

What is claimed is:

1. Use of a formulation comprising a therapeutically effective amount of an antibody that binds specifically to nerve growth factor (NGF) or an antigen binding fragment thereof in the manufacture of a medicament for averting opioid addiction in a patient suffering from moderate to severe low back pain (LBP), wherein

the antibody or antigen-binding fragment comprises three heavy chain complementarity determining region (HCDR) sequences (HCDR1, HCDR2, HCDR3) comprising SEQ ID NOs: 4, 6 and 8, respectively, and three light chain complementarity determining (LCDR) sequences (LCDR1, LCDR2, LCDR3) comprising SEQ ID NOs: 12, 14 and 16, respectively.

2. The use of claim 1, wherein the antibody or antigen-binding fragment comprises a heavy chain variable region (HCVR)/light chain variable region (LCVR) amino acid sequence pair of SEQ ID NOs: 2/10.

3. The use of claim 1, wherein the patient is further diagnosed to have non-radicular back pain, and a history of inadequate pain relief from, or is resistant, inadequately responsive, or intolerant to standard analgesic therapy.

4. The use of claim 1, wherein the patient is further diagnosed to have a history of opioid addiction.

5. The use of claim 1, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 1-20 mg at a frequency of about every 4 weeks (Q4W).

6. The use of claim 1, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 1 mg at a frequency of about every 8 weeks (Q8W).

7. The use of claim 1, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 3 mg at a frequency of about every 4 weeks (Q4W).

8. The use of claim 1, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 6 mg at a frequency of about every 4 weeks (Q4W).

9. The use of claim 1, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 9 mg at a frequency of about every 4 weeks (Q4W).

10. The use of claim 1, wherein it is to be determined if it is inadvisable to treat the patient with standard analgesic therapy due to safety and health risks to the patient and/or coupled with suboptimal efficacy.

11. The use of claim 10, wherein the standard analgesic therapy is inadvisable for administration to the patient due to a condition selected from the group consisting of medical contraindications, hypersensitivity to standard analgesic therapy, or excipients, use of a concomitant medication prohibited with standard analgesic therapy, increased risk of kidney damage, increased risk of liver damage, increased risk of gastrointestinal bleeding, increased risk of an allergic reaction and increased risk of developing drug dependence.

12. The use of claim 1, wherein the opioid is selected from the group consisting of hydrocodone, oxycodone, percocet, morphine, meperidine, hydromorphone, fentanyl, and methadone.

13. The use of claim 1, wherein the antibody or antigen-binding fragment is to be administered subcutaneously (SC), or intravenously (IV), and wherein the antibody is fasinumab.

14. Use of a formulation comprising an NGF antibody that specifically binds NGF, or an antigen binding fragment thereof in the manufacture of a medicament for improving a pain-associated parameter in a patient suffering from moderate to severe low back pain (LBP),

wherein

a patient is selected on the basis of exhibiting a history of inadequate pain relief, or intolerance to standard analgesic therapy, and/or when standard analgesic therapy is inadvisable;

the patient is to be administered with a single initial dose of the formulation, followed
5 by one or more secondary doses of the formulation, wherein the antibody or antigen-binding fragment comprises three heavy chain complementarity determining region (HCDR) sequences (HCDR1, HCDR2, HCDR3) comprising SEQ ID NOs: 4, 6 and 8, respectively, and three light chain complementarity determining (LCDR) sequences (LCDR1, LCDR2, LCDR3) comprising
10 SEQ ID NOs: 12, 14 and 16, respectively,

wherein the pain-associated parameter is selected from the group consisting of: (a) a change from baseline at week 16 in the average daily Low Back Pain Intensity (LBPI) Numerical Rating Scale (NRS) score; (b) a change from baseline at week 16 in the Roland Morris Disability Questionnaire (RMDQ) total score; (c) a change from baseline at week 16 in the Patient Global Assessment (PGA) of Low Back Pain (LBP) score; and (d) a change from baseline at week 2, 4,
15 8 and 12 in the average daily LBPI NRS score.

15. The use of claim 14, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 1-20 mg at a frequency of about every 4 weeks (Q4W).

16. The use of claim 14, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 1 mg at a frequency of about every 8 weeks (Q8W).

17. The use of claim 14, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 3 mg at a frequency of about every 4 weeks (Q4W).

18. The use of claim 14, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 6 mg at a frequency of about every 4 weeks (Q4W).

19. The use of claim 14, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 9 mg at a frequency of about every 4 weeks (Q4W).

5 20. The use of claim 14, wherein the improvement in a pain-associated parameter further comprises e) a change from baseline at week 16 in the percentage of patients who are responders as defined by a 30% reduction or a 50% reduction in one or more of the following: i) average daily LBPI NRS score; ii) RMDQ total score; and iii) PGA of LBP score.

10 21. The use of claim 15, wherein the improvement in a pain-associated parameter further comprises f) a change from baseline at week 16 in the Medical Outcomes Study (MOP) sleep subscale score; g) a change from baseline at week 16 in the short form health survey (SF-36) subscale scores; h) a change from baseline at week 16 in the EQ-5D-5L; and i) change from baseline at week 16 in the percentage of patients who use rescue medication for LBP.

15 22. The use of claim 14, wherein the antibody or antigen-binding fragment comprises a heavy chain variable region (HCVR)/light chain variable region (LCVR) amino acid sequence pair of SEQ ID NOs: 2/10.

20 23. The use of claim 14, wherein the standard analgesic therapy is inadvisable due to a condition selected from the group consisting of medical contraindications, hypersensitivity to standard analgesic therapy, or excipients, use of a concomitant medication prohibited with standard analgesic therapy, increased risk of kidney damage, increased risk of liver damage, increased risk of gastrointestinal bleeding, increased risk of an allergic reaction and increased
25 risk of developing drug dependence.

24. The use of claim 23, wherein the standard analgesic therapy is selected from the group consisting of paracetamol/acetaminophen, a non-steroidal anti-inflammatory (NSAID), and an opioid.

30 25. The use of claim 24, wherein the opioid is selected from the group consisting of hydrocodone, oxycodone, percocet, morphine, meperidine, hydromorphone, fentanyl, and methadone.

26. The use of claim 14, wherein the initial dose of the formulation is a dose that is equivalent to about two times the secondary dose of the anti-NGF antibody that is to be administered to the patient.

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27. The use of claim 14, wherein the initial dose and the one or more secondary doses of the formulation each comprise about 6.0 mg to about 9.0 mg of the NGF antibody, wherein the NGF antibody comprises an HCVR having the amino acid sequence of SEQ ID NO:2 and an LCVR having the amino acid sequence of SEQ ID NO: 10.

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28. The use of claim 27, wherein the initial dose and the one or more secondary doses are to be administered either subcutaneously or intravenously, and wherein the one or more secondary doses of the NGF antibody are to be administered every four weeks, every eight weeks, or every 12 weeks after the initial dose.

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29. The use of claim 28, wherein the one or more secondary doses of the NGF antagonist are to be administered every four weeks, or every eight weeks after the initial dose.

30. Use of one or more doses of a pharmaceutical composition comprising a therapeutically effective amount of an antibody that binds specifically to nerve growth factor (NGF) or an antigen binding fragment thereof in the manufacture of a medicament for reducing pain in a patient suffering from moderate to severe low back pain (LBP), wherein the low back pain is inadequately controlled by standard analgesic therapy, , wherein the antibody or antigen-binding fragment comprises three heavy chain complementarity determining regions (HCDRs) and three light chain complementarity determining regions (LCDRs) contained within a heavy chain variable region (HCVR)/light chain variable region (LCVR) amino acid sequence pair of SEQ ID NOs: 2/10;

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and whereby LBP is reduced.

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31. The use of claim 30, wherein the low back pain is chronic, non-radicular back pain and wherein the patient exhibits a history of inadequate pain relief from, or is resistant,

inadequately responsive, or intolerant to standard analgesic therapy.

32. The use of claim 30, wherein the patient is unwilling to take standard analgesic therapy, or wherein the standard analgesic therapy is inadvisable for administration to the patient due to safety and health risks and/or coupled with suboptimal efficacy.

33. The use of claim 32, wherein the standard analgesic therapy is inadvisable for administration to the patient due to a condition selected from the group consisting of medical contraindications, hypersensitivity to standard analgesic therapy, or excipients, use of a concomitant medication prohibited with standard analgesic therapy, increased risk of kidney damage, increased risk of liver damage, increased risk of gastrointestinal bleeding, increased risk of an allergic reaction and increased risk of developing drug dependence.

34. The use of claim 30, wherein the standard analgesic therapy is selected from the group consisting of paracetamol/acetaminophen, a non-steroidal anti-inflammatory (NSAID), and an opioid.

35. The use of claim 34, wherein the opioid is selected from the group consisting of hydrocodone, oxycodone, percocet, morphine, meperidine, hydromorphone, fentanyl, and methadone.

36. The use of claim 30, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 6 mg, or a dose of about 9 mg at a frequency of about every 4 weeks (Q4W), or every 8 weeks (Q8W).

37. The use of claim 36, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 6 mg at a frequency of about every 4 weeks (Q4W).

38. The use of claim 37, wherein the antibody or antigen-binding fragment thereof that binds specifically to NGF is to be administered to the patient at a dose of about 9 mg at a

frequency of about every 8 weeks (Q8W).

39. The use of claim 30, wherein the antibody or antigen-binding fragment is to be administered subcutaneously (SC), or intravenously (IV).

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40. Use of one or more doses of a pharmaceutical composition comprising a therapeutically effective amount of an antibody that binds specifically to nerve growth factor (NGF) or an antigen binding fragment thereof in the manufacture of a medicament for reducing pain in a patient suffering from moderate to severe low back pain (LBP), wherein the low back pain is inadequately controlled by standard analgesic therapy, , wherein the antibody or antigen-binding fragment comprises three heavy chain complementarity determining regions (HCDRs) and three light chain complementarity determining regions (LCDRs) contained within a heavy chain variable region (HCVR)/light chain variable region (LCVR) amino acid sequence pair of SEQ ID NOs: 2/10; and

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wherein the patient, following administration of the pharmaceutical composition, exhibits an improvement in one or more pain-associated parameters selected from the group consisting of: (a) a change from baseline at week 16 in the average daily Low Back Pain Intensity (LBPI) Numerical Rating Scale (NRS) score; (b) a change from baseline at week 16 in the Roland Morris Disability Questionnaire (RMDQ) total score; (c) a change from baseline at week 16 in the Patient Global Assessment (PGA) of Low Back Pain (LBP) score; and (d) a change from baseline at week 2, 4, 8 and 12 in the average daily LBPI NRS score.

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41. The use of claim 40, wherein the improvement in a pain-associated parameter further comprises e) a change from baseline at week 16 in the percentage of patients who are responders as defined by a 30% reduction or a 50% reduction in one or more of the following: i) average daily LBPI NRS score; ii) RMDQ total score; and iii) PGA of LBP score.

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42. The use of claim 41, wherein the improvement in a pain-associated parameter further comprises f) a change from baseline at week 16 in the Medical Outcomes Study (MOP) sleep subscale score; g) a change from baseline at week 16 in the short form health survey (SF-36) subscale scores; h) a change from baseline at week 16 in the EQ-5D-5L; and i) change from

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baseline at week 16 in the percentage of patients who use rescue medication for LBP.