WHAT IS CLAIMED IS:

1. A composition comprising an antibody that specifically binds to progastrin for use in a method for preventing or preventing recurrence or treating breast cancer, wherein a therapeutically effective amount of the composition is administered to a patient in need thereof.

2. The composition for use according to claim 1, wherein the breast cancer is a primary breast cancer or a metastatic breast cancer.

3. The composition for use according to claim 1, wherein the administration of the anti-progastrin antibody composition is effected before or after surgical resection of a breast tumor.

4. The composition for use according to claim 1, wherein the administration of the anti-progastrin antibody composition is effected before or after administration of a dose of radiation therapy for breast cancer.

5. The composition for use according to claim 1, wherein the administration of the anti-progastrin antibody composition is effected before, concurrently or after administration of a chemotherapeutic agent to treat breast cancer.

6. The composition for use according to claim 1, wherein the administration of the anti-progastrin antibody composition is effected before, concurrently or after administration of a hormone therapy agent to treat breast cancer.

7. The composition for use according to claim 1, wherein the administration of the anti-progastrin antibody composition is effected before, concurrently or after administration of a second therapeutic antibody with specificity other than for progastrin.

8. The composition for use according to claim 7, wherein said second antibody specifically binds to an antigen selected from among the group consisting of: EGFR, VEGF and HER2.

9. The composition for use according to claim 1, wherein the anti-progastrin antibody is selected from among the group consisting of: polyclonal antibodies, monoclonal antibodies, humanized monoclonal antibodies, chimeric antibodies, single chain antibodies, camelized antibodies, IgA1 antibodies, IgA2 antibodies, IgD antibodies, IgE antibodies, IgG1 antibodies, IgG2 antibodies, IgG3 antibodies, IgG4 antibodies, and IgM antibodies.

10. The composition for use according to claim 1, wherein the antibody is conjugated to a moiety.

11. The composition for use according to claim 1, wherein the antibody has a progastrin binding affinity of at least about 0.001 nM to at least about 5000 nM.

12. The composition for use according to claim 1, wherein the composition comprises a plurality of antibodies having specificities for distinct epitopes of progastrin.

13. The composition for use according to claim 1, wherein the progastrin specific antibody is a monoclonal antibody selected from among the group consisting of : MAb1, MAb2, MAb3, MAb4, MAb5, MAb6, MAb7, MAb8, MAb9, MAb10, MAb11, MAb12, MAb13, MAb14, MAb15, MAb16, MAb17, MAb18, MAb19, MAb20, MAb21, MAb22 and MAb23.

14. The composition for use according to claim 1, wherein the monoclonal antibody is humanized.

15. The composition for use according to claim 1, wherein the progastrin specific antibody is a monoclonal antibody comprising a heavy chain variable region (V_H) in which complementarity determining region 1 (CDR1) is selected from V_H CDR 1.3, V_H CDR 1.4, V_H CDR 1.8, V_H CDR 1.13, V_H CDR 1.16, V_H CDR 1.19, CDR2 is selected from V_H CDR 2.3, V_H CDR 2.4, V_H CDR 2.8, V_H CDR 2.13, V_H CDR 2.16, V_H CDR 2.19, and CDR3 is selected from V_H CDR 3.3, V_H CDR 3.4, V_H CDR 3.8, V_H CDR 3.13, V_H CDR 3.16, V_H CDR 3.19 and/or a light chain variable region (V_L) in which complementary determining region 1 (CDR1) is selected from V_L CDR 1.3, V_L CDR 1.4, V_L CDR 1.8, V_L CDR 1.13, V_L CDR 1.16, V_L CDR 1.19, CDR2 is selected from V_L CDR 2.3, V_L CDR 2.4, V_L CDR 2.8, V_L CDR 2.13, V_L CDR 2.16, V_L CDR 2.19, and CDR3 is selected from V_L CDR 3.3, V_L CDR 3.4, V_L CDR 3.8, V_L CDR 3.13, V_L CDR 3.16, V_L CDR 3.19.

16. The composition for use according to claim 1, wherein the anti-progastrin antibody is administered at a dose from about 0.001 mg/kg to about 250 mg/kg.

17. The composition for use according to claim 1, wherein the dose of said anti-progastrin antibody is administered over a plurality of temporally spaced administrations.

18. A method for inhibiting the growth of a breast cancer stem cell in a patient, comprising the step of administering to a patient in need of inhibition of growth of a breast cancer stem cell of a composition comprising an antibody that specifically binds to progastrin in an amount effective to inhibit said breast cancer stem cell, wherein said breast cancer stem cell is progastrin sensitive.

19. A method for monitoring the efficacy of a treatment for breast cancer in a patient comprising the steps: (i) determining the concentration of progastrin in a first sample obtained from a patient before treatment for breast cancer, and (ii) comparing the

concentration of progastrin in said first sample to that in a second sample obtained from the same patient after treatment for breast cancer, wherein a reduction in the concentration of progastrin in said second sample compared to said first sample is indicative that the treatment was effective.

20. A method for diagnosing the presence of breast cancer in a patient comprising the steps: (i) determining the concentration of progastrin in a sample obtained from a patient suspected of having breast cancer, and (ii) comparing the concentration of progastrin in said sample to a predetermined value, wherein an elevated level of progastrin in the sample compared to the predetermined value is indicative of the presence of breast cancer in said patient.

The claims defining the invention are as follows:

1. Use of an anti-human progastrin monoclonal antibody for the manufacture of a medicament for use in treatment, in prevention and recurrence prevention of breast cancer.

2. The use of claim 1, wherein said breast cancer is a primary breast cancer or metastatic breast cancer.

3. The use of claim 1 or 2, wherein the medicament is formulated for administering said anti-human progastrin monoclonal antibody before, concurrently or after administration of a chemotherapeutic agent to treat breast cancer.

4. The use of claim 3, wherein said chemotherapeutic agent is selected from among the group of chemotherapeutic agents consisting of: olate antagonists, purine antagonists, pyrimidine antagonists, DNA alkylating agents, DNA cross-linking drugs, antibiotics, platinum complexes, proteosome inhibitors, mitotic spindle poisons, topoisomerase inhibitors, and tyrosine kinase inhibitors.

5. The use of claim 1, wherein the medicament is formulated for administration of said anti-human progastrin monoclonal antibody composition is before, concurrently or after administration of a hormone therapy agent to treat breast cancer.

6. The use of claim 5 wherein said hormone therapy agent is selected from among the group consisting of: bicalutamide, flutamide, fulvestrant, leuprolide acetate, megestrol acetate, tamoxifen, raloxifene, anastrozole, exemestane and letrozole.

7. The use of claim 1, wherein the medicament is formulated for administering said anti-human progastrin monoclonal antibody before, simultaneously or after administration of a second therapeutic antibody with specificity other than for progastrin.

8. The use of claim 7, wherein said second antibody is selected from the group of monoclonal antibodies consisting of: panitumumab, bevacizumab, cetuximab and trastuzumab.

9. The use of claim 7, wherein said second antibody specifically binds to an antigen selected from among the group consisting of: EGFR, VEGF and HER2.

10. The method of any one of claims 1 to 9, wherein said monoclonal antibody has a human progastrin binding affinity of at least about 0.001 nM to at least about 5000 nM.

11. The use of any one of claims 1 to 9, wherein said anti-human progastrin monoclonal antibody is selected from among the group consisting of: MAb1, MAb2, MAb3, MAb4, MAb5, MAb6, MAb7, MAb8, MAb9, MAb10, MAb11, MAb12, MAb13, MAb14, MAb15, MAb16, MAb17, MAb18, MAb19, MAb20, MAb21, MAb22 and MAb23.

12. The use of claim 11, wherein said monoclonal antibody is humanized.

13. The use of any one of claims 1 to 10, wherein said anti-human progastrin monoclonal antibody comprising a heavy chain variable region (V_H) in which complementarity determining region 1 (CDR1) is selected from V_H CDR 1.3, V_H CDR 1.4, V_H CDR 1.8, V_H CDR 1.13, V_H CDR 1.16, V_H CDR 1.19, CDR2 is selected from V_H CDR 2.3, V_H CDR 2.4, V_H CDR 2.8, V_H CDR 2.13, V_H CDR 2.16, V_H CDR 2.19, and CDR3 is selected from V_H CDR 3.3, V_H CDR 3.4, V_H CDR 3.8, V_H CDR 3.13, V_H CDR 3.16, V_H CDR 3.19.

14. The use of any one of claims 1 to 10, wherein said anti-human progastrin monoclonal antibody comprising a light chain variable region (V_L) in which complementarity determining region 1 (CDR1) is selected from V_L CDR 1.3, V_L CDR 1.4, V_L CDR 1.8, V_L CDR 1.13, V_L CDR 1.16, V_L CDR 1.19, CDR2 is selected from V_L CDR 2.3, V_L CDR 2.4, V_L CDR 2.8, V_L CDR 2.13, V_L CDR 2.16, V_L CDR 2.19, and CDR3 is selected from V_L CDR 3.3, V_L CDR 3.4, V_L CDR 3.8, V_L CDR 3.13, V_L CDR 3.16, V_L CDR 3.19.

15. The use of any one of claims 1 to 14, wherein a dose of the medicament comprises from about 0.001 mg/kg to about 250 mg/kg of said anti-human progastrin.

16. Use of an anti-human progastrin monoclonal antibody for the manufacture of a medicament for use in inhibition of the growth of a breast cancer stem cell.

17. The use of claim 16, wherein the medicament is formulated to be administered concurrently with or after administration of a second agent effective to inhibit the growth of breast cancer stem cells.

18. The use of claim 16 or 17, wherein said anti-human progastrin monoclonal antibody is selected from among the group consisting of: MAb1, MAb2, MAb3, MAb4, MAb5, MAb6, MAb7, MAb8, MAb9, MAb10, MAb11, MAb12, MAb13, MAb14, MAb15, MAb16, MAb17, MAb18, MAb19, MAb20, MAb21, MAb22 and MAb23.

19. The use of claim 18, wherein said monoclonal antibody is humanized.

20. The use of claim 16 or 17, wherein said anti-human progastrin monoclonal antibody comprising a heavy chain variable region (V_H) in which complementarity determining region 1 (CDR1) is selected from V_H CDR 1.3, V_H CDR 1.4, V_H CDR 1.8, V_H CDR 1.13, V_H CDR 1.16, V_H CDR 1.19, CDR2 is selected from V_H CDR 2.3, V_H CDR 2.4, V_H CDR 2.8, V_H CDR 2.13, V_H CDR 2.16, V_H CDR 2.19, and CDR3 is selected from V_H CDR 3.3, V_H CDR 3.4, V_H CDR 3.8, V_H CDR 3.13, V_H CDR 3.16, V_H CDR 3.19.

21. The use of claim 16 or 17, wherein said anti-human progastrin monoclonal antibody comprising a light chain variable region (V_L) in which complementarity determining region 1 (CDR1) is selected from V_L CDR 1.3, V_L CDR 1.4, V_L CDR 1.8, V_L CDR 1.13, V_L CDR 1.16, V_L CDR 1.19, CDR2 is selected from V_L CDR 2.3, V_L CDR 2.4, V_L CDR 2.8, V_L CDR 2.13, V_L CDR 2.16, V_L CDR 2.19, and CDR3 is selected from V_L CDR 3.3, V_L CDR 3.4, V_L CDR 3.8, V_L CDR 3.13, V_L CDR 3.16, V_L CDR 3.19.

22. The use of any one of claims 16 to 21, wherein a dose of the medicament comprises from about 0.001 mg/kg to about 250 mg/kg of said anti-human progastrin monoclonal antibody.