WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising a compound

4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide or

4-[7-[4-cyano-3-(trifluoromethyl)phenyl]-8-oxo-6-thioxo-5, 7-diazaspiro[3 .4]oct-5-yl]-2-fluoro-N-methylbenzamide

for use in a method of treating a male human with non-metastatic castration-resistant prostate cancer, wherein the method comprises administering the therapeutically effective amount of the compound to a male human with a non-metastatic castration-resistant prostate cancer in combination with a gonadotropin-releasing hormone (GnRH) agonist.

2. The use of a therapeutically effective amount of a compound:

4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide or

4-[7-[4-cyano-3-(trifluoromethyl)phenyl]-8-oxo-6-thioxo-5, 7-diazaspiro[3 .4]oct-5-yl]-2-fluoro-N-methylbenzamide

in the manufacture of a medicament for treating a male human with non-metastatic castration-resistant prostate cancer in combination with a gonadotropin-releasing hormone (GnRH) agonist.

3. The use according to claim 2, wherein the non-metastatic castration-resistant prostate cancer is a high risk non-metastatic castration-resistant prostate cancer.

4. The use according to claim 2 that provides an increase in the metastasis-free survival of the male human with prostate cancer.

5. The use according to claim 2, wherein the compound is 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide.

6. The use according to claim 5, wherein the 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5, 7-diazaspiro[3 .4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered daily to the male human.

7. The use according to claim 5, wherein the 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered orally to the male human.

8. The use according to claim 5, wherein the 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5, 7-diazaspiro[3 .4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered orally to the male human at a dose of from about 30 mg per day to about 480 mg per day, preferably at a dose of from about 180 mg per day to about 480 mg per day.

9. The use according to claim 5, wherein the 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5, 7-diazaspiro[3 .4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered orally to the male human at a dose of about 30 mg per day, about 60 mg per day, about 90 mg per day, about 120 mg per day, or about 240 mg per day.

10. The use according to claim 5, wherein the 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide is administered orally to the male human on a continuous daily dosing schedule.

11. The use according to claim 2, wherein the compound is 4-[7-[4-cyano-3-(trifluoromethyl)phenyl]-8-oxo-6-thioxo-5, 7-diazaspiro[3 .4]oct-5-yl]-2-fluoro-N-methylbenzamide.

12. The use according to claim 5 or 11, wherein the GnRH agonist is leuprolide, buserelin, nafarelin, histrelin, goserelin, or deslorelin.

13. The use according to claim 12, wherein the GnRH agonist is leuprolide.

14. The use according to claim 12, wherein the GnRH agonist is goserelin.