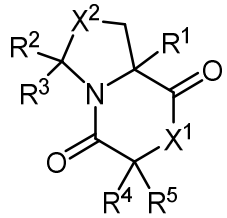
Claims

1. Use of a compound of Formulas I, II, III or IV, or a pharmaceutically acceptable salt, hydrate, stereoisomer, or prodrug thereof:



Formula I;

wherein:

X^1 is selected from the group consisting of NR', O, and S;

X^2 is selected from the group consisting of CH_2, NR', O, and S;

R^1, R^2, R^3, R^4, and R^5 are independently selected from the group consisting of hydrogen, halogen, -OR', -SR', -NR'R', $-NO_2$, -CN, -C(O)R', -C(O)OR', -C(O)NR'R', -C(NR')NR'R', alkyl, heteroalkyl, alkenyl, alkynyl, 3-10-membered carbocycle, and 3-10-membered heterocycle,

wherein each alkyl, heteroalkyl, alkenyl, alkynyl, 3-10-membered carbocycle, and 3-10-membered heterocycle is unsubstituted or substituted with one or more substituents selected from the group consisting of halogen, -OR', -SR', -NR'R', $-NO_2$, -CN, -C(O)R', -C(O)OR', -C(O)NR'R', -C(NR')NR'R', alkyl, heteroalkyl, alkenyl, and alkynyl;

wherein each R' is independently selected from the group consisting of hydrogen, alkyl, heteroalkyl, alkenyl, alkynyl, 3-10-membered carbocycle, and 3-10-membered heterocycle;

or R^4 and R^5 taken together are $-CH_2-(CH_2)_n-CH_2-$ where n is an integer from 0-6;

or R^2 and R^3 taken together are $-CH_2-(CH_2)_n-CH_2-$ where n is an integer from 0-6;

with the proviso that when R^1 is CH_3, R^2 is hydrogen, R^3 is hydrogen, and R^4 is hydrogen, then R^5 is not benzyl; and when R^1 is hydrogen, then at least one of R^2 and R^3 is not hydrogen;

in the manufacture of a medicament for the treatment of Prader-Willi Syndrome in a subject.

2. The use of claim 1, wherein R^1 is selected from the group consisting of hydrogen, $-CH_3$, and $-CH_2CHCH_2$.

3. The use of claim 1 or claim 2, wherein R^2 is selected from the group consisting of hydrogen and $-CH_3$.

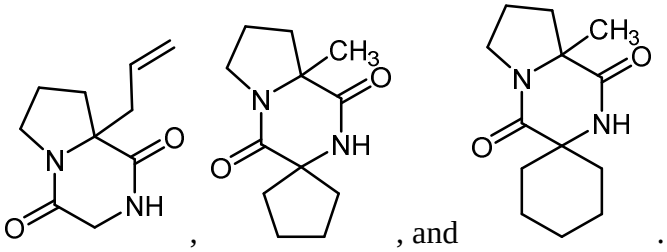
4. The use of any one of claims 1 to 3, wherein R^3 is selected from the group consisting of hydrogen and $-CH_3$.

5. The use of any one of claims 1 to 4, wherein X^1 is NH.

6. The use of any one of claims 1 to 5, wherein X^2 is selected from the group consisting of CH_2 and S.

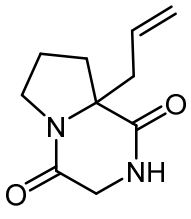
7. The use of any one of claims 1 to 6, wherein R^4 and R^5 are each hydrogen, or taken together are selected from the group consisting of $-CH_2-(CH_2)_3-CH_2-$ and $-CH_2-(CH_2)_2-CH_2-$.

8. The use of any one of claims 1 to 7, wherein the compound of Formula I is selected from the group consisting of:



Formula II Formula III Formula IV

9. The use of any one of claims 1 to 8, wherein the compound of Formula I is:



Formula II.

10. The use of any one of claims 1 to 9, wherein the treatment comprises preventing or reducing the likelihood or severity of one or more symptoms of Prader-Willi Syndrome.

11. The use of claim 10, wherein the symptom associated with Prader-Willi Syndrome is selected from the group consisting of early failure to thrive, excessive appetite (hyperphagia),

obesity, type 2 diabetes, elevated blood insulin, metabolic syndrome, multiple endocrine abnormalities, hypotonia, hypogonadism, sleep disturbances, sleep apnoea, speech disorders, reduced pain sensitivity, poor bone health, strabismus, depigmentation, decreased gastrointestinal motility, scoliosis, adrenal insufficiencies, seizures, hypothyroidism, hypoglycaemia, hypogonadotropic hypogonadism, distinctive facial features, mild to moderate intellectual and learning disabilities, cognitive impairment, neurobehavioural disorders, intellectual disability, cognitive rigidity, heightened anxiety, severe temper outbursts, obsessive-compulsive behaviours, self-injurious behaviours, mental illness, autistic symptomatology, and growth hormone deficiency (GHD).

12. The use of any one of claims 1 to 11, wherein the medicament is formulated for administration in combination with a therapeutic agent.

13. The use of claim 12, wherein the therapeutic agent is selected from the group consisting of recombinant human growth hormone (rhGH), human growth hormone, recombinant human IGF-1 (rhIGF-1), IGF-1, IGF-2, any IGF Binding Protein (IGFBP), IGFBP-3, insulin, any statin, any appetite suppressant, transforming growth factor-β1, activin, nerve growth factor, growth hormone binding protein, basic fibroblast growth factor, acidic fibroblast growth factor, the hst/Kfgk gene product, FGF-3, FGF-4, FGF-6, keratinocyte growth factor, androgen-induced growth factor, int-2, fibroblast growth factor, homologous factor-1 (FHF-1), FHF-2, FHF-3, FHF-4, keratinocyte growth factor 2, glial activating factor, FGF-10, FGF-16, ciliary neurotrophic factor, brain derived nerve growth factor, neurotrophin 3, neurotrophin 4, bone morphogenetic protein 2 (BMP-2), glial-cell line derived neurotrophic factor, activity-dependant neurotrophic factor, cytokine leukaemia inhibiting factor, oncostatin M, an interleukin, a-interferon, β-interferon, γ-interferon, consensus interferon, TNF-a, clomethiazole; kynurenic acid, Semax, tacrolimus, L-threo-1-phenyl-2-decanoylamino3, 3-morpholino-1-propanol, adrenocorticotropin-(4-9) analogue (ORG 2766), dizolcipine [MK-801], selegiline, NPS1506, GV1505260, MK-801, GV150526, 2,3-dihydroxy-6-nitro-7-sulfamoylbenzo(f)quinoxaline (NBQX), LY303070, LY300164, and the anti-MAdCAM-1 antibody MECA-367.

14. The use of any one of claims 1 to 13, wherein the medicament is formulated for oral administration.

15. The use of any one of claims 1 to 14, wherein the medicament is formulated as an aqueous solution.

16. The use of any one of claims 1 to 15, wherein the medicament is formulated for administration in a dosage of from about 0.001 mg/kg to and including about 600 mg/kg.

17. The use of claim 15 or claim 16, wherein the medicament is formulated as an oral solution or an oral suspension.

18. The use of any one of claims 1 to 17, wherein the medicament is formulated in the form of a pharmaceutical composition comprising a pharmaceutically acceptable excipient.

19. The use of any one of claims 1 to 18, wherein said compound is cG-2-AllylP (Formula II), or Cyclic Cyclopentyl-G-2-MeP (Formula III), or Cyclic Cyclohexyl-G-2-MeP (Formula IV).

20. The use of any one of claims 1 to 19, wherein the subject is a human.