

tube cancer, lung cancer, colorectal cancer, biliary cancer and bladder cancer, e.g. early breast cancer (EBC) or metastatic breast cancer (MBC).

5 In yet a further aspect, the present disclosure provides use of a HER2 antibody comprising the variable light and variable heavy amino acid sequences in SEQ ID Nos. 7 and 8, respectively, in the manufacture of a medicament for treating HER2 positive cancer, wherein the HER2 antibody is to be administered subcutaneously at a fixed loading dose of 1200 mg followed by at least one fixed maintenance dose of 600 mg.

10 In a further example, the disclosure concerns a method for treating cancer comprising subcutaneously administering to a human subject with a HER2 positive cancer one or more fixed dose(s) of a HER2 antibody comprising the variable light and variable heavy amino acid sequences in SEQ ID Nos. 7 and 8, respectively, in an amount effective to treat the cancer, wherein the fixed dose is about 600 mg and/or about 1200 mg.

The HER2 antibody preferably is pertuzumab.

15 In one example, the method comprises administering to the human subject pertuzumab at a fixed loading dose of about 1200 mg followed by at least one maintenance dose of about 600 mg.

In a second example, the administration of the loading dose is followed by administration of multiple maintenance doses.

20 In a third example, the first maintenance dose of pertuzumab is administered to the human subject approximately two weeks or approximately three weeks after administration of the loading dose of pertuzumab.

In further examples, the fixed doses of pertuzumab are administered to the human subject approximately every 2 weeks or approximately every 3 weeks.

25 The cancer may be HER2 positive cancer, such as breast cancer, peritoneal cancer, fallopian tube cancer, lung cancer, colorectal cancer, biliary cancer and bladder cancer, e.g. early breast cancer (EBC) or metastatic breast cancer (MBC).

Optionally, the method may further comprise administering a second therapeutic agent to the patient, such as a different HER2 antibody, e.g. trastuzumab, or a chemotherapeutic agent.

In one example, the fixed dose pertuzumab is administered subcutaneously in combination with subcutaneously administered trastuzumab.

30 In another example, the fixed dose pertuzumab and the trastuzumab are co-administered subcutaneously as two separate subcutaneous injections.

In yet another example, the fixed dose pertuzumab is co-mixed with fixed dose trastuzumab, and administered as a single subcutaneous injection.

35 In a further example, the fixed dose pertuzumab and fixed dose trastuzumab are administered as a single co-formulation for subcutaneous administration, such as any of the co-formulations described hereinabove and throughout the disclosure.

The chemotherapeutic agent, if administered, may, for example, be a taxane and/or an anthracycline, such as paclitaxel, docetaxel, daunorubicin, doxorubicin, and/or epirubicin.

WHAT IS CLAIMED IS:

1. A liquid pharmaceutical composition comprising 600 mg pertuzumab at a concentration of 60 mg/ml, 600 mg trastuzumab at a concentration of 60 mg/ml, 2,000 U/mL rHuPH20, 20 mM His-HCl pH 5.5, 105 mM trehalose, 100 mM sucrose, 0.04% polysorbate 20, 10 mM methionine, and sterile water for injection up to a total volume of 10 ml.
2. The liquid pharmaceutical composition of claim 1, contained in a 15-ml vial.
3. A liquid pharmaceutical composition comprising 1,200 mg pertuzumab at a concentration of 80 mg/ml, 600 mg trastuzumab at a concentration of 40 mg/ml, 2,000 U/mL rHuPH20, 20 mM His-HCl pH 5.5, 70 mM trehalose, 133 mM sucrose, 0.04% polysorbate 20, 10 mM methionine, and sterile water for injection up to a total volume of 15 ml.
4. The liquid pharmaceutical composition of claim 3, contained in a 20-ml vial.
5. An article of manufacture comprising a liquid pharmaceutical composition of any one of claims 1 to 4.
6. The article of manufacture of claim 5, further comprising a package insert with instructions to subcutaneously administer the liquid pharmaceutical composition contained therein to a human subject with HER2 positive cancer.
7. The article of manufacture of claim 6, wherein the HER2 positive cancer is selected from the group consisting of breast cancer, peritoneal cancer, fallopian tube cancer, lung cancer, colorectal cancer, biliary cancer and bladder cancer.
8. The article of manufacture of claim 7, wherein the cancer is breast cancer.
9. The article of manufacture of claim 8, wherein the breast cancer is early breast cancer (EBC) or metastatic breast cancer (MBC).
10. Use of a HER2 antibody comprising the variable light and variable heavy amino acid sequences in SEQ ID Nos. 7 and 8, respectively, in the manufacture of a medicament for treating HER2 positive cancer, wherein the HER2 antibody is to be administered subcutaneously at a fixed loading dose of 1200 mg followed by at least one fixed maintenance dose of 600 mg.
11. The use of claim 10, wherein the HER2 antibody is pertuzumab.
12. The use of claim 10 or 11, wherein the administration of the loading dose is to be followed by administration of multiple maintenance doses.
13. The use of claim 11 or 12, wherein the first maintenance dose of pertuzumab is to be administered to said human subject two weeks or three weeks after administration of the loading dose of pertuzumab.
14. The use of any one of claims 11 to 13, wherein fixed maintenance doses of pertuzumab are to be administered to said human subject every 2 weeks or every 3 weeks.

15. The use of claim 14, wherein the fixed maintenance doses of pertuzumab are to be administered every 3 weeks.

16. The use of claim 10, wherein the HER2 positive cancer is selected from the group consisting of breast cancer, peritoneal cancer, fallopian tube cancer, lung cancer, colorectal cancer, biliary cancer and bladder cancer.

17. The use of claim 16, wherein the cancer is breast cancer.

18. The use of claim 17, wherein the breast cancer is early breast cancer (EBC) or metastatic breast cancer (MBC).

19. The use of any one of claims 10 to 18, wherein a second therapeutic agent is to be administered to the patient.

20. The use of claim 19, wherein the second therapeutic agent is a different HER2 antibody.

21. The use of claim 20, wherein the HER2 antibody is trastuzumab.

22. The use of claim 21, wherein the fixed dose pertuzumab is to be administered subcutaneously in combination with subcutaneously administered trastuzumab.

23. The use of claim 22, wherein the fixed dose pertuzumab and the trastuzumab are to be co-administered subcutaneously as two separate subcutaneous injections.

24. The use of claim 22, wherein the fixed dose pertuzumab is co-mixed with fixed dose trastuzumab, and is to be administered as a single subcutaneous injection.

25. The use of claim 22, wherein fixed dose pertuzumab and fixed dose trastuzumab are to be administered as a single co-formulation for subcutaneous administration.

26. The use of claim 25, wherein the co-formulation is a liquid pharmaceutical composition of any one of claims 1 to 4.

27. The use of claim 19, wherein the further therapeutic agent is a chemotherapeutic agent.

28. The use of claim 27, wherein the chemotherapeutic agent is taxane and anthracycline.

29. The use of claim 28, wherein the taxane is paclitaxel or docetaxel.

30. The use of claim 28, wherein the anthracycline comprises daunorubicin, doxorubicin, or epirubicin.