presence of one or more FGFR mutants including at least the FGFR2 C383R; and treating the patient with an FGFR inhibitor if one or more FGFR mutants as described above are present in the sample; in particular treating the patient with an FGFR inhibitor if one or more FGFR mutants including at least the FGFR2 SNP C383R are present in the sample.

[0005] Disclosed herein are methods of treating cholangiocarcinoma in a patient harboring the FGFR2 SNP C383R, or harboring the fusion FGFR2-BICC1; or harboring the fusion FGFR2-CCAR1; or harboring the fusion FGFR2-KIAA1598; or harboring the fusion DTWD2-FGFR2; or harboring the fusion ESR2-FGFR2; or harboring the fusion FGFR2-MGEA5; or harboring the fusion FGFR2-SBNO2; or harboring the mutation FGFR2 C390>YS; or harboring the mutation FGFR2 N549K; in particular harboring FGFR2 C383R, comprising administering a FGFR inhibitor to said patient. The patient may comprise one or more further FGFR mutants.

[0006] Disclosed herein is a FGFR inhibitor for use in the treatment of cholangiocarcinoma in a patient harboring the FGFR2 SNP C383R, or harboring the fusion FGFR2-BICC1; or harboring the fusion FGFR2-CCAR1; or harboring the fusion FGFR2-KIAA1598; or harboring the fusion DTWD2-FGFR2; or harboring the fusion ESR2-FGFR2; or harboring the fusion FGFR2-MGEA5; or harboring the fusion FGFR2-SBNO2; or harboring the mutation FGFR2 C390>YS; or harboring the mutation FGFR2 N549K; in particular harboring FGFR2 C383R. The patient may comprise one or more further FGFR mutants.

[0007] Disclosed herein is the use of a FGFR inhibitor in the manufacture of a medicament for the treatment of cholangiocarcinoma in a patient harboring the FGFR2 SNP C383R, or harboring the fusion FGFR2-BICC1; or harboring the fusion FGFR2-CCAR1; or harboring the fusion FGFR2-KIAA1598; or harboring the fusion DTWD2-FGFR2; or harboring the fusion ESR2-FGFR2; or harboring the fusion FGFR2-MGEA5; or harboring the fusion FGFR2-SBNO2; or harboring the mutation FGFR2 C390>YS; or harboring the mutation FGFR2 N549K; in particular harboring FGFR2 C383R. The patient may comprise one or more further FGFR mutants.

[0008] Disclosed herein is a FGFR inhibitor for use in the treatment of cholangiocarcinoma in a patient wherein the patient is identified as being responsive or likely to respond to the treatment with the FGFR inhibitor by evaluating a biological sample obtained from the patient for the presence of one or more FGFR mutants

more FGFR mutants including at least the mutation FGFR2 N549K; in particular for the presence of one or more FGFR mutants including at least the FGFR2 C383R, wherein the presence of one or more FGFR mutants including at least the FGFR2 SNP C383R; or one or more FGFR mutants including at least the fusion FGFR2-BICC1; or one or more FGFR mutants including at least the fusion FGFR2-CCAR1; or one or more FGFR mutants including at least the fusion FGFR2-KIAA1598; or one or more FGFR mutants including at least the fusion DTWD2-FGFR2; or one or more FGFR mutants including at least the fusion ESR2-FGFR2; or one or more FGFR mutants including at least the fusion FGFR2-MGEA5; or one or more FGFR mutants including at least the fusion FGFR2-SBNO2; or one or more FGFR mutants including at least the mutation FGFR2 C390>YS; or one or more FGFR mutants including at least the mutation FGFR2 N549K; in particular wherein the presence of one or more FGFR mutants including at least the FGFR2 C383R is detected.

[0009a] In another aspect, there is provided use of a FGFR inhibitor in the manufacture of a medicament for the treatment of cholangiocarcinoma in a patient wherein the patient is identified as being responsive to the treatment with the FGFR inhibitor by evaluating a biological sample obtained from the patient for the presence of one or more FGFR mutants including at least the FGFR2 SNP C383R or FGFR2 C390>YS, wherein the presence of one or more FGFR mutants including at least the FGFR2 SNP C383R or FGFR2 C390>YS is detected.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0010] Reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. When a range of values is expressed, another embodiment includes from the one particular value and/or to the other particular value. Further, reference to values stated in ranges include each and every value within that range. All ranges are inclusive and combinable.

[0011] The following abbreviations are used throughout the specification: FGFR (fibroblast growth factor receptor); FFPET (Formalin-Fixed Paraffin-Embedded Tissue); SNP (single nucleotide polymorphism).

CLAIMS

1. Use of a FGFR inhibitor in the manufacture of a medicament for the treatment of cholangiocarcinoma in a patient wherein the patient is identified as being responsive to the treatment with the FGFR inhibitor by evaluating a biological sample obtained from the patient for the presence of one or more FGFR mutants including at least the FGFR2 SNP C383R or FGFR2 C390>YS, wherein the presence of one or more FGFR mutants including at least the FGFR2 SNP C383R or FGFR2 C390>YS is detected.

2. The use according to claim 1 wherein the FGFR inhibitor is erdafitinib.

3. The use according to claim 2 wherein erdafitinib is to be administered at a dose of 10 mg.

4. The use according to claim 3 wherein the dose of 10 mg is to be administered intermittently.

5. The use according to claim 4 wherein erdafitinib is to be administered at a dose of 10 mg intermittently 7days on/7 days off.

6. The use according to claim 2 wherein erdafitinib is to be administered at a dose of 8 mg once daily.

7. The use according to claim 6 wherein erdafitinib is to be administered at a dose of 8 mg once daily with an option to uptitrate to 9 mg depending on serum phosphate level and depending on treatment-related adverse events observed.

8. The use according to claim 7 wherein the levels of serum phosphate for determining whether or not to up-titrate are measured on a treatment day during the first cycle of erdafitinib treatment.

9. The use according to claim 8 wherein the serum phosphate level is measured on day 14 ± 2 days of the first cycle of erdafitinib treatment.

10. The use according to any one of claims 7 to 9 wherein erdafitinib is uptitrated to 9 mg when the serum phosphate level is < 5.5 mg/dL.

11. The use according to any one of claims 7 to 9 wherein erdafitinib is uptitrated to 9 mg when the serum phosphate level is < 7 mg/dL.

12. The use according to any one of claims 7 to 9 wherein erdafitinib is uptitrated to 9 mg when the serum phosphate level ranges from and includes 7 mg/dL to ≤9 mg/dL.

13. The use according to any one of claims 7 to 9 wherein erdafitinib is uptitrated to 9 mg when the serum phosphate level is ≤9 mg/dL.

14. The use according to any one of claims 1 to 13 wherein the one or more FGFR mutants includes at least the FGFR2 SNP C383R.

15. The use according to any one of claims 1 to 13 wherein the one or more FGFR mutants includes at least FGFR2 C390>YS.