CLAIMS

1. Use of a composition in the manufacture of a medicament for reducing mammographic breast density and/or breast stiffness in a patient, wherein the composition comprises:

i) an effective amount of a selective androgen receptor modulator; and

ii) an effective amount of an aromatase inhibitor.

2. The use of claim 1, wherein the patient has, or is diagnosed with having, a breast with:

i) a mammographic breast density of 7.5% or greater;

ii) an area breast density percentage (ABD%) of 7.5% or greater;

iii) a volume breast density percentage (VBD%) of 7.5% or greater; and/or

iv) a BIRADS score of 3 or 4 (or c or d).

3. The use of claim 1 or claim 2, wherein:

i) the reduction in mammographic breast density is in the range of between 5% to 25% or 10% to 25% after 1 year, 2 years, 3 years, 4 years or 5 years of treatment with the medicament;

ii) the medicament reduces the VBD% or absolute volume breast density (AVBD) of the patient's breast between one or more annual intervening mammographic detections; and/or

iii) the medicament reduces the ABD% or absolute area breast density (AABD) of the patient's breast between one or more annual intervening mammographic detections.

4. The use of any one of claims 1-3, wherein the breast stiffness reduces by at least 10% after 1 year, 2 years, 3 years, 4 years or 5 years of treatment with the medicament.

5. The use of any one of claims 1-4, wherein the medicament provides one or more of the following:

i) enhances mammographic detection due to reduced breast density enabling the mammogram to visualize malignancy at an earlier and/or less aggressive stage;
ii) enhances the ability to achieve better mammographic compression due at least in part due to reduced pain;
iii) enhances the ability to achieve better patient compliance in having regular mammographic check- ups;
iv) enhances the ability to treat the patient and at the same time not causing perturbations in the hypothalamic-pituitary axis and/or other endocrine axis;
v) reduces breast pain in a patient;
vi) reduces breast elasticity in a patient;
vii) decreases mechano-transduction on the genome of a cell in order to reduce the risk of malignant transformation in a patient;
viii) increases ratio of fibro-glandular and adipose tissue in a patient;
ix) increases CD36 in a patient;
x) stabilizes and/or an increase in levels of androgen receptor expression in breast tissue of a patient;
xi) increases the level of GCDFP15 in a patient;
xii) reduces BPE in an MRI breast image of a patient;
xiii) improves detection of breast abnormalities due to reduced BPE in an MRI breast image of a patient; and
xiv) reduces cysts in size and/or quantity in a patient’s breast.

6. Use of a composition in the manufacture of a medicament for reducing breast pain in a patient, wherein the composition comprises:

i) an effective amount of a selective androgen receptor modulator; and
ii) an effective amount of an aromatase inhibitor.

7. The use of claim 6, wherein the medicament:

i) reduces the patient’s breast pain associated with having a mammography image taken;
ii) reduces the patient’s breast pain in at least one of the patient’s breasts between one or more annual intervening mammographic detections;
iii) reduces VBD% and/or AVBD in at least one of the patient's breasts between one or more annual intervening mammographic detections;
iv) reduces breast stiffness in at least one of the patient's breasts between one or more annual intervening mammographic detections;
v) stabilizes and/or increases levels of androgen receptor expression in breast tissue in at least one of the patient's breasts between one or more annual intervening mammographic detections; and/or
vi) reduces and/or treats macromastia in at least one of the patient's breasts between one or more annual intervening mammographic detections.

8. The use of claim 6 or claim 7, wherein the medicament reduces breast pain in at least one of the patient's breasts by between 20% to 100% over a 2 week, 3 month, 6 month, one year, two year, three year or five year treatment period.

9. The use of any one of claims 1-8, wherein the medicament reduces the treated patient’s risk of developing breast cancer between one or more annual intervening mammographic detections.

10. The use of any one of claims 1-9, wherein the medicament:
i) provides a reduction in breast elasticity; and/or
ii) reduces breast inflammation.

11. The use of any one of claims 1-11, wherein the medicament:
i) provides a reduction in macromastia or a reduction in breast cysts; and/or
ii) reduces breast inflammation associated with macromastia or breast cysts.

12. The use of any one of claims 1-11, wherein the patient is pre-menopausal, peri-menopausal, or post-menopausal.

13. The use of any one of claims 1-12, wherein the medicament reduces or reverses peri-menopausal symptoms.

14. The use of any one of claims 1-13, wherein the medicament increases or improves the patient's fat to breast tissue ratio from 1:19 to 19:1 over a 3 month period, over a 6 month period, over a 9 month period, over a 1 year period, or over a 5 year period.

15. The use of any one of claims 1-14, wherein the selective androgen receptor modulator is selected from the group consisting of:

(2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide (also known as Enobosarm, Ostarine, GTx-024, and MK-2866);

(7R,7aS)-2-Chloro-4-(7-hydroxy-1,3-dioxotetrahydropyrrolo[1,2-c]imidazol-2-yl)-3-methylbenzonitrile (also known as BMS-564,929);

4-((R)-2-((R)-2,2,2-trifluoro-1-hydroxyethyl)pyrrolidin-1-yl)-2-trifluoromethyl)benzonitrile (also known as LGD-4033, or Ligandrol);

4-(3-Hydroxy-8-aza-bicyclo[3.2.1]octyl)-naphthalene-1-carbonitrile (also known as AC-262,356);

JNJ-28330835;

6-(bis-(2,2,2-trifluoroethyl)amino)-4-trifluoromethyl-1H-quinolin-2-one (also known as LGD-2226);

9-chloro-2-ethyl-1-methyl-3-(2,2,2-trifluoroethyl)-3H-pyrrolo[3,2-f]quinolin-7(6H)-one (also known as LGD-3303);

2-[4-(dimethylamino)-6-nitro-1,2,3,4-tetrahydroquinolin-2-yl]-2-methylpropan-1-ol (also known as S-40503); or

(2S)-N-(4-cyano-3-trifluoromethylphenyl)-3-(3-fluoro-4-chlorophenoxy)-2-hydroxy-2-methyl-propanamide (also known as S-23);

or derivatives thereof.

16. The use of any one of claims 1-15, wherein the aromatase inhibitor is selected from the group consisting of: exemestane, formestane, anastrozole, letrozole, vorozole, and fadrozole.17. Use of an effective amount of a selective androgen receptor modulator in the manufacture of a medicament for reducing mammographic breast density and/or breast stiffness in a patient, the medicament including an effective amount of an aromatase inhibitor.

18. Use of an effective amount of a selective androgen receptor modulator in the manufacture of a medicament for reducing breast pain in a patient, the medicament including an effective amount of an aromatase inhibitor.

19. The use according to claim 17 or 18, wherein the selective androgen receptor modulator is selected from the group consisting of:

(2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide (also known as Enobosarm, Ostarine, GTx-024, and MK-2866);

(7R,7aS)-2-Chloro-4-(7-hydroxy-1,3-dioxotetrahydropyrrolo[1,2-c]imidazol-2-yl)-3-methylbenzonitrile (also known as BMS-564,929);

4-((R)-2-((R)-2,2,2-trifluoro-1-hydroxyethyl)pyrrolidin-1-yl)-2-trifluoromethyl)benzonitrile (also known as LGD-4033, or Ligandrol);

4-(3-Hydroxy-8-aza-bicyclo[3.2.1]octyl)-naphthalene-1-carbonitrile (also known as AC-262,356);

JNJ-28330835;

6-(bis-(2,2,2-trifluoroethyl)amino)-4-trifluoromethyl-1H-quinolin-2-one (also known as LGD-2226);

9-chloro-2-ethyl-1-methyl-3-(2,2,2-trifluoroethyl)-3H-pyrrolo[3,2-f]quinolin-7(6H)-one (also known as LGD-3303);

2-[4-(dimethylamino)-6-nitro-1,2,3,4-tetrahydroquinolin-2-yl]-2-methylpropan-1-ol (also known as S-40503); or

(2S)-N-(4-cyano-3-trifluoromethylphenyl)-3-(3-fluoro-4-chlorophenoxy)-2-hydroxy-2-methyl-propanamide (also known as S-23);

or derivatives thereof.

20. The use according to any one of claims 17-19, wherein the aromatase inhibitor is selected from the group consisting of: exemestane, formestane, anastrozole, letrozole, vorozole, and fadrozole.

21. The use according to any one of claims 1-8, wherein the medicament reduces the patient's risk of developing breast cancer.

22. The use according to any one of claims 17-20, wherein the medicament reduces the patient's risk of developing breast cancer.