

CLAIMS

1) Use of camizestrant or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of HR+, HER2-, metastatic or loco-regionally recurrent breast cancer that has recurred or progressed following at least one prior line of endocrine therapy and that:

i) has recurred or progressed following at least one prior line of therapy with a CDK4/6 inhibitor;
or

ii) has been identified as having visceral metastases; or

iii) has been identified as having a mutation of the estrogen receptor α .

2) The use according to claim 1, wherein the cancer has recurred or progressed following at least one prior line of therapy with a CDK4/6 inhibitor.

3) The use according to claim 1, wherein the cancer has been identified as having visceral metastases.

4) The use according to claim 1, wherein the cancer has been identified as having a mutation of the estrogen receptor α .

5) The use according to claim 4, wherein the cancer has been identified as having a mutation to the estrogen receptor α selected from E380Q, V422del, S463P, L536H, L536P, L536R, Y537C, Y537D, Y537N, Y537S and D538G.

6) The use according to claim 4 or claim 5, wherein the identification of a mutation of the estrogen receptor α is made on the basis of test of a sample obtained from the patient.

7) The use according to claim 6, wherein the sample obtained from the patient is a tumour biopsy or a blood sample.

8) The use according to claim 7, wherein the identification of a mutation of the estrogen receptor α is performed by analysing circulating tumor DNA.

9) The use according to any preceding claim wherein the camizestran or a pharmaceutically acceptable salt thereof is to be orally administered once daily at a dose of 75mg.

10) The use according to any one of claims 1 to 8 wherein the camizestran or a pharmaceutically acceptable salt thereof is to be orally administered once daily at a dose of 150mg.

11) The use according to any of claims 1 to 10, wherein the use delivers an improvement in the clinical benefit rate at 24 weeks relative to fulvestrant.

12) The use according to any of claims 1 to 10, wherein the use delivers an improvement in the objective response rate relative to fulvestrant.

13) A kit comprising a pharmaceutical composition comprising a camizestran and at least one pharmaceutically acceptable excipient and instructions for use of the pharmaceutical composition in the treatment of HR+, HER2-, metastatic or loco-regionally recurrent breast cancer, characterised in that the cancer has recurred or progressed following at least one prior line of endocrine therapy, and wherein:

i) the cancer has recurred or progressed following at least one prior line of therapy with a CDK4/6 inhibitor; or

ii) the cancer has been identified as having visceral metastases; or

iii) the cancer has been identified as having a mutation of the estrogen receptor α .