SUMMARY OF RISK MANAGEMENT PLAN FOR ERIVEDGE (VISMODEGIB)

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

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

This summary of the RMP for Erivedge should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Erivedge is authorized for metastatic breast cancer and locally advanced basal cell carcinoma mBCC and laBCC (see SmPC for the full indication). It contains vismodegib as the active substance and it is given by mouth.

Further information about the evaluation of Erivedge benefits can be found in Erivedge EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Erivedge, together with measures to minimize such risks and the proposed studies for learning more about Erivedge 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 SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 Erivedge, these measures are supplemented with *additional risk minimization measures* mentioned under relevant risks, below.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed, including PSUR assessment, 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 Erivedge are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. 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 Erivedge. 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
Important potential risks	None
Missing information	None

II.B SUMMARY OF IMPORTANT RISKS

Important identified risk of Teratogenicity	
Evidence for linking the risk to the medicine	Nonclinical study results and literature.
Risk factors and risk groups	The 'at risk' group for experiencing vismodegib-related teratogenicity comprises female patients of child-bearing potential or female partners of male patients treated with vismodegib. *Risk factor in cancer patients receiving chemotherapy:* Treatment with chemotherapy in the first trimester, during organogenesis, substantially increases the risk of fetal malformation compared to exposure to chemotherapy in the second and third trimesters of pregnancy.
Risk minimization measures	**Routine risk communication**: Text in SmPC: • Section 4.3 (Contraindications) • Section 4.4 (Special warnings and precautions for use) • Section 4.6 (Fertility, pregnancy and lactation) **Routine risk minimization activities recommending specific clinical measures to address the risk**: • Women of childbearing potential must have a negative pregnancy test prior to initiating treatment and during treatment is included in SmPC section 4.4 • Women of childbearing potential must use two methods of recommended contraception during Erivedge therapy and after the final dose is included in SmPC section 4.4 • Contraception recommendation for men while taking Erivedge and after the final dose is included in SmPC section 4.4 **Other risk minimization measures beyond the Product Information**: Medicine's legal status: Erivedge is subject to restricted medical prescription **Additional risk minimization measures**: Erivedge Pregnancy Prevention Programme : I. For Health Care Providers • Health Care Provider Card • Patient Counselling Guideline II. For Patients • Patient Brochure
Additional pharmacovigilance activities	**Additional pharmacovigilance activities**: None See section II.C of this summary for an overview of the post-authorization development plan.

SmPC = Summary of product characteristics

II.C POST-AUTHORIZATION DEVELOPMENT PLAN

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

Not applicable.

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

Not Applicable.