CLAIMS

1. A stable sustained release letrozole composition for intramuscular administration suitable for forming an *in situ* intramuscular implant comprising from 10 to 500 mg of letrozole and a sterile biodegradable thermoplastic polymer of poly(lactic acid) (PLA), wherein said PLA is milled; and wherein said PLA has a particle size mass distribution with not more than 10% above 300 microns, preferably not above 250 microns, when measured by analytical sieving according to USP<786> and said PLA has a particle size volume distribution with a D90 not above 330 microns, preferably not above 280 microns when measured by laser diffraction analysis; and wherein said PLA has a particle size mass distribution where not more than 80 % of the particles have a particle size below 125 microns, when measured by analytical sieving according to USP<786> and said PLA has a particle size volume distribution with a D80 not below 135 microns when measured by laser diffraction analysis; and wherein the release of the active agent from the implant is between 2 and 30 % of the active agent each 28 days, preferably is between 5 and 25 % of the active agent each 28 days; and/or wherein the composition releases from 0.1 to 2 milligrams of letrozole every day, preferably from 0.13 to 0.80 milligrams of letrozole every day.

2. The stable sustained release letrozole composition according to the preceding claim, characterized in that said composition releases up to 30 % of the letrozole in 30 days, preferably up to 25 % of the letrozole in 30 days; or up to 50 % of the letrozole in 100 days, preferably in 120 days and more preferably in 130 days; or said composition releases up to 80 % of the letrozole in 140 days, preferably in 180 days, more preferably in 200 days; or composition releases up to 80 % of the letrozole in 240 days, in an *in vitro* dissolution test performed with horizontal orbital motion at 50 rpm; medium: PBS pH 7.4.; temperature: 37 ± 0.5 °C; analytical technique HPLC/UV; wavelength 230 nm.

3. The stable sustained release composition according to any one of the preceding claims, wherein the composition releases the drug with an immediate onset of action and continuously for at least 1 month, preferably at least 3 months, more preferably at least 6 moths, even more preferably at least 12 months.

4. The stable sustained release composition according to any one of the preceding claims, wherein the composition releases the drug with an immediate onset of action and continuously between 3 and 6 months.

5. The stable sustained release composition according to any one of the preceding claims, wherein the composition is an injectable intramuscular depot and sterile composition suitable for forming an *in situ* solid, semisolid or a gel implant in a body.

6. A process for preparing the stable sustained release letrozole composition of any one of the preceding claims, comprising mixing the components of the composition up to 15 minutes prior to administration, preferably 10 minutes prior to administration, more preferably 5 minutes prior to administration.

7. The process according to the preceding claim, wherein the composition is prepared by mixing the solvent with a previous solid mix of letrozole and PLA.

8. The stable sustained release composition of any one of claims 1 to 5, for use in administering a patient in need thereof from 0.1 -2 milligrams of letrozole every day.

9. The stable sustained release composition for use according to the preceding claim, for administering a patient in need thereof from 0.13-0.8 milligrams of letrozole every day.

10. The stable sustained release composition for use according to any one of the two preceding claims, wherein the composition provides a plasma level of letrozole between 1 and 40 ng/ml after 2 days from the implant administration.

11. The stable sustained release composition for use according to any one of the three preceding claims, wherein the composition provides a plasma level of letrozole between 1.5 and 30 ng/ml after 2 days from the implant administration.

12. The stable sustained release composition for use according to any one of the four preceding claims, for suppressing estradiol plasma levels to less than 1 pg/ml after 4 days from the implant administration.

13. The stable sustained release composition for use according to any one of the five preceding claims, for aromatase inhibition, preferably in humans.

14. The stable sustained release composition for use according to any one of the six preceding claims, for treating breast cancer.

15. The stable sustained release composition for use according to any one of the seven preceding claims, for adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer or for extended adjuvant treatment of postmenopausal women with early breast cancer who have received prior standard adjuvant tamoxifen therapy, or for first and second-line treatment of postmenopausal women with hormone receptor positive or unknown advanced breast cancer.

16. A kit suitable for the *in situ* preparation of the composition of any one of claims 1 to 5, comprising two containers or syringes, wherein the first container or syringe comprises the letrozole and the PLA and the second container or syringe comprises the solvent, preferably DMSO.