

CLAIMS

[Claim 1]

Use of serabelisib or a pharmaceutically acceptable salt thereof in the manufacture of a pharmaceutical composition for treating or managing vascular malformation in a subject in need thereof,

wherein the subject is to be administered a daily dose of the serabelisib or the pharmaceutically acceptable salt thereof in a range from 50 mg to 100 mg.

[Claim 2]

Use of serabelisib or a pharmaceutically acceptable salt thereof in the manufacture of a pharmaceutical composition for shrinking a swelling lesion in a vascular malformation patient,

wherein the patient is to be administered a daily dose of the serabelisib or the pharmaceutically acceptable salt thereof in a range from 50 mg to 100 mg.

[Claim 3]

Use of serabelisib or a pharmaceutically acceptable salt thereof in the manufacture of a pharmaceutical composition for reducing pain in a vascular malformation patient,

wherein the patient is to be administered a daily dose of the serabelisib or the pharmaceutically acceptable salt thereof in a range from 50 mg to 100 mg.

[Claim 4]

The use according to any one of claims 1 to 3, wherein

the pharmaceutical composition causes a volume of a target lesion during a treatment period or after treatment to be reduced by at least 20% in comparison to the volume of the target lesion before the treatment.

[Claim 5]

The use according to any one of claims 1 to 4, wherein the pharmaceutical composition can treat a vascular malformation while suppressing the occurrence of a side effect that may occur during the treatment period.

[Claim 6]

The use according to claim 5, wherein the side effect that may occur during the treatment period is hyperglycemia.

[Claim 7]

Use of serabelisib or a pharmaceutically acceptable salt thereof in the manufacture of a pharmaceutical composition for treating or managing vascular malformation, wherein the pharmaceutical composition is to be administered at a dose that

(a) causes a volume of a target lesion during a treatment period or after treatment to be reduced by at least 20% in comparison to the volume of the target lesion before the treatment, and also

(b) does not cause a drug-induced side effect of hyperglycemia during the treatment period.

[Claim 8]

The use according to claim 7, wherein a daily dose of

the serabelisib is in a range from 50 mg to 100 mg.

[Claim 9]

The use according to any one of claim 1 to claim 8, wherein a serabelisib content is in a range from 2 w/w% to 40 w/w% with reference to a total amount of the pharmaceutical composition.

[Claim 10]

The use according to claim 9, wherein the serabelisib content is 20 w/w% with reference to the total amount of the pharmaceutical composition.

[Claim 11]

The use according to any one of claims 1 to 10, wherein the vascular malformation is a slow-flow vascular malformation or a mixed vascular malformation.

[Claim 12]

The use according to any one of claims 1 to 11, wherein the vascular malformation is a venous malformation, a lymphatic malformation, or Klippel-Trenaunay syndrome.

[Claim 13]

The use according to claim 12, wherein the vascular malformation is a venous malformation.

[Claim 14]

The use according to claim 12, wherein the vascular malformation is a lymphatic malformation.

[Claim 15]

The use according to claim 12, wherein the vascular

malformation is Klippel-Trenaunay syndrome.

[Claim 16]

The use according to any one of claims 1 to 15, wherein the pharmaceutical composition is to be administered once per day over a treatment period of at least 2 weeks.

[Claim 17]

The use according to claim 16, wherein the pharmaceutical composition is to be administered once per day over a treatment period of at least 4 weeks, at least 12 weeks, at least 24 weeks, at least 36 weeks, at least 48 weeks, at least 52 weeks, at least 2 years, or at least 3 years.

[Claim 18]

Use of serabelisib or a pharmaceutically acceptable salt thereof in the manufacture of a pharmaceutical composition for treating or managing vascular malformation in a subject in need thereof, wherein the subject is to be administered a dose that

(a) causes a volume of a target lesion during a treatment period or after treatment to be reduced by at least 20% in comparison to the volume of the target lesion before the treatment, and also

(b) does not cause a drug-induced side effect of hyperglycemia during the treatment period.