currently evaluating the use of anti-CGRP antibodies for the treatment of headaches and migraine (See, for example, Dodick et al. Lancet Neurolology; 13(9): 885-892 (2014)).

Summary

In one aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of migraine in a patient.

In another aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of migraine in a patient.

In a further aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of migraine in a patient inadequately controlled by lasmiditan or a CGRP antagonist therapy alone.

In another aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab for the treatment of migraine in a patient inadequately controlled by lasmiditan or galcanezumab therapy alone.

In a further aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of migraine in a patient suffering from therapy resistant migraine wherein the patient's migraines have been refractory to two or more prior monotherapy and/or dual therapy treatment regimens.

In another aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of migraine in a patient suffering from therapy resistant migraine wherein the patient's migraines have been refractory to two or more prior monotherapy and/or dual therapy treatment regimens.

In a further aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient.

In another aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient.

In a further aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient inadequately controlled by lasmiditan or a CGRP antagonist therapy alone.

In another aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient inadequately controlled by lasmiditan or galcanezumab therapy alone.

In a further aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient suffering from therapy resistant headaches wherein the patient's headaches have been refractory to two or more prior monotherapy and/or dual therapy treatment regimens.

In another aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient suffering from therapy resistant headaches wherein the patient's headaches have been refractory to two or more prior monotherapy and/or dual therapy treatment regimens.

In a further aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 50 mg once or twice a day.

In another aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 100 mg once or twice a day.

In a further aspect of the present disclosure, there is provided use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 200 mg once or twice a day.

What is claimed:

1. Use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of migraine in a patient.

2. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of migraine in a patient.

3. Use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of migraine in a patient inadequately controlled by lasmiditan or a CGRP antagonist therapy alone.

4. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab for the treatment of migraine in a patient inadequately controlled by lasmiditan or galcanezumab therapy alone.

5. Use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of migraine in a patient suffering from therapy resistant migraine wherein the patient’s migraines have been refractory to two or more prior monotherapy and/or dual therapy treatment regimens.

6. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of migraine in a patient suffering from therapy resistant migraine wherein the patient's migraines have been refractory to two or more prior monotherapy and/or dual therapy treatment regimens.

7. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 50 mg once or twice a day.

8. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 100 mg once or twice a day.

9. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 200 mg once or twice a day.

10. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 50 mg once or twice a day.

11. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 100 mg once or twice a day.

12. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 200 mg once or twice a day.

13. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 50 mg once a day.

14. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 100 mg once a day.

15. The use of any one of claims 2, 4, or 6, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 200 mg once a day.

16. Use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient.

17. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient.

18. Use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient inadequately controlled by lasmiditan or a CGRP antagonist therapy alone.

19. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient inadequately controlled by lasmiditan or galcanezumab therapy alone.

20. Use of lasmiditan in simultaneous, separate, or sequential combination with a calcitonin gene-related peptide (CGRP) antagonist in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient suffering from therapy resistant headaches wherein the patient’s headaches have been refractory to two or more prior monotherapy and/or dual therapy treatment regimens.

21. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the

group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient suffering from therapy resistant headaches wherein the patient's headaches have been refractory to two or more prior monotherapy and/or dual therapy treatment regimens.

22. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 50 mg once or twice a day.

23. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 100 mg once or twice a day.

24. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered in an initial loading dose of 240 mg of followed by a monthly maintenance dose of 120 mg, and lasmiditan is to be administered at a dose of 200 mg once or twice a day.

25. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is

to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 50 mg once or twice a day.

26. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 100 mg once or twice a day.

27. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 200 mg once or twice a day.

28. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 50 mg once a day.

29. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 100 mg once a day.

30. Use of lasmiditan in simultaneous, separate, or sequential combination with galcanezumab in the manufacture of a medicament for the treatment of a headache selected from the

group consisting of episodic headache, chronic headache, chronic cluster headache, or episodic cluster headache in a patient, wherein galcanezumab is to be administered at a monthly dose of 120 mg, and lasmiditan is to be administered at a dose of 200 mg once a day.