

[0006] It has now been discovered in an N-MOmentum clinical trial, that VIB551 is an effective B-cell depletion monotherapy for the prevention of relapses and disability in NMOSD. VIB551 has been shown to be superior over placebo in reducing: a) the risk of an NMOSD attack, b) the risk of disability worsening, c) MRI lesion activity and d) disease-related hospitalizations in a globally representative population of patients with NMOSD, recruited from 99 centres in 24 countries.

SUMMARY

[0007] The description provides for a method of treating NMOSD. The method comprises a step of administering VIB551 to a patient in need of treatment for NMOSD, and a step of treating the NMOSD. The VIB551 is administered intravenously at a dose of 300 mg every 6 months or 26 weeks.

[0007a] In one aspect, the present disclosure provides for a use of a composition comprising: (a) 10 mg/mL of Inebilizumab; (b) 20 mM histidine/histidine hydrochloride; (c) 70 mM NaCl; (d) 106 mM trehalose dihydrate; and (e) 0.01% (w/v) polysorbate 80 in the manufacture of a medicament for treating neuromyelitis optica spectrum disorder (NMOSD) in a subject.

[0008] The description also provides for a method of reducing active magnetic resonance imaging (MRI) lesions in a patient diagnosed with NMOSD. The method comprises a step of administering VIB551 to a patient in need of treatment for NMOSD, and a step of reducing the MRI lesions in the patient. The VIB551 is administered intravenously at a dose of 300 mg every 6 months or 26 weeks.

[0009] The description further provides for a method of reducing AQP4-IgG titers in an AQP4-IgG⁺ patient in need of treatment NMOSD. The method comprises a step of administering VIB551 to a patient in need of treatment for NMOSD, and a step of reducing the AQP4-IgG titers in the patient. The VIB551 is administered intravenously at a dose of 300 mg every 6 months or 26 weeks.

[0010] The description provides for an additional method of treating patient diagnosed with NMOSD. The method comprises a step of administering VIB551 to a patient in need of treatment for NMOSD and a step of treating the NMOSD. The VIB551 is administered at a dose that (i) depletes at least 90% of circulating CD20+ B cells for at least six months, and (ii) does not increase risk of infections in the patient.

[0011] The description further provides for a method of reducing disability in a patient diagnosed with NMOSD. The method comprises a step of administering VIB551 to a patient in

CLAIMS

1. Use of a composition comprising: (a) 10 mg/mL of Inebilizumab; (b) 20 mM histidine/histidine hydrochloride; (c) 70 mM NaCl; (d) 106 mM trehalose dihydrate; and (e) 0.01% (w/v) polysorbate 80 in the manufacture of a medicament for treating neuromyelitis optica spectrum disorder (NMOSD) in a subject.
2. The use of claim 1, wherein the medicament has a pH of 6.
3. The use of claim 1, wherein the medicament is to be administered at a dose of 300 mg of Inebilizumab.
4. The use of claim 1, wherein the medicament is to be administered every 6 months.
5. The use of claim 1, wherein the medicament is effective in reducing worsening of Expanded Disability Status Scale (EDSS) in the subject, as determined by: a worsening of fewer than 2 points in EDSS score if the subject has a baseline score of 0; a worsening of fewer than 1 point if the subject has a baseline score of 1 to 5; or a worsening of less than 0.5 point if the subject has a baseline score of 5.5 or more, when the medicament is to be administered to the subject.
6. The use of claim 1, wherein the medicament is effective in reducing a number of lesions, as determined by magnetic resonance imaging (MRI), when the medicament is to be administered to the subject.
7. The use of claim 6, wherein the lesions are T2 MRI lesions.
8. The use of claim 6, wherein the lesions are new MRI lesions.
9. The use of claim 1, wherein the medicament is effective in reducing worsening of a modified Rankin score when the medicament is to be administered to the subject.
10. The use of claim 1, wherein the medicament is effective in reducing frequency of in-patient hospitalizations related to the NMOSD when the medicament is to be administered to the subject.
11. The use of claim 1, wherein the medicament is effective in reducing risk of an NMOSD-related attack, as determined by appearance of a new symptom of the NMOSD or worsening of an existing symptom of the NMOSD, when the medicament is to be administered to the subject.
12. The use of claim 4, wherein prior to the administration every 6 months an initial administration of the medicament is to be administered.

13. The use of claim 12, wherein the initial administration comprises a dosage of 300 mg of Inebilizumab.