and/or FGFR3 genetic alteration. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is a combination of a FGFR inhibitor at a dose of about 8 mg per day and an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg every two weeks, in particular for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is a FGFR inhibitor for use in combination with an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is administered or is to be administered at a dose of about 8 mg per day and wherein the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg every two weeks. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is an anti-PD1 antibody or antigen binding fragment thereof for use in combination with a FGFR inhibitor for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is administered or is to be administered at a dose of about 8 mg per day and wherein the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg every two weeks. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is the use of a FGFR inhibitor at a dose of about 8 mg per day for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the FGFR inhibitor is used or is to be used in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg every two weeks. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is the use of an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg every two weeks for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the anti-PD1 antibody or antigen binding fragment thereof is used or is to be used in combination with a FGFR inhibitor at a dose of

about 8 mg per day. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

In one aspect, there is provided a fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient that has been diagnosed with urothelial carcinoma and harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day, and wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg.

Described herein are methods of treating urothelial carcinoma comprising, for example, administering erdafitinib at a dose of about 8 mg per day, in particular orally, in combination with an anti-PD1 antibody or antigen binding fragment thereof, in particular cetrelimab, in particular cetrelimab at a dose of about 240 mg every two weeks, in particular cetrelimab at a dose of about 240 mg every two weeks IV, to a patient that has been diagnosed with urothelial carcinoma who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is a combination of erdafitinib at a dose of about 8 mg per day, in particular orally, and an anti-PD1 antibody or antigen binding fragment thereof, in particular cetrelimab, in particular cetrelimab at a dose of about 240 mg every two weeks, in particular cetrelimab at a dose of about 240 mg every two weeks IV, in particular for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is erdafitinib for use in combination with an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein erdafitinib is administered or is to be administered at a dose of about 8 mg per day, in particular orally, and wherein in a particular example the anti-PD1 antibody or antigen binding fragment thereof is cetrelimab, and wherein in a particular example cetrelimab is administered or is to be administered at a dose of about 240 mg every two weeks IV. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is an anti-PD1 antibody or antigen binding fragment thereof for use in combination with erdafitinib for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein erdafitinib is administered or is to be administered at a dose of about 8 mg per day, in particular orally, and wherein in a particular example, the anti-PD1 antibody or antigen binding fragment thereof is cetrelimab, and wherein in a particular example cetrelimab is administered or is to be administered at a dose of about 240 mg every two weeks IV. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is the use of erdafitinib at a dose of about 8 mg per day, in particular orally, for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein erdafitinib is used or is to be used in combination with an anti-PD1 antibody or antigen binding fragment thereof, in particular cetrelimab, in particular cetrelimab at a dose of about 240 mg every two weeks IV. In certain examples, the urothelial carcinoma is locally advanced or metastatic.

Described herein is the use of an anti-PD1 antibody or antigen binding fragment thereof, in particular cetrelimab, in particular cetrelimab at a dose of about 240 mg every two weeks IV for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the anti-PD1 antibody or antigen binding fragment thereof is used or is to be used in combination with erdafitinib at a dose of about 8 mg per day, in particular orally. In certain examples, the urothelial carcinoma is locally advanced or metastatic. In further examples, administration of the FGFR inhibitor in combination with the anti-PD1 antibody or antigen binding fragment thereof provides improved anti-tumor activity as measured by objective response rate relative to a patient that has been diagnosed with urothelial carcinoma that has not received treatment with an FGFR inhibitor and an anti-PD1 antibody or antigen binding fragment thereof. In some examples, administration of the FGFR inhibitor in combination with the anti-PD1 antibody or antigen binding fragment thereof does not result in hematological toxicity, in particular does not result in hematological toxicity of Grade 3 or higher. In still further examples, administration of the FGFR inhibitor in combination with the anti-PD1 antibody or antigen binding fragment thereof does not result in non-hematological toxicity of Grade 3 or higher.

In another aspect, there is provided a fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient that has been diagnosed with urothelial carcinoma, wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day, and wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg, and wherein the fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof are to be administered in further combination with a platinum chemotherapy.

In certain examples, the patient received at least one systemic therapy for the treatment of urothelial carcinoma prior to administration of said FGFR inhibitor and said anti-PD1 antibody or antigen binding fragment thereof. In some examples, the at least one systemic therapy for the treatment of urothelial carcinoma is platinum-containing chemotherapy. In further examples, the urothelial carcinoma progressed during or following at least one line of the platinum-containing chemotherapy. In still further examples, the platinum-containing chemotherapy is neoadjuvant platinum-containing chemotherapy or adjuvant platinum-containing chemotherapy. In even further examples, the urothelial carcinoma progressed within 12 months following at least one line of the

neoadjuvant platinum-containing chemotherapy or adjuvant platinum-containing chemotherapy.

In some examples, the patient did not receive systemic therapy for the treatment of urothelial carcinoma prior to said administration of said FGFR inhibitor and said anti-PD1 antibody or antigen binding fragment thereof. In certain examples, the patient is cisplatin-ineligible. In further examples, the patient has an ECOG performance status of less than or equal to 2.

In certain examples, the FGFR2 genetic alteration and/or FGFR3 genetic alteration is an FGFR3 gene mutation, FGFR2 gene fusion, or FGFR3 gene fusion. In some examples, the FGFR3 gene mutation is R248C, S249C, G370C, Y373C, or any combination thereof. In still further examples, the FGFR2 or FGFR3 gene fusion is FGFR3-TACC3, FGFR3-BAIAP2L1, FGFR2-BICC1, FGFR2-CASP7, or any combination thereof.

In some examples, said methods or uses further comprise evaluating a biological sample from the patient for the presence of one or more FGFR2 or FGFR3 genetic alterations prior to administration of said FGFR inhibitor and said anti-PD1 antibody or antigen binding fragment thereof. In certain examples, the biological sample is blood, lymph fluid, bone marrow, a solid tumor sample, or any combination thereof.

In further examples, the FGFR inhibitor is erdafitinib. In further examples, erdafitinib is administered daily, in particular once daily. In still further examples, erdafitinib is administered orally. In certain examples, erdafitinib is administered orally on a continuous daily dosing schedule. In some examples, erdafitinib is administered orally at a dose of about 8 mg once daily. In some examples, erdafitinib is administered orally at a dose of about 8 mg once daily on a continuous daily dosing schedule. In further examples, the dose of erdafitinib is increased from 8 mg per day to 9 mg per day after initiating treatment if the patient exhibits a serum phosphate (PO_4) level that is less than about 5.5 mg/dL. In certain examples, erdafitinib is present in a solid dosage form. In further examples, the solid dosage form is a tablet.

In certain examples, the anti-PD1 antibody or antigen binding fragment thereof is cetrelimab. In further examples, the cetrelimab is administered by intravenous infusion. In still further examples, the cetrelimab is administered at a dose of about 240 mg: (a) once every two weeks, once every three weeks, once every four weeks, once every five weeks or once every six weeks; (b) once every two weeks; (c) once every three weeks; (d)

once every four weeks; (e) once every five weeks; or (f) once every six weeks. In further examples, the cetrelimab is administered at a dose of about 240 mg, in particular 240 mg once every two weeks in cycle 1 to 4 of treatment. In further examples, the cetrelimab is administered at a dose of about 480 mg, in particular 480 mg once every 4 weeks. In further examples, the cetrelimab is administered at a dose of about 480 mg, in particular 480 mg once every 4 weeks, as of cycle 5 of treatment and beyond. In further examples, the cetrelimab is administered at a dose of about 360 mg, in particular 360 mg once every three weeks.

Also described herein are methods of improving objective response rate in a patient with urothelial carcinoma relative to a patient that has been diagnosed with urothelial carcinoma that has not received treatment with an FGFR inhibitor and an anti-PD1 antibody or antigen binding fragment thereof, said method comprising administering a FGFR inhibitor at a dose of about 8 mg per day in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg (e.g. every two weeks) to a patient that has been diagnosed with urothelial carcinoma who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks) in cycle 1 to 4 of treatment.

Further provided herein are methods of treating urothelial carcinoma comprising: (a) evaluating a biological sample from a patient with urothelial carcinoma for the presence of one or more FGFR gene alterations, in particular FGFR2 or 3 gene alterations; and (b) administering a FGFR inhibitor at a dose of about 8 mg per day in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg (e.g. every two weeks) to the patient if one or more FGFR gene alterations, in particular FGFR2 or 3 gene alterations, is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks) in cycle 1 to 4 of treatment.

Further provided herein is a combination of a FGFR inhibitor at a dose of about 8 mg per day and an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg (e.g. every two weeks), in particular for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene

alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks) in cycle 1 to 4 of treatment.

Further provided herein is a FGFR inhibitor for use in combination with an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is administered or is to be administered at a dose of about 8 mg per day and wherein the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks), and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks) in cycle 1 to 4 of treatment.

Further provided herein is an anti-PD1 antibody or antigen binding fragment thereof for use in combination with a FGFR inhibitor for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is administered or is to be administered at a dose of about 8 mg per day and wherein the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks), and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks) in cycle 1 to 4 of treatment.

Further provided herein is the use of a FGFR inhibitor at a dose of about 8 mg per day for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the FGFR inhibitor is used or is to be used in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg (e.g. every two weeks), and

wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks) in cycle 1 to 4 of treatment.

Further provided herein is the use of an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg (e.g. every two weeks) for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the anti-PD1 antibody or antigen binding fragment thereof is used or is to be used in combination with a FGFR inhibitor at a dose of about 8 mg per day, and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 240 mg (e.g. every two weeks) in cycle 1 to 4 of treatment.

Also described herein are methods of improving objective response rate in a patient with urothelial carcinoma relative to a patient that has been diagnosed with urothelial carcinoma that has not received treatment with an FGFR inhibitor and an anti-PD1 antibody or antigen binding fragment thereof, said method comprising administering a FGFR inhibitor at a dose of about 8 mg per day in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 480 mg (e.g. every four weeks) to a patient that has been diagnosed with urothelial carcinoma who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks) as of cycle 5 of treatment and beyond.

Further provided herein are methods of treating urothelial carcinoma comprising: (a) evaluating a biological sample from a patient with urothelial carcinoma for the presence of one or more FGFR gene alterations, in particular FGFR2 or 3 gene alterations; and (b) administering a FGFR inhibitor at a dose of about 8 mg per day in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 480 mg (e.g. every four weeks) to the patient if one or more FGFR gene alterations, in particular FGFR2 or 3 gene

alterations, is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks) as of cycle 5 of treatment and beyond.

Further provided herein is a combination of a FGFR inhibitor at a dose of about 8 mg per day and an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 480 mg (e.g. every four weeks), in particular for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks) as of cycle 5 of treatment and beyond.

Further provided herein is a FGFR inhibitor for use in combination with an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is administered or is to be administered at a dose of about 8 mg per day and wherein the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks), and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks) as of cycle 5 of treatment and beyond.

Further provided herein is an anti-PD1 antibody or antigen binding fragment thereof for use in combination with a FGFR inhibitor for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is administered or is to be administered at a dose of about 8 mg per day and wherein the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks), and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene

alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks) as of cycle 5 of treatment and beyond.

Further provided herein is the use of a FGFR inhibitor at a dose of about 8 mg per day for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the FGFR inhibitor is used or is to be used in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 480 mg (e.g. every four weeks), and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks) as of cycle 5 of treatment and beyond.

Further provided herein is the use of an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 480 mg (e.g. every four weeks) for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the anti-PD1 antibody or antigen binding fragment thereof is used or is to be used in combination with a FGFR inhibitor at a dose of about 8 mg per day, and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 480 mg (e.g. every four weeks) as of cycle 5 of treatment and beyond.

As described herein, a cycle is defined as a 4 week period; or a cycle is defined as a 28 day period.

Also described herein are methods of improving objective response rate in a patient with urothelial carcinoma relative to a patient that has been diagnosed with urothelial carcinoma that has not received treatment with an FGFR inhibitor and an anti-PD1 antibody or antigen binding fragment thereof, said method comprising administering a FGFR inhibitor at a dose of about 8 mg per day in combination with an anti-PD1 antibody or antigen binding

fragment thereof at a dose of about 360 mg (e.g. every three weeks) to a patient that has been diagnosed with urothelial carcinoma who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration.

In another aspect, there is provided a fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in improving objective response rate in a patient that has been diagnosed with urothelial carcinoma who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration relative to a patient that has been diagnosed with urothelial carcinoma who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration that has not received treatment with an FGFR inhibitor or an anti-PD1 antibody or antigen binding fragment thereof, wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day, and wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg.

In an example, the treatment further comprises a platinum chemotherapy, in particular cisplatin or carboplatin. In an example the platinum chemotherapy is administered or is to be administered every three weeks. In an example, the platinum chemotherapy is administered or is to be administered at a dose of 50 mg/m^2, or 60 mg/m^2, or at a dose for a AUC of 4 mg/mL*min, or at a dose for a AUC of 5 mg/mL*min. In an example, cisplatin is administered or is to be administered at a dose of 50 mg/m^2 or 60 mg/m^2. In an example, carboplatin is administered or is to be administered at a dose for an AUC of 4 mg/mL*min or at a dose for an AUC of 5 mg/mL*min.

Further provided herein are methods of treating urothelial carcinoma comprising: (a) evaluating a biological sample from a patient with urothelial carcinoma for the presence of one or more FGFR gene alterations, in particular FGFR2 or 3 gene alterations; and (b) administering a FGFR inhibitor at a dose of about 8 mg per day in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 360 mg (e.g. every three weeks) to the patient if one or more FGFR gene alterations, in particular FGFR2 or 3 gene alterations, is present in the sample.

In another aspect, there is provided a fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in treating urothelial carcinoma. wherein the use comprises: (a) evaluating a biological sample from a patient that has been diagnosed with urothelial carcinoma for the presence of one or more fibroblast growth factor receptor (FGFR) gene alterations; and (b) wherein the FGFR

inhibitor is to be administered at a dose of about 8 mg per day and the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg to the patient if one or more FGFR gene alterations is present in the sample.

In an example, the treatment further comprises a platinum chemotherapy, in particular cisplatin or carboplatin. In an example the platinum chemotherapy is administered or is to be administered every three weeks. In an example, the platinum chemotherapy is administered or is to be administered at a dose of 50 mg/m^2, or 60 mg/m^2, or at a dose for a AUC of 4 mg/mL*min, or at a dose for a AUC of 5 mg/mL*min. In an example, cisplatin is administered or is to be administered at a dose of 50 mg/m^2 or 60 mg/m^2. In an example, carboplatin is administered or is to be administered at a dose for an AUC of 4 mg/mL*min or at a dose for an AUC of 5 mg/mL*min.

Further provided herein is a combination of a FGFR inhibitor at a dose of about 8 mg per day and an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 360 mg (e.g. every three weeks), in particular for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the treatment further comprises a platinum chemotherapy, in particular cisplatin or carboplatin. In an example the platinum chemotherapy is administered or is to

be administered every three weeks. In an example, the platinum chemotherapy is administered or is to be administered at a dose of 50 mg/m^2, or 60 mg/m^2, or at a dose for a AUC of 4 mg/mL*min, or at a dose for a AUC of 5 mg/mL*min. In an example, cisplatin is administered or is to be administered at a dose of 50 mg/m^2 or 60 mg/m^2. In an example, carboplatin is administered or is to be administered at a dose for an AUC of 4 mg/mL*min or at a dose for an AUC of 5 mg/mL*min.

Further provided herein is a FGFR inhibitor for use in combination with an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is administered or is to be administered at a dose of about 8 mg per day and wherein the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 360 mg (e.g. every three weeks), and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the treatment further comprises a platinum chemotherapy, in particular cisplatin or carboplatin. In an example the platinum chemotherapy is administered or is to be administered every three weeks. In an example, the platinum chemotherapy is administered or is to be administered at a dose of 50 mg/m^2, or 60 mg/m^2, or at a dose for a AUC of 4 mg/mL*min, or at a dose for a AUC of 5 mg/mL*min. In an example, cisplatin is administered or is to be administered at a dose of 50 mg/m^2 or 60 mg/m^2. In an example, carboplatin is administered or is to be administered at a dose for an AUC of 4 mg/mL*min or at a dose for an AUC of 5 mg/mL*min.

Further provided herein is an anti-PD1 antibody or antigen binding fragment thereof for use in combination with a FGFR inhibitor for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is administered or is to be administered at a dose of about 8 mg per day and wherein the anti-PD1 antibody or antigen binding fragment thereof is administered or is to be administered at a dose of about 360 mg (e.g. every three weeks), and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the treatment further comprises a platinum chemotherapy, in particular cisplatin

or carboplatin. In an example the platinum chemotherapy is administered or is to be administered every three weeks. In an example, the platinum chemotherapy is administered or is to be administered at a dose of 50 mg/m^2, or 60 mg/m^2, or at a dose for a AUC of 4 mg/mL*min, or at a dose for a AUC of 5 mg/mL*min. In an example, cisplatin is administered or is to be administered at a dose of 50 mg/m^2 or 60 mg/m^2. In an example, carboplatin is administered or is to be administered at a dose for an AUC of 4 mg/mL*min or at a dose for an AUC of 5 mg/mL*min.

Further provided herein is the use of a FGFR inhibitor at a dose of about 8 mg per day for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the FGFR inhibitor is used or is to be used in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 360 mg (e.g. every three weeks), and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the treatment further comprises a platinum chemotherapy, in particular cisplatin or carboplatin. In an example the platinum chemotherapy is administered or is to be administered every three weeks. In an example, the platinum chemotherapy is administered or is to be administered at a dose of 50 mg/m^2, or 60 mg/m^2, or at a dose for a AUC of 4 mg/mL*min, or at a dose for a AUC of 5 mg/mL*min. In an example, cisplatin is administered or is to be administered at a dose of 50 mg/m^2 or 60 mg/m^2. In an example, carboplatin is administered or is to be administered at a dose for an AUC of 4 mg/mL*min or at a dose for an AUC of 5 mg/mL*min.

Further provided herein is the use of an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 360 mg (e.g. every three weeks) for the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration wherein the anti-PD1 antibody or antigen binding fragment thereof is used or is to be used in combination with a FGFR inhibitor at a dose of about 8 mg per day, and wherein the combination is administered or is to be administered after evaluation of a biological sample from the patient for the presence of one or more FGFR2 or 3 gene alterations and if one or more FGFR2 or 3 gene alterations is present in the sample. In an example, the treatment further comprises a platinum chemotherapy, in particular cisplatin or carboplatin. In an example the platinum

chemotherapy is administered or is to be administered every three weeks. In an example, the platinum chemotherapy is administered or is to be administered at a dose of 50 mg/m^2, or 60 mg/m^2, or at a dose for a AUC of 4 mg/mL*min, or at a dose for a AUC of 5 mg/mL*min. In an example, cisplatin is administered or is to be administered at a dose of 50 mg/m^2 or 60 mg/m^2. In an example, carboplatin is administered or is to be administered at a dose for an AUC of 4 mg/mL*min or at a dose for an AUC of 5 mg/mL*min.

In another aspect, there is provided a fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day, and wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg.

In another aspect, there is provided use use of a FGFR inhibitor at a dose of about 8 mg per day in the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is to be used in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg.

In another aspect, there is provided use of an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg in the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the anti-PD1 antibody or antigen binding fragment thereof is to be used in combination with a FGFR inhibitor at a dose of about 8 mg per day.

BRIEF DESCRIPTION OF THE DRAWINGS

The summary, as well as the following detailed description, is further understood when read in conjunction with the appended drawings. For the purpose of illustrating the disclosed methods and uses, the drawings show exemplary embodiments of the methods and uses; however, the methods and uses are not limited to the specific embodiments disclosed. In the drawings:

FIG. 1 is a study schematic for the phase 1b/2, multicenter, open-label dose escalation study to evaluate erdafitinib plus cetrelimab. ERDA stands for erdafitinib, CET stands for cetrelimab, UpT stands for uptitration, C1D1 stands for Cycle 1 Day 1, C2D2 stands for Cycle 2 Day 2, R stands for randomized, and DL stands for dose level. Footnote (a): 8 mg with or without uptitration (DL2 and DL2A) may be considered as the same dose level. Footnote (b): No UpT = no uptitration allowed. Footnote (c): UpT = uptitration of ERDA (after RP2D, uptitration of ERDA dose from 8 mg to 9 mg on C1D15 based on phosphate [PO_4] level) was permitted. Footnote (d): The RP2D was originally determined to be 8 mg ERDA UpT + CET, but after an amendment to the protocol, this was revised to 8 mg ERDA no UpT for phase 2 of the study.

FIG. 2 is a graph showing maximal percentage reduction of sum of target lesion diameters from baseline for the safety analysis population. The y-axis is maximal reduction from baseline (%) and the x-axis is patient. For a response to qualify as stable disease (SD), follow-up measurements must have met the stable disease criteria at least once at a minimum interval not less than 6 weeks after first dose of study drug. One patient was not response evaluable as they did not have measurable disease at baseline, and therefore this patient was excluded from the analysis for response. As of the time of data cutoff, 1 other patient did not have a subsequent on-study tumor assessment. To be counted as a PR, a second scan to confirm response was required. Bars are designated uPR (unconfirmed PR), SD (stable disease), PR (partial response) and NE (not evaluable).

What is claimed:

1. A fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient that has been diagnosed with urothelial carcinoma and harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day, and wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg.

2. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 1, wherein further a platinum chemotherapy is to be administered.

3. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 1, wherein the urothelial carcinoma is locally advanced or metastatic.

4. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims, wherein administration of the FGFR inhibitor in combination with the anti-PD1 antibody or antigen binding fragment thereof provides improved anti-tumor activity as measured by objective response rate relative to a patient that has been diagnosed with urothelial carcinoma that has not received treatment with an FGFR inhibitor and an anti-PD1 antibody or antigen binding fragment thereof.

5. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims, wherein administration of the FGFR inhibitor in combination with the anti-PD1 antibody or antigen binding fragment thereof does not result in hematological toxicity of Grade 3 or higher.

6. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims, wherein the patient received at least one systemic therapy for the treatment of urothelial

carcinoma prior to administration of said FGFR inhibitor and said anti-PD1 antibody or antigen binding fragment thereof.

7. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 6, wherein the at least one systemic therapy for the treatment of urothelial carcinoma is platinum-containing chemotherapy.

8. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 7, wherein the urothelial carcinoma progressed during or following at least one line of the platinum-containing chemotherapy.

9. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 8, wherein the platinum-containing chemotherapy is neoadjuvant platinum-containing chemotherapy or adjuvant platinum-containing chemotherapy.

10. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 9, wherein the urothelial carcinoma progressed within 12 months following at least one line of the neoadjuvant platinum-containing chemotherapy or adjuvant platinum-containing chemotherapy.

11. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claims 1 to 5, wherein the patient did not receive systemic therapy for the treatment of urothelial carcinoma prior to said administration of said FGFR inhibitor and said anti-PD1 antibody or antigen binding fragment thereof.

12. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 11, wherein the patient is cisplatin-ineligible.

13. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims, wherein the patient has an ECOG performance status of less than or equal to 2.

14. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims, wherein the FGFR2 genetic alteration and/or FGFR3 genetic alteration is an FGFR3 gene mutation, FGFR2 gene fusion, or FGFR3 gene fusion.

15. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 14, wherein the FGFR3 gene mutation is R248C, S249C, G370C, Y373C, or any combination thereof.

16. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 14, wherein the FGFR2 or FGFR3 gene fusion is FGFR3-TACC3, FGFR3-BAIAP2L1, FGFR2-BICC1, FGFR2-CASP7, or any combination thereof.

17. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims, further comprising evaluating a biological sample from the patient for the presence of one or more FGFR2 genetic alteration and/or FGFR3 genetic alteration prior to administration of said FGFR inhibitor and said anti-PD1 antibody or antigen binding fragment thereof.

18. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 17, wherein the biological sample is blood, lymph fluid, bone marrow, a solid tumor sample, or any combination thereof.

19. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims wherein the FGFR inhibitor is erdafitinib.

20. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 19, wherein erdafitinib is to be administered orally.

21. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 19 or 20, wherein erdafitinib is to be administered orally on a continuous daily dosing schedule.

22. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claims 19 to 21, wherein erdafitinib is to be administered at a dose of about 8 mg once daily.

23. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claims 19 to 22, wherein the dose of erdafitinib is increased from 8 mg per day to 9 mg per day after initiating treatment.

24. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 23, wherein the dose of erdafitinib is increased from 8 mg per day to 9 mg per day after initiating treatment if the patient exhibits a serum phosphate (PO_4) level that is less than about 5.5 mg/dL, in particular if the patient exhibits a serum phosphate (PO_4) level that is less than about 5.5 mg/dL at 14-21 days after initiating treatment and administration of erdafitinib at 8 mg once daily resulted in no ocular disorder; or (b) administration of erdafitinib at 8 mg once daily resulted in no Grade 2 or greater adverse reaction.

25. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claims 19 to 24, wherein erdafitinib is to be administered in a solid dosage form.

26. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 25, wherein the solid dosage form is a tablet.

27. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims, wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg once every two weeks or at a dose of about 360 mg once every three weeks or at a dose of about 480 mg once every four weeks.

28. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of the preceding claims, wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg once every two weeks.

29. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claims 1 to 27, wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 360 mg once every three weeks.

30. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claims 1 to 27, wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 480 mg once every four weeks.

31. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claims 1 to 30 wherein said anti-PD1 antibody or antigen binding fragment thereof is cetrelimab.

32. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 31, wherein the cetrelimab is to be administered by intravenous infusion.

33. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 1, wherein said anti-PD1 antibody or antigen binding fragment thereof is cetrelimab and the cetrelimab is to be administered:

(a) once every two weeks, once every three weeks, once every four weeks, once every five weeks or once every six weeks;
(b) once every two weeks;
(c) once every three weeks;
(d) once every four weeks;
(e) once every five weeks; or
(f) once every six weeks.

34. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claim 2 to 33 wherein the platinum chemotherapy is cisplatin.

35. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 34, wherein the cisplatin is to be administered at a dose of about 50 mg/m^2.

36. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 34, wherein the cisplatin is to be administered at a dose of about 60 mg/m^2.

37. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of any one of claim 2 to 22 wherein the platinum chemotherapy is carboplatin.

38. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 37, wherein the carboplatin is to be administered at a dose of about AUC 4 mg/mL/min.

39. The fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof for use of claim 37, wherein the carboplatin is to be administered at a dose of about AUC 5 mg/mL/min.

40. A fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient that has been diagnosed with urothelial carcinoma, wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day, and wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg, and wherein the fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof are to be administered in further combination with a platinum chemotherapy.

41. A fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in improving objective response rate in a patient that has been diagnosed with urothelial carcinoma who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration relative to a patient that has been diagnosed with urothelial carcinoma who harbors at least one FGFR2

genetic alteration and/or FGFR3 genetic alteration that has not received treatment with an FGFR inhibitor or an anti-PD1 antibody or antigen binding fragment thereof, wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day, and wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg.

42. A fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in treating urothelial carcinoma. wherein the use comprises:

(a) evaluating a biological sample from a patient that has been diagnosed with urothelial carcinoma for the presence of one or more fibroblast growth factor receptor (FGFR) gene alterations; and

(b) wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day and the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg to the patient if one or more FGFR gene alterations is present in the sample.

43. A fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use in the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is to be administered at a dose of about 8 mg per day, and wherein the anti-PD1 antibody or antigen binding fragment thereof is to be administered at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg.

44. The use of a FGFR inhibitor at a dose of about 8 mg per day in the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the FGFR inhibitor is to be used in combination with an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg.

45. The use of an anti-PD1 antibody or antigen binding fragment thereof at a dose of about 240 mg or at a dose of about 360 mg or at a dose of about 480 mg in the manufacture of a medicament for the treatment of urothelial carcinoma in a patient who harbors at least one FGFR2 genetic alteration and/or FGFR3 genetic alteration, wherein the anti-PD1 antibody or antigen binding fragment thereof is to be used in combination with a FGFR inhibitor at a dose of about 8 mg per day.

46. The fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use or the use of a fibroblast growth factor receptor (FGFR) inhibitor or the use of an anti-PD1 antibody or antigen binding fragment thereof of any one of claims 41-45, wherein the fibroblast growth factor receptor (FGFR) inhibitor and anti-PD1 antibody or antigen binding fragment thereof are to be administered in further combination with a platinum chemotherapy.

47. The fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use or the use of a fibroblast growth factor receptor (FGFR) inhibitor or the use of an anti-PD1 antibody or antigen binding fragment thereof of any one of claims 41-46, wherein the FGFR inhibitor is erdafitinib.

48. The fibroblast growth factor receptor (FGFR) inhibitor and an anti-PD1 antibody or antigen binding fragment thereof for use or the use of a fibroblast growth factor receptor (FGFR) inhibitor or the use of an anti-PD1 antibody or antigen binding fragment thereof of any one of claims 41-47, wherein the anti-PD1 antibody or antigen binding fragment thereof is cetrelimab.