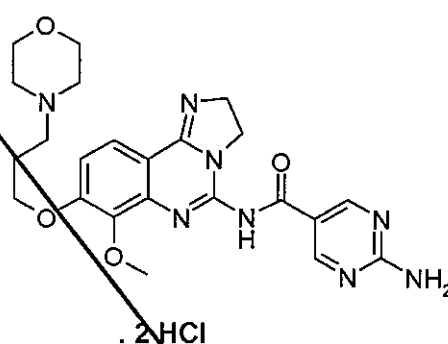


## CLAIMS

1. 2-amino-N-[7-methoxy-8-(3-morpholin-4-ylpropoxy)-2,3-dihydroimidazo[1,2-c]quinazolin-5-yl]pyrimidine-5-carboxamide dihydrochloride salt of formula

5 (II) :

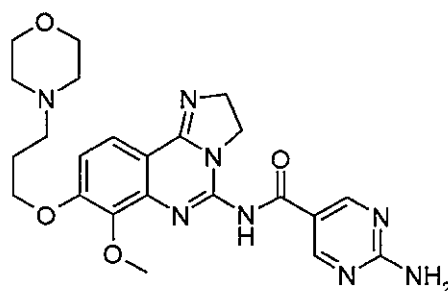


(II).

10 or a solvate, hydrate or tautomer thereof.

2. The dihydrochloride salt of formula (II) according to claim 1, which is in crystalline form.

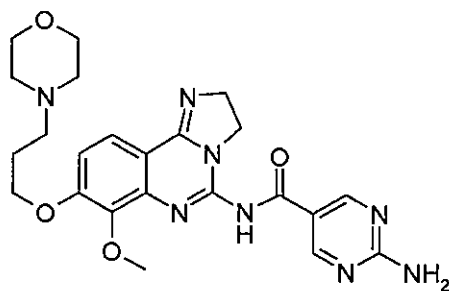
15 3. A method of preparing the dihydrochloride salt according to claim 1 or 2, said method comprising adding hydrochloric acid to a compound of formula (I) :



(I),

preferably in suspension,

thereby forming said dihydrochloride salt of formula (II) :



. 2 HCl

(II).

4. The method according to claim 3, said method comprising :

- a) adding hydrochloric acid, such as aqueous hydrochloric acid solution (32%) for example, to a suspension of said compound of formula (I) in a medium, such as water for example, at a temperature of between the freezing point of the mixture and the boiling point of the mixture, such as at a temperature of 20 °C (+2°), until a pH of 3 to 4 is reached ;
- b) stirring the resulting mixture at a temperature of between the freezing point of the mixture and the boiling point of the mixture, such as at room temperature for example, for a period of time, such as for more than 10 minutes for example ; and, optionally
- c) filtering off the resulting solid and washing the filtercake, such as with water for example, then adjusting the pH of the filtrate to pH 1.8 to 2.0 using hydrochloric acid, such as aqueous hydrochloric acid solution (32%) for example ; and, optionally,
- d) stirring the mixture for a period of time, such as 10 minutes for example, at a temperature between the freezing point and the boiling

point of the mixture, such as at room temperature for example, adding ethanol, followed by further stirring for a period of time, such as for 10 minutes for example ; and, optionally,

5 e) adding seed crystals, optionally followed by adding ethanol over a period of time such as within 5 hours for example ; and, optionally,

f) filtering off the resulting dihydrochloride of formula (II), optionally washing with a water-ethanol mixture and optionally drying, such as *in vacuo* for example,

thus providing the dihydrochloride salt according to claim 1 or 2.

10

5. The method according to claim 3, said method comprising :

a) adding said hydrochloric acid to said compound of formula (I) in acetone/water or ethanol/water for example ; and, then, optionally,

15 b) heating at a temperature between the boiling point and the freezing point of the mixture, such as at 40 to 60 °C for example, such as at 50 °C for example, for a period of time preferably of 0,2 to 2 hours for example, such as for 0,5 hours for example ; then, optionally,

20 c) heating further at a temperature between the boiling point and the freezing point of the mixture, such as at 30 to 40 °C for example, such as at 35°C for example, for a period of time such as 1 to 4 hours for example, with optional stirring of said suspension at a temperature of between the boiling point and the freezing point of the mixture, such as 10 to 45 °C for example, such as at 35°C for example, for a period of time preferably 12 to 72 hours for example, such as for 72 hours for example, optionally followed by stirring said suspension at a temperature of between the freezing point of the mixture and the boiling point of the mixture, such as at room temperature for example, for a period of time of 0 to 4 hours, such as 2 hours for example ; and, optionally,

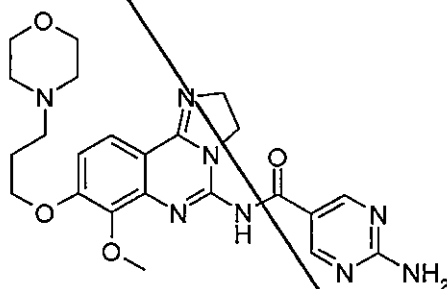
30

d) filtering, optional washing and drying,

thus providing the dihydrochloride salt according to claim 1 or 2.

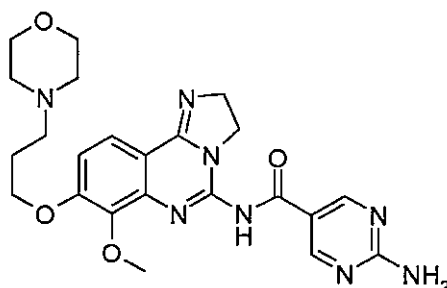
6. The method according to claim 3 or 5, wherein said hydrochloric acid is concentrated aqueous hydrochloric acid solution (36% HCl) and is added to said compound of formula (I) in an acetone / water mixture (8:2 v/v), followed by heating at a temperature of 50 °C, for a period of time of 0,5 hours, then followed by further heating, at a temperature of 35 °C, for a period of time of 72 hours, then, with stirring of said suspension at a temperature of room temperature, for a period of time of 2 hours, followed by filtration, washing with an acetone/water mixture, and drying in a vacuum oven (for example 40 °C, 100 mbar, 16 h), thus providing said dihydrochloride salt according to claim 1 or 2.

7. Use of a compound of formula (I) :



(I),

for the preparation of the dihydrochloride salt of formula (II) :



. 2 HCl

(II).

8. The dihydrochloride salt according to claim 1 or 2, for use in the treatment and/or prophylaxis of a disease.

5

9. Use of the dihydrochloride salt according to claim 1 or 2 for the preparation of a medicament for the treatment and/or prophylaxis of a disease, in particular of a hyper-proliferative and/or angiogenesis disorder, more particularly for the treatment or prophylaxis of a cancer, particularly lung cancer, in particular non-small cell lung carcinoma, colorectal cancer, melanoma, pancreatic cancer, hepatocyte carcinoma, or breast cancer.

10

10. The dihydrochloride salt according to claim 1 or 2 for use in the treatment and/or prophylaxis of a disease selected from a hyper-proliferative and/or angiogenesis disorder, more particularly for the treatment or prophylaxis of a cancer, particularly lung cancer, in particular non-small cell lung carcinoma, colorectal cancer, melanoma, pancreatic cancer, hepatocyte carcinoma, pancreatic cancer, hepatocyte carcinoma or breast cancer.

15

11. A pharmaceutical composition comprising the dihydrochloride salt according to claim 1 or 2.

20

12. A pharmaceutical composition comprising the dihydrochloride salt according to claim 1 or 2, and a further pharmaceutical agent.

25

13. A pharmaceutical combination comprising the dihydrochloride salt according to claim 1 or 2, and one or more further pharmaceutical agents.

14. The pharmaceutical combination according to claim 11, wherein said further pharmaceutical agent is selected from : <sup>131</sup>I-chTNT, abarelix, abiraterone, aclarubicin, aldesleukin, alemtuzumab, alitretinoin, altretamine,

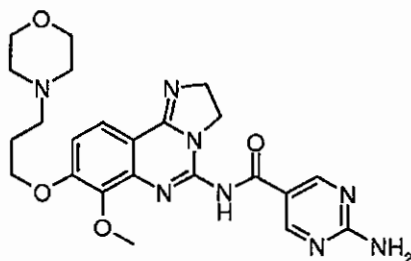
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aminoglutethimide, amrubicin, amsacrine, anastrozole, arglabin, arsenic trioxide, asparaginase, azacitidine, basiliximab, BAY 80-6946, BAY 1000394, BAY 86-9766 (RDEA 119), belotecan, bendamustine, bevacizumab, bexarotene, bicalutamide, bisantrene, bleomycin, bortezomib, buserelin, busulfan, cabazitaxel, calcium folinate, calcium levofolinate, capecitabine, carboplatin, carmofur, carmustine, catumaxomab, celecoxib, celmoleukin, cetuximab, chlorambucil, chlormadinone, chlormethine, cisplatin, cladribine, clodronic acid, clofarabine, crisantaspase, cyclophosphamide, cyproterone, cytarabine, dacarbazine, dactinomycin, darbepoetin alfa, dasatinib, daunorubicin, decitabine, degarelix, denileukin diftitox, denosumab, deslorelin, dibrospidium chloride, docetaxel, doxifluridine, doxorubicin, doxorubicin + estrone, eculizumab, edrecolomab, elliptinium acetate, eltrombopag, endostatin, enocitabine, epirubicin, epitiostanol, epoetin alfa, epoetin beta, eptaplatin, eribulin, erlotinib, estradiol, estramustine, etoposide, everolimus, exemestane, fadrozole, filgrastim, fludarabine, fluorouracil, flutamide, formestane, fotemustine, fulvestrant, gallium nitrate, ganirelix, gefitinib, gemcitabine, gemtuzumab, glutoxim, goserelin, histamine dihydrochloride, histrelin, hydroxycarbamide, I-125 seeds, ibandronic acid, ibritumomab tiuxetan, idarubicin, ifosfamide, imatinib, imiquimod, improsulfan, interferon alfa, interferon beta, interferon gamma, ipilimumab, irinotecan, ixabepilone, lanreotide, lapatinib, lenalidomide, lenograstim, lentinan, letrozole, leuprorelin, levamisole, lisuride, lobaplatin, lomustine, lonidamine, masoprocol, medroxyprogesterone, megestrol, melphalan, mepitiostane, mercaptopurine, methotrexate, methoxsalen, Methyl aminolevulinate, methyltestosterone, mifamurtide, miltefosine, miriplatin, mitobronitol, mitoguazone, mitolactol, mitomycin, mitotane, mitoxantrone, nedaplatin, nelarabine, nilotinib, nilutamide, nimotuzumab, nimustine, nitracrine, ofatumumab, omeprazole, oprelvekin, oxaliplatin, p53 gene therapy, paclitaxel, palifermin, palladium-103 seed, pamidronic acid, panitumumab, pazopanib, pegaspargase, PEG-epoetin beta (methoxy PEG-epoetin beta), pegfilgrastim, peginterferon alfa-2b, pemetrexed, pentazocine, pentostatin, peplomycin, perfosfamide, picibanil, pirarubicin, plerixafor, plicamycin,

poliglusam, polyestradiol phosphate, polysaccharide-K, porfimer sodium, pralatrexate, prednimustine, procarbazine, quinagolide, raloxifene, raltitrexed, ranimustine, razoxane, regorafenib, risedronic acid, rituximab, romidepsin, romiplostim, sargramostim, sipuleucel-T, sizofiran, sobuzoxane, sodium glycididazole, sorafenib, streptozocin, sunitinib, talaporfin, tamibarotene, tamoxifen, tasonermin, teceleukin, tegafur, tegafur + gimeracil + oteracil, temoporfin, temozolomide, temsirolimus, teniposide, testosterone, tetrofosmin, thalidomide, thiotepa, thymalfasin, tioguanine, tocilizumab, topotecan, toremifene, tositumomab, trabectedin, trastuzumab, treosulfan, tretinoin, trilostane, triptorelin, trofosfamide, tryptophan, ubenimex, valrubicin, vandetanib, vaporeotide, vemurafenib, vinblastine, vincristine, vindesine, vinflunine, vinorelbine, vorinostat, vorozole, yttrium-90 glass microspheres, zinostatin, zinostatin stimalamer, zoledronic acid, zorubicin.

## CLAIMS

1. 2-amino-N-[7-methoxy-8-(3-morpholin-4-ylpropoxy)-2,3-dihydroimidazo[1,2-c]quinazolin-5-yl]pyrimidine-5-carboxamide dihydrochloride salt of formula  
5 (II) :



. 2 HCl

(II),

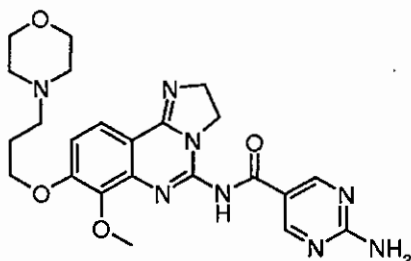
10

or a solvate, hydrate or tautomer thereof.

2. The dihydrochloride salt of formula (II) according to claim 1, which is in crystalline form.

15

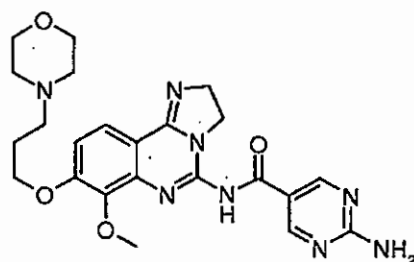
3. A method of preparing the dihydrochloride salt according to claim 1 or 2, said method comprising adding hydrochloric acid to a compound of formula  
(I) :



(I),

preferably in suspension,

thereby forming said dihydrochloride salt of formula (II) :



. 2 HCl

(II).

4. The method according to claim 3, said method comprising :

- a) adding hydrochloric acid, such as aqueous hydrochloric acid solution (32%) for example, to a suspension of said compound of formula (I) in a medium, such as water for example, at a temperature of between the freezing point of the mixture and the boiling point of the mixture, such as at a temperature of 20 °C (+/-2°), until a pH of 3 to 4 is reached ;
- b) stirring the resulting mixture at a temperature of between the freezing point of the mixture and the boiling point of the mixture, such as at room temperature for example, for a period of time, such as for more than 10 minutes for example ; and, optionally
- c) filtering off the resulting solid and washing the filtercake, such as with water for example, then adjusting the pH of the filtrate to pH 1.8 to 2.0 using hydrochloric acid, such as aqueous hydrochloric acid solution (32%) for example ; and, optionally,
- d) stirring the mixture for a period of time, such as 10 minutes for example, at a temperature between the freezing point and the boiling

point of the mixture, such as at room temperature for example, adding ethanol, followed by further stirring for a period of time, such as for 10 minutes for example ; and, optionally,

e) adding seed crystals, optionally followed by adding ethanol over a period of time such as within 5 hours for example ; and, optionally,

f) filtering off the resulting dihydrochloride of formula (II), optionally washing with a water-ethanol mixture and optionally drying, such as *in vacuo* for example,

thus providing the dihydrochloride salt according to claim 1 or 2.

5. The method according to claim 3, said method comprising :

a) adding said hydrochloric acid to said compound of formula (I) in acetone/water or ethanol/water for example ; and, then, optionally,

b) heating at a temperature between the boiling point and the freezing point of the mixture, such as at 40 to 60 °C for example, such as at 50 °C for example, for a period of time preferably of 0,2 to 2 hours for example, such as for 0,5 hours for example ; then, optionally,

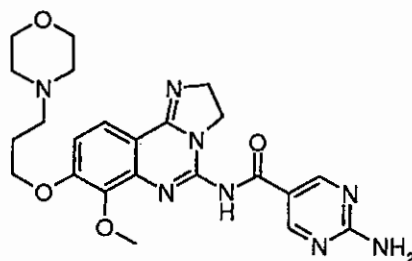
c) heating further at a temperature between the boiling point and the freezing point of the mixture, such as at 30 to 40 °C for example, such as at 35°C for example, for a period of time such as 1 to 4 hours for example, with optional stirring of said suspension at a temperature of between the boiling point and the freezing point of the mixture, such as 10 to 45 °C for example, such as at 35°C for example, for a period of time preferably 12 to 72 hours for example, such as for 72 hours for example, optionally followed by stirring said suspension at a temperature of between the freezing point of the mixture and the boiling point of the mixture, such as at room temperature for example, for a period of time of 0 to 4 hours, such as 2 hours for example ; and, optionally,

d) filtering, optional washing and drying,

thus providing the dihydrochloride salt according to claim 1 or 2.

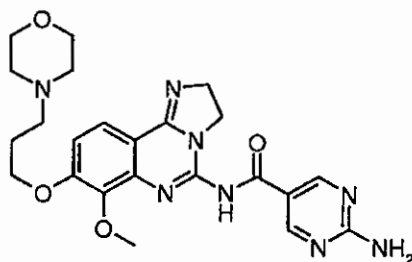
6. The method according to claim 3 or 5, wherein said hydrochloric acid is concentrated aqueous hydrochloric acid solution (36% HCl) and is added to said compound of formula (I) in an acetone / water mixture (8:2 v/v), followed by heating at a temperature of 50 °C, for a period of time of 0,5 hours, then followed by further heating, at a temperature of 35 °C, for a period of time of 72 hours, then with stirring of said suspension at a temperature of room temperature, for a period of time of 2 hours, followed by filtration, washing with an acetone/water mixture, and drying in a vacuum oven (for example 40 °C, 100 mbar, 16 h), thus providing said dihydrochloride salt according to claim 1 or 2.

7. Use of a compound of formula (I) :



(I),

for the preparation of the dihydrochloride salt of formula (II) :



. 2 HCl

70

(II).

8. The dihydrochloride salt according to claim 1 or 2, for the treatment and/or prophylaxis of a disease.

5

9. Use of the dihydrochloride salt according to claim 1 or 2 for the preparation of a medicament for the treatment and/or prophylaxis of a disease, in particular of a hyper-proliferative and/or angiogenesis disorder, more particularly for the treatment or prophylaxis of a cancer, particularly lung cancer, in particular non-small cell lung carcinoma, colorectal cancer, melanoma, pancreatic cancer, hepatocyte carcinoma, or breast cancer.

10

10. Use of the dihydrochloride salt according to claim 9, wherein said cancer is a lymphoma.

15

11. Use of the dihydrochloride salt according to claim 10, wherein said lymphoma is selected from AIDS-related lymphoma, non-Hodgkin's lymphoma, cutaneous T-cell lymphoma, Burkitt lymphoma, Hodgkin's disease, and lymphoma of the central nervous system.

20

12. Use of the dihydrochloride salt according to claim 10 or 11, wherein said lymphoma is non-Hodgkin's lymphoma.

13. A pharmaceutical composition comprising the dihydrochloride salt according to claim 1 or 2.

25

14. A pharmaceutical composition comprising the dihydrochloride salt according to claim 1 or 2, and a further pharmaceutical agent.

30

15. A pharmaceutical combination comprising the dihydrochloride salt according to claim 1 or 2, and one or more further pharmaceutical agents.

16. The pharmaceutical combination according to claim 15, wherein said  
5 further pharmaceutical agent is selected from: 131I-chTNT, abarelix, abiraterone, aclarubicin, aldesleukin, alemtuzumab, alitretinoin, altretamine, aminoglutethimide, amrubicin, amsacrine, anastrozole, arglabin, arsenic trioxide, asparaginase, azacitidine, basiliximab, BAY 80-6946, BAY 1000394, BAY 86-9766 (RDEA 119), belotecan, bendamustine, bevacizumab, bexarotene,  
10 bicalutamide, bisantrene, bleomycin, bortezomib, buserelin, busulfan, cabazitaxel, calcium folinate, calcium levofolinate, capecitabine, carboplatin, carmofur, carmustine, catumaxomab, celecoxib, celmoleukin, cetuximab, chlorambucil, chlormadinone, chlormethine, cisplatin, cladribine, clodronic acid, clofarabine, crisantaspase, cyclophosphamide, cyproterone, cytarabine,  
15 dacarbazine, dactinomycin, darbepoetin alfa, dasatinib, daunorubicin, decitabine, degarelix, denileukin diftitox, denosumab, deslorelin, dibrospidium chloride, docetaxel, doxifluridine, doxorubicin, doxorubicin + estrone, eculizumab, edrecolomab, elliptinium acetate, eltrombopag, endostatin, enocitabine, epirubicin, epitio stanol, epoetin alfa, epoetin beta, eptaplatin,  
20 eribulin, erlotinib, estradiol, estramustine, etoposide, everolimus, exemestane, fadrozole, filgrastim, fludarabine, fluorouracil, flutamide, formestane, fotemustine, fulvestrant, gallium nitrate, ganirelix, gefitinib, gemcitabine, gemtuzumab, glutoxim, goserelin, histamine dihydrochloride, histrelin, hydroxycarbamide, I-125 seeds, ibandronic acid, ibritumomab  
25 tiuxetan, idarubicin, ifosfamide, imatinib, imiquimod, improsulfan, interferon alfa, interferon beta, interferon gamma, ipilimumab, irinotecan, ixabepilone, lanreotide, lapatinib, lenalidomide, lenograstim, lentinan, letrozole, leuporelin, levamisole, lisuride, lobaplatin, lomustine, lonidamine, masoproc ol, medroxyprogesterone, megestrol, melphalan, mepitiostane,  
30 mercaptopurine, methotrexate, methoxsalen, Methyl aminolevulinate, methyltestosterone, mifamurtide, miltefosine, miriplatin, mitobronitol, mitoguazone, mitolactol, mitomycin, mitotane, mitoxantrone, nedaplatin,

nelarabine, nilotinib, nilutamide, nimotuzumab, nimustine, nitracrine, ofatumumab, omeprazole, oprelvekin, oxaliplatin, p53 gene therapy, paclitaxel, palifermin, palladium-103 seed, pamidronic acid, panitumumab, pazopanib, pegaspargase, PEG-epoetin beta (methoxy PEG-epoetin beta),  
5 pegfilgrastim, peginterferon alfa-2b, pemetrexed, pentazocine, pentostatin, peplomycin, perfosfamide, picibanil, pirarubicin, plerixafor, plicamycin, poliglusam, polyestradiol phosphate, polysaccharide-K, porfimer sodium, pralatrexate, prednimustine, procarbazine, quinagolide, raloxifene, raltitrexed, ranimustine, razoxane, regorafenib, risedronic acid, rituximab,  
10 romidepsin, romiplostim, sargramostim, sipuleucel-T, sizofiran, sobuzoxane, sodium glycididazole, sorafenib, streptozocin, sunitinib, talaporfin, tamibarotene, tamoxifen, tasonermin, teceleukin, tegafur, tegafur + gimeracil + oteracil, temoporfin, temozolomide, temsirolimus, teniposide, testosterone, tetrofosmin, thalidomide, thiotepa, thymalfasin, tioguanine, tocilizumab,  
15 toptecan, toremifene, tositumomab, trabectedin, trastuzumab, treosulfan, tretinoin, trilostane, triptorelin, trofosfamide, tryptophan, ubenimex, valrubicin, vandetanib, vaporeotide, vemurafenib, vinblastine, vincristine, vindesine, vinflunine, vinorelbine, vorinostat, vorozole, yttrium-90 glass microspheres, zinostatin, zinostatin stimalamer, zoledronic acid, zorubicin.

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