Female B

Informed Consent Form for Treatment with Lenalidomide/Pomalidomide

Drug to be administered ☐ Lenalidomide ☐ Pomalidomide

As you have selected above, Lenalidomide and Pomalidomide (hereinafter referred to as "the drugs") marketed by Bristol-Myers Squibb K.K. (hereinafter referred to as "BMS") and companies other than BMS (hereinafter referred to as "Generic Companies") will be used for the treatment of your disease. To ensure proper use of the drug, please be sure you understand the content of RevMate® and then place a checkmark next to the items you consent to.

*Please understand that this document is designed for all female patients with no childbearing potential; thus, some items may not be applicable to your daily life.

RevMate®

☐ I have received and confirmed an explanation of risks to the fetus that are associated with the drug.

☐ I have confirmed that if a woman uses the drug and later gets pregnant or a pregnant woman uses the drug, the drug may cause birth defects in the fetus.

☐ I meet any one of the following criteria:

(1) Have had natural menopause (45 years old or older and with no menses for at least one year), have undergone hysterectomy or bilateral oophorectomy, or have congenital absence of the uterus or bilateral ovaries.

(2) Classified into the Female B Category based on a medical examination by an obstetrician/gynecologist for long-term absence of menstruation. However, I have a correct understanding of the risks associated with the drug, and I consent to the following: to periodically undergo medical examinations by an obstetrician/gynecologist, to receive education for Female C Category and accept a change in my patient category if there is any change in my clinical conditions.

(3) Physician prescribing Lenalidomide and Pomalidomide (hereinafter referred to as "prescribing physician") recognized the declaration that the patient had no chance of conception due to serious physical reasons such as poor general conditions, and she was identified as a Female B. However, I agree that I understand the risks of this drug correctly, that I will receive confirmation through periodic visits that my judgment about Female B in (3) is still valid, and that if there is a change in my condition, I will promptly report it to the prescribing physician and my patient classification will be changed with education as Female C.

☐ I have not and will never donate my blood.

☐ I will only use the drug for myself and will never give it to any other person. I will keep the drug out of children's reach in a place dedicated for me, separately from foods/drinks.

☐ I will inform the prescribing physician of the number of remaining capsules at the time of hospital visits, if there are any unused capsules.

☐ I have confirmed that I must return any of the drug that I do not plan to use to the Pharmaceutical Department (hospital pharmacy) and that no refund for the returned drug will be made.

☐ I have confirmed that I will also be responsible for any accident caused by inappropriate use of the drug.

☐ I have confirmed that if I have deviated from RevMate®, treatment with the drug may discontinue or terminate, depending on the significance of the deviation.

Handling of Patients' Information

☐ I consent to my date of birth, disease name, patient classification, and other information *1 (hereinafter referred to as "RevMate® Registration Information") will be provided by the prescribing physician to the RevMate® Center operated by BMS, and I agree to be registered in RevMate®, which is managed and operated by the RevMate® Center.

☐ I further agree that my RevMate® registration information may be provided to the generic company by the RevMate® Center operated by BMS if I take any of the drugs manufactured and marketed by the generic company now or in the future.

☐ I understand that the purpose of the use of my RevMate® registration information by BMS and the generic companies is to manage the safe and appropriate prescription, administration, and disposal of the drugs marketed by BMS and the generic companies.

☐ I also agree that RevMate® registration information may be provided by BMS and the generic companies to the RevMate® Joint Steering Committee *2 and the RevMate® Third Party Evaluation Committee *3 to the extent necessary for the purpose of improving the operation of RevMate® if there are any problems in the operation.

☐ I further consent to the provision of my medical institute registration information (name, address, and telephone number) by the medical institute to BMS or the generic company in the event that the medical institute deems it necessary in the follow-up investigation if there are serious deviations that may result in fetal damage.

☐ I agree that my RevMate® registration information and medical institute registration information will be provided to BMS or the generic company (if applicable) by the transferring hospital, if I continue to receive the prescription of the drugs at the transferring hospital.

☐ I agree that RevMate® personnel and RevMate® information personnel may look at the consent form with my name on it when reviewing the RevMate® storage records at the medical institute. I understand that in such cases, confidentiality will be maintained and will not be divulged to anyone else.

*1: RevMate® registration information includes Date of application / Date of registration / RevMate® patient ID / Date of birth / Name of registered physician / Patient classification (Male A, Female B, Female C) / Disease category (disease name: MM, MDS(5q-), ATLL, FL, MZL, Others) / Prescription date / Prescribed drugs / Prescribing physician / Confirmation of prescribing requirements / Dosage form / Quantity prescribed / Quantity of remaining drugs /Date of return / Drugs to be returned / Quantity of drugs to be returned /Existence or non-existence of consent form / Whether or not submitting the periodic "RevMate® Patient Survey Sheet (Form 27)" (except for Female B) / Date and details of change in patient registration information / Necessity of a medication care partner.

*2: The RevMate® Joint Steering Committee is a committee consisting of BMS, the generic companies, and medical and pharmaceutical experts to properly operate and manage RevMate®.

*3: The RevMate® Third-Party Evaluation Committee is a committee independent of BMS and the generics company that periodically inspects and evaluates the operational status of RevMate®. The committee conducts surveys of patients, families, and health care provider involved with RevMate®, examines problems and issues with RevMate®, and makes specific recommendations for improvement. The committee is composed of physicians, pharmacists, lawyers, and other experts, and the Ministry of Health, Labour and Welfare participates as an observer.

Signature of the person giving the consent	I have received an explanation of RevMate® from Prescribing Physician. I understand the things I need to comply with, and I give informed consent.	
	Signature of patient	Date of consent (Year/Month/Day) / /
	Legal representative (Note: Fill in if necessary) (Relationship:)	

Note) If the patient has difficulty signing or giving consent, the legal representative must sign after writing the patient's name in the space for the patient's signature.

Prescribing physician's name	

Please make a copy of this form after entry, give the original to the patient, and retain the copy at the medical institute.

Female B