CLAIMS

1. Use of ribociclib or a pharmaceutically acceptable salt thereof, in combination with an aromatase inhibitor in the manufacture of a medicament for maintaining remission in an adult patient who had previously been diagnosed with HR+/HER2- stage II or stage III early breast cancer, wherein a treatment comprising a dose of ribociclib or a pharmaceutically acceptable salt thereof, in combination with an aromatase inhibitor is to be administered to the patient.

2. The use of claim 1, wherein the dose of ribociclib is 200 mg/day or 400 mg/day.

3. The use of claim 2, wherein ribociclib is to be administered as ribociclib succinate, and the total dose of ribociclib is 400 mg/day.

4. The use of claim 3, wherein the treatment reduces the risk of invasive disease.

5. The use of claim 4, wherein the treatment reduces the risk of invasive disease corresponding to a hazard ratio of less than or equal to 0.78 when the risk is calculated relative to patients that received the treatment except for administration of ribociclib.

6. Use of ribociclib in combination with an aromatase inhibitor in the manufacture of a medicament for the adjuvant treatment of HR+/HER2- stage II or stage III early breast cancer in an adult patient, wherein ribociclib in combination with an aromatase inhibitor is to be administered to the patient, wherein the patient at start of the adjuvant treatment is in complete remission, and wherein the administration of ribociclib in combination with aromatase inhibitor maintains the adult patient in complete remission for at least 3 months.

7. The use of claim 6, wherein ribociclib and aromatase inhibitor are to be administered for a treatment duration, and the administration maintains the adult patient in complete remission for at least the treatment duration.

8. The use of claim 6, wherein a dose of 400 mg ribociclib is to be orally administered once daily on days 1-21 of a 28-day cycle and aromatase inhibitor is to be administered once daily on each day of the 28-day cycle.

9. The use of claim 6, wherein a dose of 400 mg ribociclib is to be orally administered once daily on days 1-21 of a 28-day cycle for a treatment duration of up to three years and the aromatase inhibitor is to be administered once daily on each day of the 28-day cycle for the up to three years.

10. The use of claim 6, wherein the treatment reduces the risk of invasive disease in the adult patient corresponding to a hazard ratio of less than or equal to 0.78 when the risk is calculated relative to other patients having received the same treatment as the adult patient except that the other patients did not receive the ribociclib.

11. The use of any one of the preceding claims, wherein the aromatase inhibitor is letrozole or anastrozole.

12. Use of ribociclib in the manufacture of a medicament for the treatment of HR+/HER2- stage II or III early breast cancer in an adult patient in need thereof, wherein 400 mg ribociclib on days 1 to 21 of a 28-day cycle for 36 months is to be administered to the patient, in combination with endocrine therapy, and wherein the endocrine therapy comprises an aromatase inhibitor to be administered.

13. The use of claim 12, wherein the patient is a postmenopausal woman, and the endocrine therapy comprises 2.5 mg letrozole once daily or 1 mg anastrozole once daily to be administered to the patient.

14. The use of claim 12 or 13, wherein the treatment is characterized by improving invasive disease-free survival which is overall consistent for patient subgroups including stage II, stage III, premenopausal women and men, and postmenopausal.

15. The use of any one of claims 12 to 14, wherein the treatment is characterized by an improvement of invasive disease-free survival corresponding to hazard ratio of less than or equal to about 0.78.

16. Use of ribociclib in the manufacture of a medicament for the treatment of HR+/HER2- stage II or III early breast cancer in an adult patient in need thereof, wherein 400 mg ribociclib on days 1 to 21 of a 28-day cycle for 36 months is to be administered to the patient, in combination with endocrine therapy to improve invasive disease-free survival

(iDFS), and wherein the endocrine therapy comprises an aromatase inhibitor to be administered.

17. The use of claim 16, wherein the patient is a postmenopausal woman, and the endocrine therapy comprises 2.5 mg letrozole once daily or 1 mg anastrazole once daily to be administered to the patient.

18. The use of claim 16 or 17, wherein the treatment is characterized by an improvement of invasive disease-free survival which is overall consistent for patient subgroups including stage II, stage III, premenopausal women and men, and postmenopausal.

19. The use of any one of claims 16 to 380, wherein the treatment is characterized by an improvement of invasive disease-free survival corresponding to hazard ratio of less than or equal to about 0.78.

20. The use of any one of claims 11 to 19, wherein the treatment is an adjuvant treatment.

21. The use of any one of claims 11 to 20, wherein the treatment continues while the patient is diagnosed to have no cancer recurrence.