

CANCER TREATMENT

The present invention provides for the treatment of cancer with erdafitinib with a high potential for response while limiting potential toxicities such as for example nail toxicities.

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The present invention provides for treatment of cancer with erdafitinib that maximizes erdafitinib exposure while limiting potential toxicities.

10 The present invention provides for treatment of cancer with erdafitinib with a high objective response rate, in particular with an objective response rate of at least 40%, in particular with an objective response rate of at least 40 % in chemo-naïve cancer patients, with an objective response rate of at least 40 % in cancer patients who had disease progression after one prior line of chemotherapy, with an objective response rate of at least 40 % in cancer patients who had disease progression after two or more prior lines of
15 chemotherapy.

The present invention provides for treatment of cancer with erdafitinib with a short time to response, in particular with a median time to response less than 2 months.

20 Description of the Figures

Figure 1 represents the study scheme for the Phase 2, multicenter, open-label study to evaluate the efficacy and safety of erdafitinib in subjects with metastatic or surgically unresectable urothelial cancer harboring selected FGFR (fibroblast growth factor receptor) genetic alterations (FGFR translocations or mutations).

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Figure 2 represents a Waterfall plot of maximum percentage reduction from baseline in sum of target lesion diameters among patients treated with the regimen of 8 mg continuous erdafitinib (Regimen 3 of the phase 2 study (Fig. 1)). M, *FGFR* mutation; T, *FGFR* translocation.

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Summary

In one aspect, there is provided the use of erdafitinib for the manufacture of a medicament for the treatment of cancer, in an amount so that the levels of serum phosphate range from and including 5.5 mg/dL to < 7 mg/dL or range from and including 5.5 mg/dL to ≤9
35 mg/dL.

In another aspect, there is provided erdafitinib for use in the treatment of cancer, wherein erdafitinib is to be administered in an amount so that the levels of serum phosphate range from and including 5.5 mg/dL to < 7 mg/dL or range from and including 5.5 mg/dL to ≤ 9 mg/dL.

- 5 In another aspect, there is provided the use of erdafitinib for the manufacture of a medicament for the treatment of cancer, wherein the medicament comprises erdafitinib in an amount of 8 mg and wherein the medicament is for daily, in particular once daily, administration on a continuous basis.

10 In another aspect, there is provided erdafitinib for use in the treatment of cancer, wherein erdafitinib is administered in an amount of 8 mg daily, in particular once daily, on a continuous basis.

In another aspect, there is provided the use of erdafitinib for the manufacture of a medicament for the treatment of cancer in a cancer patient, wherein

- a) the medicament comprises erdafitinib in an amount of 8 mg and wherein the
15 medicament is for daily, in particular once daily, administration on a continuous basis;
b) the serum phosphate levels of the patient are to be measured on a treatment day during the first cycle of erdafitinib treatment, in particular on day 14 ± 2 days, more in particular on day 14, of erdafitinib administration;
c-1) when the serum phosphate levels are <5.5 mg/dL, the amount of erdafitinib in the
20 medicament for daily, in particular once daily, administration on a continuous basis is to be increased to 9 mg;
c-2) when the serum phosphate levels range from and including 5.5 mg/dL to < 7 mg/dL, the patient remains on the 8 mg daily, in particular once daily, continuous treatment;
25 c-3) when the serum phosphate levels are ≥ 7 mg/dL, the erdafitinib treatment is to be interrupted temporarily until serum phosphate levels are <5.5 mg/dL and then erdafitinib treatment is to be re-started with 8 mg daily, in particular once daily, on a continuous basis.

30 In another aspect, there is provided erdafitinib for use in the treatment of cancer in a cancer patient, wherein

- a) erdafitinib is to be administered in an amount of 8 mg daily, in particular once daily, on a continuous basis;
b) the serum phosphate levels of the patient are to be measured on a treatment day during the first cycle of erdafitinib treatment, in particular on day 14 ± 2 days, more in
35 particular on day 14, of erdafitinib administration;
c-1) when the serum phosphate levels are <5.5 mg/dL, erdafitinib is to be administered in an amount of 9 mg daily, in particular once daily, on a continuous basis;

c-2) when the serum phosphate levels range from and including 5.5 mg/dL to < 7 mg/dL, erdafitinib is to be further administered in an amount of 8 mg daily, in particular once daily, on a continuous basis;

c-3) when the serum phosphate levels are ≥ 7 mg/dL, the erdafitinib treatment is to be interrupted temporarily until serum phosphate levels are <5.5 mg/dL and then erdafitinib treatment is to be re-started with 8 mg daily, in particular once daily, on a continuous basis.

Detailed description of the invention

The present invention provides for the treatment of cancer with erdafitinib that maximizes erdafitinib exposure already within the first cycle of treatment (set at, for example, the first 28 days of treatment or the first 21 days of treatment, in particular with daily continuous dosing) as well as during further treatment cycles (set at, for example, 28 days/cycle or 21 days/cycle, in particular with daily continuous dosing) while limiting potential toxicities.

Claims

1. The use of erdafitinib for the manufacture of a medicament for the treatment of cancer, in an amount so that the levels of serum phosphate range from and including 5.5 mg/dL to < 7 mg/dL or range from and including 5.5 mg/dL to ≤ 9 mg/dL.
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2. The use according to claim 1 wherein the levels of serum phosphate range from and including 5.5 mg/dL to < 7 mg/dL.
3. Erdafitinib for use in the treatment of cancer, wherein erdafitinib is to be administered in
10 an amount so that the levels of serum phosphate range from and including 5.5 mg/dL to < 7 mg/dL or range from and including 5.5 mg/dL to ≤ 9 mg/dL.
4. Erdafitinib for use according to claim 3 wherein the levels of serum phosphate range from and including 5.5 mg/dL to < 7 mg/dL.
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5. The use of erdafitinib for the manufacture of a medicament for the treatment of cancer, wherein the medicament comprises erdafitinib in an amount of 8 mg and wherein the medicament is for daily, in particular once daily, administration on a continuous basis.
- 20 6. Erdafitinib for use in the treatment of cancer, wherein erdafitinib is administered in an amount of 8 mg daily, in particular once daily, on a continuous basis.
7. The use according to any one of the claims 1, 2, or 5, or the erdafitinib for use according to any one of the claims 3, 4, or 6, wherein the cancer is urothelial cancer,
25 bladder cancer, hepatocellular cancer, squamous cell carcinoma, or lung cancer.
8. The use or erdafitinib for use according to claim 7 wherein the cancer is metastatic or surgically unresectable urothelial cancer.
- 30 9. The use or erdafitinib for use according to claim 7 wherein the cancer is advanced or metastatic cholangiocarcinoma.
10. The use of erdafitinib for the manufacture of a medicament for the treatment of cancer in a cancer patient, wherein
35 a) the medicament comprises erdafitinib in an amount of 8 mg and wherein the medicament is for daily, in particular once daily, administration on a continuous basis;

- b) the serum phosphate levels of the patient are to be measured on a treatment day during the first cycle of erdafitinib treatment, in particular on day 14 ± 2 days, more in particular on day 14, of erdafitinib administration;
 - 5 c-1) when the serum phosphate levels are <5.5 mg/dL, the amount of erdafitinib in the medicament for daily, in particular once daily, administration on a continuous basis is to be increased to 9 mg;
 - c-2) when the serum phosphate levels range from and including 5.5 mg/dL to <7 mg/dL, the patient remains on the 8 mg daily, in particular once daily, continuous treatment;
 - 10 c-3) when the serum phosphate levels are ≥ 7 mg/dL, the erdafitinib treatment is to be interrupted temporarily until serum phosphate levels are <5.5 mg/dL and then erdafitinib treatment is to be re-started with 8 mg daily, in particular once daily, on a continuous basis.
- 15 11. Erdafitinib for use in the treatment of cancer in a cancer patient, wherein
- a) erdafitinib is to be administered in an amount of 8 mg daily, in particular once daily, on a continuous basis;
 - b) the serum phosphate levels of the patient are to be measured on a treatment day during the first cycle of erdafitinib treatment, in particular on day 14 ± 2 days, more in particular on day 14, of erdafitinib administration;
 - 20 c-1) when the serum phosphate levels are <5.5 mg/dL, erdafitinib is to be administered in an amount of 9 mg daily, in particular once daily, on a continuous basis;
 - c-2) when the serum phosphate levels range from and including 5.5 mg/dL to <7 mg/dL, erdafitinib is to be further administered in an amount of 8 mg daily, in particular once daily, on a continuous basis;
 - 25 c-3) when the serum phosphate levels are ≥ 7 mg/dL, the erdafitinib treatment is to be interrupted temporarily until serum phosphate levels are <5.5 mg/dL and then erdafitinib treatment is to be re-started with 8 mg daily, in particular once daily, on a continuous basis.