first period of time; and consecutively (b) administering a second dose of said antibody for a second period of time, wherein said second dose exceeds said first dose. In some embodiments, a third dose of said antibody is administered for a third period of time. This dosage regimen can be applied in methods for treating malignant CD19 positive lymphocytes or for ameliorating and/or preventing an adverse effect mediated by the administration of said bispecific antibody. The present invention also relates to the use of a CD19xCD3 bispecific antibody for the preparation of a pharmaceutical composition to be used in a method of the present invention. A pharmaceutical package or kit comprising a first dose and a second dose and optionally a third dose of said antibody as defined in the methods/dosage regimen of the present invention is disclosed as well.

Figure for publication: None