

CLAIMS

1. A pharmaceutical composition, wherein the pharmaceutical composition comprises a therapeutically active component comprising an intranasally bioavailable CGRP inhibitor.
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2. The pharmaceutical composition according to Claim 1, wherein the intranasally bioavailable CGRP inhibitor is a CGRP antibody, a CGRP receptor antibody, an antigen-binding fragment from a CGRP antibody or a CGRP receptor antibody, a CGRP infusion inhibitory protein, a CGRP bio-neutralizing agent, a small molecule CGRP receptor antagonist, a small molecule CGRP inhibitor, or a polypeptide CGRP inhibitor.
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3. The pharmaceutical composition according to Claim 2, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.
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4. The pharmaceutical composition according to any one of Claims 1 to 3, wherein the pharmaceutical composition further comprises a pharmaceutically acceptable solubilizing agent in an amount effective to solubilize the therapeutically active component.
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5. The pharmaceutical composition according to Claim 4, wherein the solubilizing agent is water, an alcohol, or a combination thereof.
6. The pharmaceutical composition according to Claim 4 or 5, wherein the solubilizing agent is water.
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7. The pharmaceutical composition according to any one of Claims 4 to 6, wherein the pharmaceutical composition further comprises a receptivity agent capable of mitigating an undesirable response to the pharmaceutical composition at or in proximity to the locus of administration in or on the subject.
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8. The pharmaceutical composition according to Claim 7, wherein the receptivity agent is an organoleptic enhancing agent comprising a natural sweetener, a synthetic sweetener, a flavorant, an aromatic compound, a taste-masking compound, or combinations thereof.

5 9. An apparatus comprising: (a) a reservoir comprising a sprayable liquid composition comprising a therapeutically active component comprising an intranasally bioavailable CGRP inhibitor, (b) an atomization device configured for insertion in a nostril, and (c) means for actuating the device to deliver droplets of the composition to the nostril.

10 10. The apparatus according to Claim 9, wherein the intranasally bioavailable CGRP inhibitor is a CGRP antibody, a CGRP receptor antibody, an antigen-binding fragment from a CGRP antibody or a CGRP receptor antibody, a CGRP infusion inhibitory protein, a CGRP bio-neutralizing agent, a small molecule CGRP receptor antagonist, a small molecule CGRP inhibitor, or a polypeptide CGRP inhibitor.

15 11. The apparatus according to Claim 10, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

20 12. The apparatus according to any one of Claims 8 or 9, wherein the apparatus is a unidose apparatus, a bi-dose apparatus, or a multi-dose apparatus.

25 13. A method for delivering a CGRP inhibitor to a subject, the method comprising intranasally administering to the subject a composition comprising a therapeutically active component comprising a CGRP inhibitor.

30 14. The method according to Claim 13, wherein the CGRP inhibitor is a CGRP antibody, a CGRP receptor antibody, an antigen-binding fragment from a CGRP antibody or a CGRP receptor antibody, a CGRP infusion inhibitory protein, a CGRP bio-neutralizing agent, a small molecule CGRP receptor antagonist, a small molecule CGRP inhibitor, or a polypeptide CGRP inhibitor.

15. The method according to Claim 14, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

16. The method according to Claim 15, wherein the intranasal administration of
5 zavegepant at 10 mg as a single dose results in at least 22.5% pain freedom in the subject.

17. The method according to Claim 15, wherein the intranasal administration of zavegepant at 20 mg as a single dose results in at least 23.1% pain freedom in the subject.

10 18. The method according to Claim 15, wherein the intranasal administration of zavegepant at 10 mg as a single dose results in at least 41.9% freedom from a most bothersome symptom of photophobia, phonophobia, or nausea in the subject.

19. The method according to Claim 15, wherein the intranasal administration of
15 zavegepant at 10 mg as a single dose results in at least 42.5% freedom from a most bothersome symptom of photophobia, phonophobia, or nausea in the subject.

20. The method according to Claim 15, wherein the intranasal administration of zavegepant at 10 mg or 20 mg is statistically superior to placebo on the co-primary endpoints of
20 pain freedom and freedom from most bothersome symptom comprising photophobia, phonophobia, or nausea at 2 hours using a single dose.

21. The method according to Claim 15, wherein the intranasal administration of zavegepant at 5 mg, 10 mg, or 20 mg results in sustained pain freedom 2 to 48 hours after the
25 dosing.

22. The method according to Claim 15, wherein the intranasal administration of zavegepant at 5 mg, 10 mg, or 20 mg results in sustained pain freedom 2 to 24 hours after the
30 dosing.

23. The method according to Claim 15, wherein the intranasal administration of zavegepant at 5 mg, 10 mg, or 20 mg results in sustained pain relief 2 to 24 hours after the dosing.

5 24. The method according to Claim 15, wherein the intranasal administration of zavegepant at 5 mg or 10 mg results in sustained pain relief 2 to 48 hours after the dosing.

25. A method for treatment or prevention of a condition associated with aberrant levels of CGRP in a subject in need thereof, wherein the method comprises intranasally
10 administering to the subject a therapeutically effective amount of a composition comprising a therapeutically active component comprising a CGRP inhibitor.

26. The method according to Claim 25, wherein the CGRP inhibitor is a CGRP antibody, a CGRP receptor antibody, an antigen-binding fragment from a CGRP antibody or a
15 CGRP receptor antibody, a CGRP infusion inhibitory protein, a CGRP bio-neutralizing agent, a small molecule CGRP receptor antagonist, a small molecule CGRP inhibitor, or a polypeptide CGRP inhibitor.

27. The method according to Claim 26, wherein the small molecule CGRP receptor
20 antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

28. The method according to any one of Claims 25 to 27, wherein the condition is a disorder selected from acute migraine, chronic migraine, cluster headache, chronic tension type headache, medication overuse headache, post-traumatic headache, post-concussion syndrome,
25 brain trauma, and vertigo.

29. The method according to any one of Claims 25 to 27, wherein the condition is a disorder selected from chronic pain, neurogenic vasodilation, neurogenic inflammation, inflammatory pain, neuropathic pain, diabetic peripheral neuropathic pain, small fiber
30 neuropathic pain, Morton's neuroma, chronic knee pain, chronic back pain, chronic hip pain, chronic finger pain, exercise-induced muscle pain, cancer pain, chronic inflammatory skin pain,

pain from burns, pain from scars, complex regional pain syndrome, burning mouth syndrome, alcoholic polyneuropathy, chronic inflammatory demyelinating polyradiculoneuropathy, human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)-associated neuropathy, drug-induced neuropathy, industrial neuropathy, lymphomatous neuropathy, myelomatous neuropathy, multi-focal motor neuropathy, chronic idiopathic sensory neuropathy, carcinomatous, neuropathy, acute pain autonomic neuropathy, compressive neuropathy, vasculitic/ischaemic neuropathy, tempero-mandibular joint pain, post-herpetic neuralgia, trigeminal neuralgia, chronic regional pain syndrome, eye pain, and tooth pain.

10 30. The method according to any one of Claims 25 to 27, wherein the condition is a disorder selected from non-insulin dependent diabetes mellitus, vascular disorders, inflammation, arthritis, thermal injury, circulatory shock, sepsis, alcohol withdrawal syndrome, opiate withdrawal syndrome, morphine tolerance, hot flashes in men and women, flushing associated with menopause, allergic dermatitis, psoriasis, encephalitis, ischaemia, stroke, epilepsy, 15 neuroinflammatory disorders, neurodegenerative diseases, skin diseases, neurogenic cutaneous redness, skin rosaceousness, erythema, tinnitus, obesity, inflammatory bowel disease, irritable bowel syndrome, vulvodynia, polycystic ovarian syndrome, uterine fibroids, neurofibromatosis, hepatic fibrosis, renal fibrosis, focal segmental glomerulosclerosis, glomerulonephritis, IgA nephropathy, multiple myeloma, myasthenia gravis, Sjogren's syndrome, osteoarthritis, 20 osteoarthritic degenerative disc disease, temporomandibular joint disorder, whiplash injury, rheumatoid arthritis, and interstitial cystitis.

 31. The method according to Claim 30, wherein the skin disease are selected from recurrent herpes, contact hypersensitivity, prurigo nodularis, chronic pruritus, and uremic 25 pruritus.

 32. The method according to any one of Claims 25 to 27, wherein the condition is a disorder selected from chronic obstructive pulmonary disease, pulmonary fibrosis, bronchial hyperreactivity, asthma, cystic fibrosis, chronic idiopathic cough, and a toxic injury.

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33. The method according to Claim 32 wherein the toxic injury is selected from chlorine gas injury, mustard gas injury, acrolein injury, smoke injury, ozone injury, warfare chemical exposure, and industrial chemical exposure.

5 34. A kit for treating a condition associated with aberrant levels of CGRP in a patient, the kit comprising:

- (a) a pharmaceutical composition of any one of Claims 1 to 8; and
- (b) instructions for administering the pharmaceutical composition.

10 35. The kit according to Claim 34, further comprising an apparatus for administering the pharmaceutical composition.

36. A method for treatment of medication overuse headache, wherein the method comprises intranasally administering to the subject a therapeutically effective amount of a
15 composition comprising a therapeutically active component comprising a CGRP inhibitor.

37. The method according to Claim 36, wherein the CGRP inhibitor is a CGRP antibody, a CGRP receptor antibody, an antigen-binding fragment from a CGRP antibody or a CGRP receptor antibody, a CGRP infusion inhibitory protein, a CGRP bio-neutralizing agent, a
20 small molecule CGRP receptor antagonist, a small molecule CGRP inhibitor, or a polypeptide CGRP inhibitor.

38. The method according to Claim 37, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

25 39. A method for treatment of post-traumatic headache, wherein the method comprises intranasally administering to the subject a therapeutically effective amount of a composition comprising a therapeutically active component comprising a CGRP inhibitor.

30 40. The method according to Claim 39, wherein the CGRP inhibitor is a CGRP antibody, a CGRP receptor antibody, an antigen-binding fragment from a CGRP antibody or a

CGRP receptor antibody, a CGRP infusion inhibitory protein, a CGRP bio-neutralizing agent, a small molecule CGRP receptor antagonist, a small molecule CGRP inhibitor, or a polypeptide CGRP inhibitor.

5 41. The method according to Claim 40, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

 42. A method for treatment of post-concussion syndrome, wherein the method comprises intranasally administering to the subject a therapeutically effective amount of a
10 composition comprising a therapeutically active component comprising a CGRP inhibitor.

 43. The method according to Claim 42, wherein the CGRP inhibitor is a CGRP antibody, a CGRP receptor antibody, an antigen-binding fragment from a CGRP antibody or a CGRP receptor antibody, a CGRP infusion inhibitory protein, a CGRP bio-neutralizing agent, a
15 small molecule CGRP receptor antagonist, a small molecule CGRP inhibitor, or a polypeptide CGRP inhibitor.

 44. The method according to Claim 43, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.
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 45. A method for treatment of vertigo, wherein the method comprises intranasally administering to the subject a therapeutically effective amount of a composition comprising a therapeutically active component comprising a CGRP inhibitor.

25 46. The method according to Claim 45, wherein the CGRP inhibitor is a CGRP antibody, a CGRP receptor antibody, an antigen-binding fragment from a CGRP antibody or a CGRP receptor antibody, a CGRP infusion inhibitory protein, a CGRP bio-neutralizing agent, a small molecule CGRP receptor antagonist, a small molecule CGRP inhibitor, or a polypeptide CGRP inhibitor.

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47. The method according to Claim 46, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.