

International Patent Application Publication No. WO 2016/082044 describes dosing regimens for anti-HER2 biparatopic antibodies.

[0005] International Patent Application Publication No. WO 2019/173911 describes anti-HER2 biparatopic antibody-drug conjugates comprising an auristatin analogue.

[0006] Most marketed antibody-based therapeutics are administered to subjects in dosages based either on the weight or the body surface area of a subject. For example, a therapeutic antibody may be administered at a dosage of X mg/kg of body weight, or Y mg/m² of body surface area. For example, the monoclonal antibody panitumumab has been approved has been approved for administration at a dosage of 6mg/kg every 2 weeks (Q2W) and the monoclonal antibody nivolumab has been approved for administration at a dosage of 3 mg/kg Q2W. The monoclonal antibody rituximab has been approved for administration at a dosage of 375 mg/m² body surface area. The monoclonal antibody cetuximab has been approved for administration at a dosage of 250 mg/m² body surface area every week after a loading dose of 400 mg/m². Recently, the administration of therapeutic antibodies at fixed dosages (independent of body weight or body surface area) has been suggested (Hendriks, J. et al., Fixed Dosing of Monoclonal Antibodies in Oncology, The Oncologist 22:1212 (2017)).

[0007] This background information is provided for the purpose of making known information believed by the applicant to be of possible relevance to the present disclosure. No admission is necessarily intended, nor should be construed, that any of the preceding information constitutes prior art against the claimed invention.

SUMMARY

[0008] Described herein are methods of treating cancer using anti-HER2 biparatopic antibodies. In one aspect, the present disclosure relates to a method of treating a subject having a HER2-expressing cancer comprising administering to the subject an effective amount of an anti-HER2 biparatopic antibody at a fixed time interval, the effective amount comprising a fixed dose of the antibody administered.

[0008a] In one aspect, provided herein is the use of an anti-HER2 biparatopic antibody in the manufacture of a medicament for treating a subject having a HER2-expressing cancer, wherein an

effective amount of the medicament is to be administered to the subject, wherein the effective amount is to be administered according to a 2-tiered fixed dosing regimen comprising a low fixed dose to be administered at a fixed time interval to a subject whose weight is less than a dose cut-off weight, and a high fixed dose to be administered at a fixed time interval to a subject whose weight is equal to or greater than the dose cut-off weight.

[0008b] In another aspect, provided herein is a pharmaceutical kit comprising: (i) one or more containers comprising an anti-HER2 biparatopic antibody and (ii) a label or package insert in or associated with the one or more containers indicating that the anti-HER2 biparatopic antibody is for administration to a subject having a HER2-expressing cancer (a) at a dose of 1800 mg for a subject weighing less than 70 kg or (b) at a dose of 2400 mg for a subject weighing 70 kg or more, administered every 3 weeks (Q3W).

[0008c] In another aspect, provided herein is a pharmaceutical kit comprising: (i) one or more containers comprising an anti-HER2 biparatopic antibody and (ii) a label or package insert in or associated with the one or more containers indicating that the anti-HER2 biparatopic antibody is for administration to a subject having a HER2-expressing cancer (a) at a dose of 1200 mg for a subject weighing less than 70 kg or (b) at a dose of 1600 mg for a subject weighing 70 kg or more, administered every 2 weeks (Q2W).

[0009] In another aspect, the present disclosure relates to a method of treating a subject having a HER2-expressing cancer comprising administering to the subject, at a fixed time interval, an