Regulatory Affairs

Beovu®

Summary of the Risk Management Plan (RMP) v1.0 for Beovu®

(Brolucizumab)

Document version: 1.0

Document status: Final

Document Date: 24-Feb-2020

Summary of the risk management plan for Beovu (Brolucizumab)

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Beovu® is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the „Arzneimittelinformation / Information sur le médicament“ approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Beovu in Switzerland is the „Arzneimittelinformation / Information sur le médicament“ (see www.swissmedicinfo.ch) approved and authorized by Swissmedic.

Novartis Pharma Schweiz AG is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Beovu®.

The medicine and what it is used for

Beovu® is authorized for the treatment of neovascular (wet) age-related macular degeneration (AMD) in adults.

It contains brolucizumab as the active substance and it is given by intravitreal injections.

Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Beovu® together with measures to minimize such risks and the proposed studies for learning more about Beovu’s risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and prescribing information addressed to patients and healthcare professionals;

- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In the case of Beovu®, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Beovu® is not yet available, it is listed under 'missing information' below.

List of important risks and missing information

Important risks of Beovu® are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Beovu®. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table 1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Intraocular inflammation Hypersensitivity
Important potential risks	not applicable
Missing information	Safety beyond two years of treatment

Summary of important risks

Table 2 Important identified risk: Intraocular inflammation

Evidence for linking the risk to the medicine	For treatment emergent AEs in the study eye, the most pronounced numerical difference between brolucizumab and aflibercept was observed for intraocular inflammation and this was more pronounced in the Study RTH258-C001.
Risk factors and risk groups	A higher intraocular inflammation incidence was observed in Japanese patients treated with brolucizumab compared to non-Japanese patients. In Study RTH258-C001 the number of patients with an intraocular inflammation event was 7/60 (11.7%) in Japanese patients and 14/300 (4.7%) in non-Japanese patients. There is also a higher incidence of intraocular inflammation in females compared to males (target posology long term S-db): brolucizumab 6 mg 5.3% in females vs. 3.2% in males.
Risk minimization measures	Routine risk minimization: Prescribing information sections Dosage/Administration, Warnings and precautions, Contraindication, Undesirable effects. Additional Risk Minimization Measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Table 3 Important identified risk: Hypersensitivity

Evidence for linking the risk to the medicine	In the two pivotal studies (Study RTH258-C001 and Study RTH258-C002), a low number of mild systemic hypersensitivity reactions were reported. Urticaria, rash, pruritus and erythema are Adverse Drug Reactions for brolucizumab. There were no reports of more severe hypersensitivity reactions like anaphylactic reactions, Stevens-Johnson syndrome etc. These severe events are expected to be rare and may be observed when given to a larger population.
Risk factors and risk groups	None identified for brolucizumab.
Risk minimization measures	Routine risk minimization: Prescribing information sections Dosage/Administration, Contraindications, Undesirable effects. Additional Risk Minimization Measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Table 4 Missing information: Safety beyond two years of treatment

Risk minimization measures	Routine risk minimization: None Additional Risk Minimization Measures: None

Post-authorization development plan

Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Beovu®.

Other studies in post-authorization development plan

There are no studies in post-authorization development plan for Beovu®.