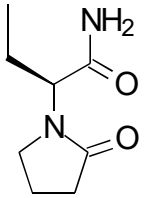
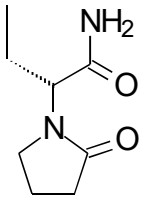
prevention of seizure-related disorders.

In a first example, the disclosure provides for a composition comprising a compound of formula (I) (herein also referred to as (S)-2-(2-oxopyrrolidin-1-yl)butanamide) and a compound of formula (II) (herein also referred to as (R)-2-(2-oxopyrrolidin-1-yl)butanamide)



(I)

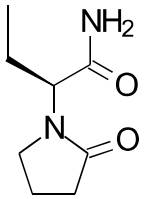


(II)

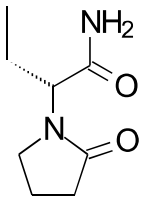
and/or pharmaceutically acceptable solvates or co-crystals thereof,

wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 20% and lower than or equal to 67% (preferably lower than or equal to 50%).

In a first aspect, the disclosure provides for a pharmaceutical composition comprising a compound of formula (I) and a compound of formula (II)



(I)



(II)

and/or pharmaceutically acceptable solvates or co-crystals thereof,

and a pharmaceutically acceptable carrier,

wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%.

In ~~a further aspect~~an example, the disclosure provides for a pharmaceutical composition comprising the composition of the present disclosure and a pharmaceutically acceptable carrier.

In yet another aspect, the present disclosure provides for a use of the pharmaceutical composition as described herein, or a composition comprising a compound of formula (I) and a compound of formula (II), and/or pharmaceutically acceptable solvates or co-crystals thereof, wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%, in the manufacture of a medicament for use in treating and/or preventing a disease, injury or disorder, wherein the disease, injury or disorder is epilepsy.

In again a further example, the disclosure provides for a kit of parts comprising a compound of formula (I) and a compound of formula (II) and instructions for combining the compound of formula (I) and the compound of formula (II) to obtain an enantiomeric excess (ee) of said compound of formula (I) of equal to or higher than 20% and lower than or equal to 67% (preferably lower than or equal to 50%). In this example, the same preferred ranges of the enantiomeric excess (ee) of said compound of formula (I) and enantiomeric ratios of the compound of formula (I) to the compound of formula (II) as set out herein with respect to the composition apply.

In again a further example, the disclosure provides for the composition of the disclosure or the pharmaceutical composition of the disclosure or the kit of the disclosure for use as a medicament.

In again a further example, the disclosure provides for the composition of the disclosure or the pharmaceutical composition of the disclosure or the kit of the disclosure for the treatment and/or prevention of seizure-related disorders.

In again a further example, the disclosure provides for a method for the treatment for the treatment and/or prevention of a seizure-related disorder.

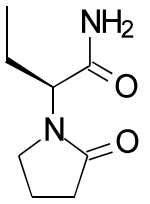
In again a further example, the disclosure provides for the use of the composition of the disclosure or the pharmaceutical composition of the disclosure or the kit of the disclosure in the manufacture of a medicament for the treatment and/or prevention of a seizure-related disorder.

In again a further example, the disclosure provides for an article of manufacture comprising the composition of the disclosure or the pharmaceutical composition of the disclosure, a container or package and a written description and administration instruction such as a package insert.

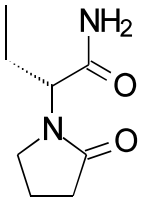
In again a further aspect, the disclosure provides for a method for preparing a composition of the disclosure or a pharmaceutical composition of the disclosure, comprising combining a compound of formula (I), and a compound of formula (II), or a compound of formula (I), and a racemate of a compound of formula (I) and (II).

In again a further aspect, the disclosure provides for a use of a compound of formula (I) and/or a compound of formula (II) and/or a racemate of a compound of formula (I) and (II) in the preparation of ~~a composition of the disclosure or~~ a pharmaceutical composition of the disclosure.

In again a further aspect, the disclosure provides for a use of a composition comprising a



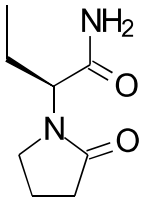
(I)



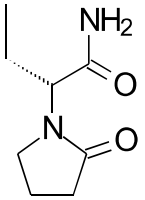
(II)

compound of formula (I) and a compound of formula (II), and/or pharmaceutically acceptable solvates or co-crystals thereof, wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%, ~~the compound of formula (I) and the compound of formula (II) and/or pharmaceutically acceptable solvates or co-crystals thereof according to the disclosure~~ in the manufacture of a medicament for combination therapy to treat and/or prevent a disease, injury or disorder, wherein the disease, injury or disorder is ~~selected from seizure-related disorders~~epilepsy.

In again a further aspect, the disclosure provides for a use of the compound of formula (I) and/or pharmaceutically acceptable solvates or co-crystals thereof ~~according to the disclosure~~ in the manufacture of a first medicament, the compound of formula (II) and/or ~~and~~ pharmaceutically



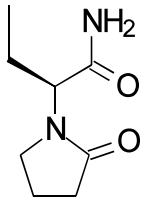
(I)



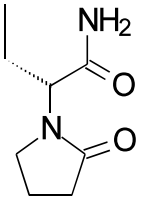
(II)

acceptable solvates or co-crystals thereof, ~~according to the disclosure~~ in the manufacture of a second medicament, wherein the first and second medicaments are to be used in combination therapy to treat and/or prevent a disease, injury or disorder, wherein the disease, injury or disorder is ~~selected from seizure-related disorders~~epilepsy, wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%.

In again a further aspect, the disclosure provides for a use of the compound of formula (I) and/or ~~and~~ pharmaceutically acceptable solvates or co-crystals thereof ~~according to the disclosure~~ in the manufacture of a medicament for use in combinatorial therapy for treating and/or preventing a disease, injury or disorder, wherein the disease, injury or disorder is ~~selected from seizure-related disorders~~epilepsy, and wherein said medicament is to be administered in combination with a compound of formula (II),



(I)



(II)

and/or with pharmaceutically acceptable solvates or co-crystals thereof, wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67% ~~according to the disclosure~~.

Further aspects and examples of the present disclosure will be become apparent as this description continues.

Detailed Description

Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art to which this invention belongs.

The term "about" where used to characterize an enantiomeric excess means ±4% referring to the given numeric value, if not indicated otherwise. In each of the invention embodiments, "about" can be deleted.

The term "preferably" is used to describe features or embodiments which are not required in the present invention but may lead to improved technical effects and are thus desirable but not essential.

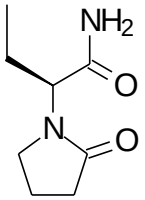
A number of compounds are described herein by reference to their structural formula and/or their chemical name, such as the IUPAC name. In case of discrepancies between the structural formula and the chemical name, the present invention expressly relates to the compounds as referred to by the structural formula as well as by the chemical name.

With respect to the numerical values mentioned herein, unless explicitly stated otherwise, the last decimal place of a numerical value preferably indicates its degree of accuracy. Thus, unless other error margins are given, the maximum margin is preferably ascertained by applying the rounding-off convention to the last decimal place. Thus, a value of 2.5 preferably includes the range of 2.45 to 2.54.

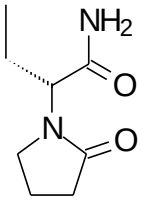
The term "treatment" of a disorder or disease as used herein is well known in the art. "Treatment" of a disorder or disease implies that a disorder or disease is suspected or has been diagnosed in a patient/subject. A patient/subject suspected of suffering from a disorder or disease typically shows specific clinical and/or pathological symptoms which a skilled person can easily attribute to a specific pathological condition (i.e., diagnose a disorder or disease). The "treatment" of a disorder or disease may, for example, lead to a halt in the progression of

CLAIMS

1. A pharmaceutical composition comprising a compound of formula (I) and a compound of formula (II),



(I)



(II)

and/or pharmaceutically acceptable solvates or co-crystals thereof,
and a pharmaceutically acceptable carrier,
wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%.

~~2. The composition of claim 1, wherein the compound of formula (I) and/or pharmaceutically acceptable solvates or co-crystals thereof and compound of formula (II) and/or pharmaceutically acceptable solvates or co-crystals thereof are packaged separately.~~

~~3. The composition of claim 1, wherein the composition is a non-racemic mixture of 2-(2-oxopyrrolidin-1-yl)butanamide and pharmaceutically acceptable solvates or co-crystals thereof, wherein the non-racemic mixture comprises the compound of formula (I) to the compound of formula (II) in an enantiomeric excess (ee) of the compound of formula (I) of equal to or higher than 20% and lower than or equal to 67%.~~

~~4. A pharmaceutical composition comprising the composition of any one of the preceding claims and a pharmaceutically acceptable carrier.~~

~~5~~2. The ~~composition of any one of claims 1 to 3 or the~~ pharmaceutical composition of claim 1~~4~~, or

a composition comprising a compound of formula (I) and a compound of formula (II), and/or pharmaceutically acceptable solvates or co-crystals thereof,
wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%,
for use as a medicament.

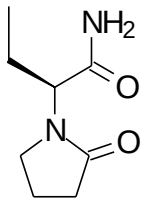
36. Use of ~~The composition or~~ the pharmaceutical composition of claim 15~~,~~ or
a composition comprising a compound of formula (I) and a compound of formula (II), and/or pharmaceutically acceptable solvates or co-crystals thereof,
wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%,
in the manufacture of a medicament for use in treating and/or preventing a disease, injury or disorder, wherein the disease, injury or disorder is ~~selected from seizure-related disorders~~epilepsy.

47. The ~~composition for~~ use ~~or the pharmaceutical composition for use~~ of claim 36, wherein the composition or the pharmaceutical composition is to be administered orally twice daily in a dose of between 10 mg and 3000 mg per administration, more preferably between 20 mg to 2000 mg per administration, again more preferably between 50 mg and 1000 mg per administration.

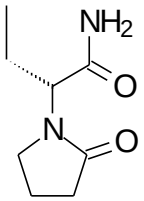
85. A method for preparing ~~a composition of any one of claims 1 to 3 or~~ a pharmaceutical composition of claim 14, comprising combining
a compound of formula (I), and a compound of formula (II), or
a compound of formula (I), and a racemate of a compound of formula (I) and (II).

69. Use of a compound of formula (I) and/or a compound of formula (II) and/or a racemate of a compound of formula (I) and (II) in the preparation of ~~a composition of any one of claims 1 to 3 or~~ a pharmaceutical composition of claim 14.

710. Use of ~~the~~ a composition comprising a compound of formula (I) and a compound of formula (II),



(I)

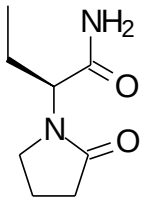


(II)

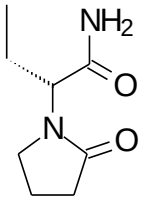
and/or pharmaceutically acceptable solvates or co-crystals thereof,

wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%, ~~compound of formula (I) and the compound of formula (II) and/or pharmaceutically acceptable solvates or co-crystals thereof according to any one of claims 1 to 3~~ in the manufacture of a medicament for combination therapy to treat and/or prevent a disease, injury or disorder, wherein the disease, injury or disorder is epilepsy~~selected from seizure-related disorders~~.

8~~11~~. Use of the compound of formula (I) and/or pharmaceutically acceptable solvates or co-crystals thereof ~~according to any one of claims 1 to 3~~ in the manufacture of a first medicament, the compound of formula (II) and/or ~~and~~ pharmaceutically acceptable solvates or co-crystals thereof, ~~according to any one of claims 1 to 3~~



(I)



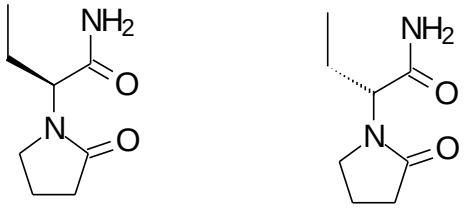
(II)

in the manufacture of a second medicament,

wherein the first and second medicaments are to be used in combination therapy to treat and/or prevent a disease, injury or disorder, wherein the disease, injury or disorder is epilepsy~~selected from seizure-related disorders~~ wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%.

9~~12~~. Use of the compound of formula (I) and/or ~~and~~ pharmaceutically acceptable solvates or co-crystals thereof ~~according to any one of claims 1 to 3~~ in the manufacture of a

medicament for use in combinatorial therapy for treating and/or preventing a disease, injury or disorder, wherein the disease, injury or disorder is epilepsy~~selected from seizure-related disorders~~, and wherein said medicament is to be administered in combination with a compound of formula (II),



(I) (II)

and/or with pharmaceutically acceptable solvates or co-crystals thereof ~~according to any one of claims 1 to 3~~, wherein the enantiomeric excess (ee) of said compound of formula (I) is equal to or higher than 50% and lower than or equal to 67%.