in the treatment of a solid tumor cancer, wherein said compound or a pharmaceutically acceptable salt or hydrate thereof is administered:

a) at a loading dose of at least one dose and up to 12 doses at 75-150 mg/dose are administered twice or three times per week during a 28 day cycle; followed by

b) a maintenance dose of 50 mg/dose administered three times per week; and optionally

c) administering, during administration of the loading dose, 1-50 mg/day of a corticosteroid.

In one example, there is provided a compound 4,4,4-Trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof, for use in the treatment of a solid tumor cancer , wherein said compound or the pharmaceutically acceptable salt or hydrate thereof is to be administered:

a. at a loading dose of at least one dose and up to 12 doses at 75-150 mg/dose twice or three times per week for at least one week during a 28 day cycle; followed by

b. a maintenance dose of 50 mg/dose three times per week.

Disclosed is the use of 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof, for preparation of a medicament for treating a solid tumor cancer wherein said medicament is administered:

a) at a loading dose of at least one dose and up to 12 doses at 75-150 mg/dose administered twice or three times per week during a 28 day cycle; followed by

b) a maintenance dose of 50 mg/dose administered three times per week; and optionally

c) administering, during administration of the loading dose, 1-50 mg/day of a corticosteroid.

In one aspect, the present disclosure refers to use of 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof, in the manufacture of a medicament for the treatment of a solid tumor cancer, wherein said medicament is to be administered:

a) at a loading dose of at least one dose and up to 12 doses at 75-150 mg/dose twice or three times per week for at least one week during a 28 day cycle; followed by

b) a maintenance dose of 50 mg/dose three times per week.

Disclosed is a method of treating a solid tumor cancer comprising administering to a patient in need of treatment 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof,

a) a loading dose of at least one dose and up to 12 doses at 75-150 mg/dose administered twice or three times per week during a 28 day cycle; followed by

b) a maintenance dose of 50 mg/dose administered three times per week; and optionally

c) administering, during administration of the loading dose, 1-50 mg/day of a corticosteroid;

WE CLAIM:

1. Use of 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof, in the manufacture of a medicament for the treatment of a solid tumor cancer, wherein said medicament is to be administered:
    a) at a loading dose of at least one dose and up to 12 doses at 75-150 mg/dose twice or three times per week for at least one week during a 28 day cycle; followed by
    b) a maintenance dose of 50 mg/dose three times per week.
2. The use of claim 1, wherein, during the administration of the loading dose, 1-80 mg/day of a corticosteroid is to be administered for one or more days of the 28 day cycle.
3. The use of claim 2, wherein the corticosteroid is to be administered at a dose of 1-50 mg/day.
4. The use of claim 2 or claim 3, wherein the corticosteroid is to be administered at a dose of 20 mg/day.
5. The use of any of claims 2-4, wherein the corticosteroid is to be administered for at least 14 days of the 28 day cycle.
6. The use of any of claims 2-5, wherein the corticosteroid is selected from the group consisting of hydrocortisone, hydrocortisone acetate, cortisone acetate, tixocortol pivalate, prednisolone, methylprednisolone, and prednisone.
7. The use of any of claims 1-6, wherein said loading dose is at least one dose and up to 6 doses.
8. The use of any of claims 1-6, wherein said loading dose is at least one dose and up to 3 doses.
9. The use of any of claims 1-8, wherein the maintenance dose is to be administered over any remaining days of the 28 day cycle following administration of the loading dose and, optionally, over one or more additional 28 day cycles.
10. The use of any of claims 1-9, wherein said solid tumor cancer is selected from the group consisting of triple negative breast cancer, breast cancer, ovarian cancer,

melanoma, lung cancer, non-small cell lung cancer, pancreatic cancer, glioblastoma, colorectal cancer, head and neck cancer, cervical cancer, prostate cancer, liver cancer, oral squamous cell carcinoma, skin cancer, medulloblastoma, hepatocellular carcinoma, intrahepatic and extrahepatic cholangiocarcinoma, desmoid tumor, soft tissue sarcoma, leiomyosarcoma, and adenoid cystic carcinoma.