

Claims

1. A method of selecting a subject determined to have a metastatic tumor with a mutation in homologous recombination pathway genes, for treatment with talazoparib, or a pharmaceutically acceptable salt thereof, comprising a) determining a homologous recombination deficiency score from a biopsy of the metastatic tumor; and b) selecting the subject for treatment with talazoparib, or a pharmaceutically acceptable salt thereof, if the homologous recombination deficiency score is at least 33%, wherein the mutation is not germline BRCA1 or germline BRCA2.
2. The method of claim 1, wherein the mutation is a somatic or a germline mutation.
3. The method of claim 1, wherein the mutation is PALB2, CHEK2, ATM, BRIP1, RAD50, ATR, PTEN, or FANCA.
4. The method of claim 1, wherein the mutation is gCHEK2, gPALB2, or sPTEN.
5. The method of claim 1, wherein the mutation is gPALB2.
6. The method of claim 1, wherein the metastatic tumor is a breast tumor.
7. The method of claim 6, wherein the breast tumor is a HER2-negative breast tumor.
8. The method of claim 1, wherein the metastatic tumor is determined to have a mutation in homologous recombination pathway genes by next generation sequencing.
9. The method of claim 1, wherein the step of determining a homologous recombination deficiency score from a biopsy of the metastatic tumor is performed by next generation sequencing.
10. The method of claim 1, wherein the homologous recombination deficiency score is at least 42%.
11. Use of talazoparib, or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of a metastatic tumor in a subject determined to have a mutation in homologous recombination pathway genes, wherein talazoparib, or a pharmaceutically acceptable salt thereof is to be administered to the subject if the homologous recombination deficiency score determined from a biopsy of

the metastatic tumor is at least 33%, wherein the mutation is not germline BRCA1 or germline BRCA2.

12. The use of claim 11, wherein the mutation is a somatic or a germline mutation.

5 13. The use of claim 11 or claim 12, wherein the mutation is PALB2, CHEK2, ATM, BRIP1, RAD50, ATR, PTEN, or FANCA.

14. The use of claim 11 or claim 12, wherein the mutation is gCHEK2, gPALB2, or sPTEN.

15. The use of claim 11 or claim 12, wherein the mutation is gPALB2.

10 16. The use of claim 11, wherein the metastatic tumor is a breast tumor.

17. The use of claim 16, wherein the breast tumor is a HER2-negative breast tumor.

18. The use of claim 11, wherein the metastatic tumor is determined to have a mutation in homologous recombination pathway genes by next generation sequencing.

15 19. The use of claim 11, wherein the homologous recombination deficiency score from a biopsy of the metastatic tumor is performed by next generation sequencing.

20. The use of claim 11, wherein the homologous recombination deficiency score is at least 42%.