NOREPINEPHRINE REUPTAKE INHIBITORS FOR TREATING SLEEP APNEA

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit under 35 U.S.C. § 119 (a) and (e) of and priority to United States Provisional Application No. 63/211,673, filed June 17, 2021, and United States Provisional Application No. 63/319,035, filed March 11, 2022, the entire contents of each of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention provides methods of treating sleep apnea and snoring comprising administering a norepinephrine reuptake inhibitor, optionally in the absence of an antimuscarinic therapy, and optionally wherein the method of treatment is a monotherapy.

BACKGROUND

[0003] Obstructive Sleep Apnea (OSA) is a common disorder caused by collapse of the pharyngeal airway during sleep. OSA can have serious health consequences.

SUMMARY

[0003a] In an aspect of the present disclosure, there is provided a pharmaceutical composition comprising (i) viloxazine or a pharmaceutically acceptable salt thereof, (ii) trazodone or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable excipient or carrier.

[0003b] In another aspect of the present disclosure, there is provided a use of viloxazine or a pharmaceutically acceptable salt thereof, and trazodone or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating obstructive sleep apnea.

[0004] One example of the present disclosure provides a method of treating a subject having a condition associated with pharyngeal airway collapse, the method comprising administering to a subject in need thereof an effective amount of a norepinephrine reuptake inhibitor (NRI).

[0005] Examples of the disclosure may include one or more of the following optional features. In some examples, the method is performed in the absence of an antimuscarinic therapy. In some examples, the method excludes an antimuscarinic therapy. In some examples, the subject does not concurrently receive an antimuscarinic therapy, i.e., is not concurrently administered an antimuscarinic agent. In some examples, the NRI is reboxetine or a pharmaceutically acceptable salt thereof. In some examples, the NRI is edivoxetine or a pharmaceutically acceptable salt thereof. In some examples, the NRI is viloxazine or a pharmaceutically acceptable salt thereof. In some examples, the method is a monotherapy with reboxetine or a pharmaceutically acceptable salt thereof as the sole active pharmaceutical ingredient. In some examples, the reboxetine or pharmaceutically acceptable salt thereof is administered at a dosage of from about 1 mg to about 8 mg. In some examples, the reboxetine or pharmaceutically acceptable salt thereof is administered at a dosage of from about 2 mg to about 6 mg. In some examples, the reboxetine is administered daily. In some examples, the reboxetine or pharmaceutically acceptable salt thereof is (S,S)-reboxetine or a

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising (i) viloxazine or a pharmaceutically acceptable salt thereof, (ii) trazodone or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable excipient or carrier.

2. The pharmaceutical composition of claim 1, wherein the viloxazine or pharmaceutically acceptable salt thereof is present as a single enantiomer.

3. Use of viloxazine or a pharmaceutically acceptable salt thereof, and trazodone or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating obstructive sleep apnea.

4. The use of claim 3, wherein the viloxazine or pharmaceutically acceptable salt thereof is present as a single enantiomer.

5. The use of claim 3 or 4, wherein the viloxazine or pharmaceutically acceptable salt thereof is to be administered at a dose of 50 mg to 800 mg.

6. The use of any one of claims 3-5, wherein the medicament is to be administered daily.

7. The use of any one of claims 3-6, wherein the medicament is an oral administration form.

8. The use of claim 7, wherein the oral administration form is a syrup, pill, tablet, troche, or capsule.