

CLAIMS

1. Use of 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of chronic graft-versus-host disease (cGVHD) in a female patient
 - a) of reproductive potential, wherein the female patient is to use effective contraception during administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, and for at least one week after the administration of a last dose of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof; or
 - b) who is pregnant or becomes pregnant during the administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof; or
 - c) of reproductive potential, wherein the administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof is to be initiated after the pregnancy status of the female patient has been verified.
2. The use according to claim 1, wherein the administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof is to be initiated after the pregnancy status of the female patient is verified.
3. The use according to claim 1, wherein the female patient becomes pregnant during the administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof .
4. Use of 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of chronic graft-versus-host disease (cGVHD)
 - a) in a male patient having a female partner of reproductive potential, wherein the male patient is to use effective contraception during administration of the 2-{3-[4-(1H-indazol-

- 5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, and for at least one week after the administration of a last dose of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof; or
- b) in a patient of reproductive potential using effective contraception during administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof; and/or
- c) wherein the patient is using effective contraception during administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, and for at least one week after the administration of a last dose of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof.
5. The use according to claim 4, wherein the patient is a female of reproductive potential.
 6. The use according to claim 4, wherein the patient is a male of reproductive potential.
 7. Use of 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of chronic graft-versus-host disease (cGVHD) in a patient who is lactating, wherein the patient is not to breastfeed during administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, and for at least one week after the administration of a last dose of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof.
 8. The use according to any one of claims 1 to 7, wherein the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof is the mesylate salt of 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide; and/or

wherein the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, is to be administered to the patient at a dose equivalent of 200 mg of the free base daily.

9. The use according to any one of claims 1 to 7, wherein the patient has chronic graft-versus-host disease and has failed at least two prior lines of systemic therapy for the chronic graft-versus-host disease, optionally wherein the prior lines of systemic therapy are selected from prednisone, tacrolimus, ECP, sirolimus, ibrutinib, ruxolitinib, MMF, rituximab, MTX, cyclosporine, imatinib, ixazomib, and ofatumumab.
10. Use of 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of chronic graft-versus-host disease (cGVHD) in a pregnancy-risk patient.
11. The use according to claim 10, wherein
 - a) the patient is a female patient of reproductive potential; wherein the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof is to be initiated after pregnancy status of the patient has been verified; or
 - b) wherein the patient is a male patient.
12. The use according to claim 10 or 11, wherein the patient is to use effective contraception during administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, and for at least one week after the administration of a last dose of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof.
13. The use according to claim 10 or 11, wherein the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, is the mesylate salt of 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide.

14. The use according to claim 10 or 11, wherein the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, is to be administered to the patient at a dose equivalent of 200 mg of the free base daily.
15. The use according to claim 10 or 11, wherein the patient has chronic graft-versus-host disease and has failed at least two prior lines of systemic therapy for the chronic graft-versus-host disease.
16. Use of 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of graft-versus-host disease in a female patient, wherein:
- (a) the administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof is to be initiated after the patient's pregnancy status has been verified; and
 - (b) the patient is to use contraception during the administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, and for at least one week after the administration of a last dose of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof.
17. Use of 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of graft-versus-host disease in a male patient with a female partner of reproduction potential, wherein:
- the patient is to use contraception during administration of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof, and for at least one week after the administration of a last dose of the 2-{3-[4-(1H-indazol-5-ylamino)-2-quinazolinyl]phenoxy}-N-(propan-2-yl) acetamide, or the pharmaceutically acceptable salt thereof .