Summary of risk management plan for Pomalidomide Anabiosis (Pomalidomide)

This is a summary of the risk management plan (RMP) for Pomalidomide Anabiosis. The RMP details important risks of Pomalidomide Anabiosis, how these risks can be minimised, and how more information will be obtained about Pomalidomide Anabiosis' risks and uncertainties (missing information).

Pomalidomide Anabiosis' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pomalidomide Anabiosis should be used.

Important new concerns or changes to the current ones will be included in updates of Pomalidomide Anabiosis' RMP.

I. The medicine and what it is used for

Pomalidomide Anabiosis in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

Pomalidomide Anabiosis in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

It contains pomalidomide as the active substance and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Pomalidomide Anabiosis, together with measures to minimise such risks and the proposed studies for learning more about Pomalidomide Anabiosis' risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Pomalidomide Anabiosis, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

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

II.A List of important risks and missing information

Important risks of Pomalidomide Anabiosis are risks that need special risk management activities to further investigate or minimise 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 Pomalidomide Anabiosis. 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);

List of important risks and missing information	
Important identified risks	• Teratogenicity • Severe infection due to neutropenia and pancytopenia • Thrombocytopenia and bleeding • Cardiac failure • Non-melanoma skin cancer
Important potential risks	• Other second primary malignancies • Cardiac arrhythmia
Missing information	None

II.B Summary of important risks

Important identified risk: Teratogenicity	
Risk minimisation measures	Routine risk communication: *Summary of Product Characteristics (SmPC) sections 4.3, 4.4, 4.6, 4.8 and 5.3* *Package Leaflet (PL) section 2* *Stringent measures to ensure that exposure of an unborn child to pomalidomide does not occur are included in SmPC section 4.4. These include:* • *Counselling*

	• *Contraception* • *Pregnancy testing* • *Precautions for men* • *Additional precautions* • *Prescription duration* Pomalidomide is subject to restricted medical prescription. Additional risk minimisation measures: *Pregnancy Prevention Programme (PPP)* *Educational Healthcare Professional's Kit containing: Educational Healthcare Professional brochure, Educational brochures for patients, Patient card, Risk awareness forms.* *Educational brochures for patients, including also Patient Card*
Additional pharmacovigilance activities	Additional pharmacovigilance activities: *Category 3 Study: Non-interventional post-authorisation registry of patients treated with pomalidomide to monitor the incidence of ADRs in "real world" situation and to monitor and the implementation and compliance of PPP and controlled distribution system on a country basis in agreement with the relevant NCA (i.e., monitoring of Patient Card completion* See section II.C of this summary for an overview of the post-authorisation development plan.
Important identified risk: Severe infection due to neutropenia and pancytopenia	
Risk minimisation measures	Routine risk communication: *SmPC sections 4.2, 4.4, 4.8 and 5.3* *PL sections 2 and 4* *Dose modification advice in case of neutropenia in included in SmPC section 4.2.* *A warning for neutropenia and advice for blood tests at baseline, weekly for the first 8 weeks and monthly thereafter, as well as recommendation for blood product support and / or growth factor is included in SmPC section 4.4.* *SmPC section 4.4 also provides a warning regarding HBV reactivation and advises that the HBV status should be established before initiating treatment with pomalidomide.*

	Patients should be closely monitored for signs and symptoms of active HBV infection throughout therapy. Pomalidomide is subject to restricted medical prescription. <u>Additional risk minimisation measures</u>: No risk minimisation measures
Important identified risk: Thrombocytopenia and bleeding	
Risk minimisation measures	Routine risk communication: *SmPC sections 4.2, 4.4 and 4.8* *PL sections 2 and 4* Routine risk minimisation activities recommending specific clinical measures to address the risk: *Dose modification advice in case of thrombocytopenia in included in SmPC section 4.2.* *A warning for thrombocytopenia and advice for blood tests at baseline, weekly for the first 8 weeks and monthly thereafter, as well as recommendation for blood product support and / or growth factor is included in SmPC section 4.4.* *Advice for physicians to observe patients for signs of bleeding including epistaxis, especially with use of concomitant medicinal products known to increase the risk of bleeding is also included in SmPC section 4.4.* Other routine risk minimisation measures beyond the Product Information: Pomalidomide is subject to restricted medical prescription. <u>Additional risk minimisation measures</u>: *Educational Healthcare Professional brochure* *Educational brochure for patients*
Important identified risk: Cardiac failure	
Risk minimisation measures	Routine risk communication: *SmPC sections 4.4 and 4.8* *PL sections 2 and 4*

	Routine risk minimisation activities recommending specific clinical measures to address the risk: *Recommendation for periodic monitoring for signs and symptoms of cardiac events is included in SmPC section 4.4.* Other routine risk minimisation measures beyond the Product Information: Pomalidomide is subject to restricted medical prescription. Additional risk minimisation measures: *Educational Healthcare Professional brochure*
Important identified risk: Non-melanoma skin cancer	
Risk minimisation measures	Routine risk communication: *SmPC sections 4.4 and 4.8* *PL section 2* Routine risk minimisation activities recommending specific clinical measures to address the risk: *Advice that physicians should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of second primary malignancies and institute treatment as indicated is included in SmPC section 4.4.* Other routine risk minimisation measures beyond the Product Information: Pomalidomide is subject to restricted medical prescription. Additional risk minimisation measures: No risk minimisation measures
Important potential risk: Other second primary malignancies	
Risk minimisation measures	Routine risk communication: *SmPC section 4.4* *PL section 2* Routine risk minimisation activities recommending specific clinical measures to address the risk:

	Advice that physicians should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of second primary malignancies and institute treatment as indicated is included in SmPC section 4.4. Other routine risk minimisation measures beyond the Product Information: Pomalidomide is subject to restricted medical prescription. <u>Additional risk minimisation measures</u>: No risk minimisation measures
Important potential risk: Cardiac arrhythmia	
Risk minimisation measures	Routine risk communication: *SmPC section 4.8* *PL sections 2 and 4* Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: Pomalidomide is subject to restricted medical prescription. <u>Additional risk minimisation measures</u>: No risk minimisation measures

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Pomalidomide Anabiosis.

II.C.2 Other studies in post-authorisation development plan

Study short name: Monitoring of the Pregnancy Prevention Programme (PPP) implementation and effectiveness

Purpose of the study: The objective of the study is the monitoring of implementation of the PPP.