monoclonal antibody trastuzumab in the treatment of cancer forms resistant to the latter is described by Hiroshi Tanaka et al. on *Clin. Cancer Res*. 17, (10) May 15 (2011).

Although the PI3K inhibitors are very effective, however the problem remains that not all the cancer forms respond effectively to a same medicament even when this is associated to other active principles.

The object of the present invention then is to provide a medicament free from such drawbacks.

Therefore, the object of the present invention is to make available new antitumour combinations providing the co-therapy with the compound of formula I and an additional antitumour agent capable of strengthening the final therapeutic effectiveness. Said object is obtained with a composition the main features thereof are specified in the first claim, whereas other features are specified in the remaining claims.

Summary

The present disclosure is based upon the finding by the present inventors that several known antitumour compounds are capable of improving the effectiveness of the compound of formula I, through a synergic effect, thus allowing to treat effectively (or at least more effectively) types of cancers resistant to the previous treatments.

In one aspect, the present disclosure refers to use of a pharmaceutical composition containing as active compound the PI3K-Class I inhibitor compound: 5-(7-methanesulfonyl-2-morpholin-4-yl-6,7-dihydro-5H-pyrrolo[2,3-d]pyrimidin-4-yl)-pyrimidin-2-amine or the pharmaceutically acceptable salt thereof in the manufacture of a first medicament, and use of~~in the manufacture of a medicament for an anticancer treatment in association with~~ a second anticancer compound in the manufacture of a second medicament, wherein the first and second medicaments are to be used in combination therapy for an anticancer treatment, and wherein said second anticancer compound is selected from the group comprising

CLAIMS

1. Use of a pharmaceutical composition containing as active compound the PI3K-Class I inhibitor compound: 5-(7-methanesulfonyl-2-morpholin-4-yl-6,7-dihydro-5H-pyrrolo[2,3-d]pyrimidin-4-yl)-pyrimidin-2-amine or the pharmaceutically acceptable salt thereof in the manufacture of a first medicament, ~~in the manufacture of a medicament for an anticancer treatment in association with~~and use of a second anticancer compound in the manufacture of a second medicament, wherein the first and second medicaments are to be used in combination therapy for an anticancer treatment, and wherein said second anticancer compound is selected from the group comprising cetuximab, bevacizumab, fulvestrant, or gefitinib.

2. The use according to claim 1, wherein the cancer is colon cancer, prostate cancer, breast cancer, lung cancer, ovarian cancer.

3. The use according to claim 2, wherein the cancer is colorectal cancer with mutations of PI3KCA and *wild-type* KRAS, colorectal cancer with mutations of PI3KCA and KRAS, non-small cell lung carcinoma (NSCLC) with or without mutation on PI3KCA and EGFR, HER2-positive breast carcinoma with PI3KCA mutation, HER2-positive and ER-positive breast cancer.

4. The use according to any one of claims 1 to 3 in association with a composition containing the second anticancer compound, wherein the pharmaceutical composition is suitable for the oral administration of the PI3k-Class I inhibitor.

5. The use according to claim 4, wherein the pharmaceutical composition comprises a quantity of PI3K-Class 1 inhibitor sufficient for a unitary dosage of 1 to 10 mg/Kg body weight.

6. The use according to claim 5, wherein the unitary dosage of the PI3K-Class 1

inhibitor ranges from 5 to 7 mg/Kg body weight.

7. The use according to any one of claims 4 to 6 in association with a pharmaceutical composition suitable for the oral or parental administration of the second anticancer compound.

8. The use according to claim 7 in association with a pharmaceutical composition comprising a quantity of the second anticancer compound suitable for a unitary dosage of 10 to 80 mg/Kg body weight.

9. The use according to claim 8 in association with a pharmaceutical composition comprising a quantity of the second anticancer compound suitable for a unitary dosage of 20 to 70 mg/Kg body weight, preferably from 30 to 50 mg/Kg body weight.

10. Use of kit of parts comprising a pharmaceutical composition containing as active compound the PI3K-Class I inhibitor compound: 5-(7-methanesulfonyl-2-morpholin-4-yl-6,7-dihydro-5H-pyrrolo[2,3-d]pyrimidin-4-yl)-pyrimidin-2-amine or the pharmaceutically acceptable salt thereof, and a second pharmaceutical composition containing a second anticancer compound, and wherein said second anticancer compound is selected from the group comprising cetuximab, bevacizumab, fulvestrant, or gefitinib, in the manufacture of a medicament for an anticancer combination treatment.

11~~12~~. The use according to ~~any one of~~ claim~~s~~ 10 ~~to 11~~, wherein the anticancer combination treatment is colon, prostate, breast, lung, ovarian cancer.

12~~13~~. The use according to claim 11~~12~~ in a combination treatment of colorectal carcinoma with mutations of PI3KCA and *wild-type* KRAS, of colorectal carcinoma with mutations of PI3KCA and KRAS, of non-small cell lung carcinoma (NSCLC) with or without mutation on PI3KCA and EGFR, HER2-positive breast cancer with PI3KCA mutation, HER2-positive and ER-positive breast cancer.

1314. The use according to any one of claims 10 to 1213 wherein the first pharmaceutical composition comprises a quantity of PI3K-Class 1 inhibitor sufficient for a unitary dosage of 1 to 10 mg/Kg body weight, preferably from 5 to 7 mg/Kg body weight.

1415. The use according to claim 1314 wherein the second composition comprises a quantity of the second anticancer compound suitable for a unitary dosage of 10 to 80 mg/Kg body weight, preferably from 20 to 70 mg/Kg or from 30 to 50 mg/Kg body weight.

1516. The use according to any one of claims 10 to 1415 wherein the first composition is suitable for the oral administration of the PI3k-Class I inhibitor, and the second composition is suitable for the oral or parental administration.