SENJU Beyond "eyesight"

September 27, 2021

General Announcement:

Senju Pharmaceutical Co., Ltd.

Ophthalmic VEGF Inhibitor

Acquisition of Marketing Approval for "Ranibizumab BS Intravitreal Injection Kit 10 mg/mL 'Senju'"

Senju Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Mr. Shuhei Yoshida) today announces that it has received approval for the marketing of the ophthalmic VEGF inhibitor "Ranibizumab BS intravitreal injection kit 10 mg/mL 'Senju'" [Nonproprietary name: Ranibizumab (genetical recombination) (Ranibizumab biosimilar 1), hereinafter referred to as this "Product"] in Japan, as of September 27, 2021.

The major drug treatment for retinal diseases (such as age-related macular degeneration) is the use of ophthalmic VEGF inhibitors, but in addition to the extremely high cost of the drugs for such treatment, continuous administration is often required, resulting in even higher treatment costs.

This Product is the first biosimilar of an ophthalmic VEGF inhibitor that has been developed in collaboration with Kidswell Bio Corporation, and is expected to become a new treatment option for retinal diseases and to contribute to reducing the economic burden on patients.

At present, this Product is expected to be launched around December of 2021, after its National Health Insurance (NHI) Price is listed in Japan.

The outline of the approved contents for the Product is as follows:

Product name	Ranibizumab BS intravitreal injection kit 10 mg/mL 'Senju'
Nonproprietary name	Ranibizumab (genetical recombination) [Ranibizumab biosimilar 1]
Dosage form/strength	Injection containing 1.65 mg of Ranibizumab (genetical recombination) [Ranibizumab biosimilar 1] in 1 syringe (0.165 mL)
Indications	Age-related macular degeneration with subfoveal choroidal neovascularization Choroidal neovascularization in pathological myopia
Dosage and administration	< Age-related macular degeneration with subfoveal choroidal neovascularization > Ranibizumab (genetical recombination) [Ranibizumab biosimilar 1] is administered intravitreally at a dose of 0.5 mg (0.05 mL) every month for three consecutive months (induction period). In the subsequent maintenance period, the dosing interval may be adjusted as appropriate according to the symptoms, but the interval should be at least one month. < Choroidal neovascularization in pathological myopia > Ranibizumab (genetical recombination) [Ranibizumab biosimilar 1] is administered intravitreally at a dose of 0.5 mg (0.05 mL) per dose. The dosing interval should be at least one month.

[Contact details for inquiries]

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