USE HOSPITAL HEADED PAPER ON PAGE 1

Patient Information Sheet Addendum for Continued Treatment and Consent Form

Patient Initials:_____ Patient number:_____

Main Study Title:	A Phase 3b, Multicenter, Randomized, Open-Label Study of Risankizumab Compared to Vedolizumab for the Treatment of Adult Subjects With Moderate to Severe Ulcerative Colitis Who are Naïve to Targeted Therapies
Protocol Number:	M25-540
EudraCT / EU CT/EUDAMED:	2024-518998-33
Sponsor:	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland
Local Representative of Sponsor	AbbVie Ltd, AbbVie House, Vanwall Road, Maidenhead, Berkshire SL6 4UB, UK
CONTACT INFORMATION:	
Study Doctor:	<<Insert investigator's name>>
Address:	<<Insert clinic and hospital>>
Telephone:	<<Insert site's contact numbers>>
After Hours Telephone:	<<Insert site's after hours contact numbers, if applicable>>
Ethics Committee or other contact information, if applicable	<< Insert Contact details>>

Invitation to take part

You previously signed a separate Patient Information Sheet and Consent Form document to agree to participate in the clinical study, M25-540. The information in the Patient Information Sheet and Consent Form document that you signed still applies. If you need to review the Patient Information Sheet and Consent Form document that you signed, please ask the study doctor for a copy.

The purpose of this Patient Information Sheet Addendum is to ask you if you would like to continue treatment with the AbbVie product AbbVie Risankizumab, because you completed or will soon complete the main study, and your study doctor has confirmed that this is the best treatment option for you at this time.

Choosing to continue treatment with the study product(s) is your decision to make. There will be no penalty or loss of benefits if you do not want to continue treatment, and your decision will not affect your regular medical care. If you decide to continue treatment as part of the study and under your study doctor's supervision, AbbVie will provide the study product(s) at no cost to you, up to approximately 144 weeks.

If you decide to continue treatment with the study drug, you may withdraw from continued treatment at any time by letting the study doctor know. There will be no consequences or penalties if you do this.

Your continued treatment with the study drug as described in this form depends on your study doctor regularly confirming that you are benefiting from and require the treatment.

Procedures for Continued Treatment for Trial Participants

If you wish to continue receiving treatment with the study drug, you will come to your study site every 24 weeks starting at Week 52 to receive study drug for continued maintenance therapy with Risankizumab.

Addition or modification of concomitant medications can be made at the study doctor's discretion.

The results of the urine pregnancy test (only for females who are able to get pregnant) must be negative in order for you to be in the study and take study drug. You need to communicate to your study doctor the results of the urine pregnancy test done at home. If the urine pregnancy test result is positive, you need to tell your study doctor immediately and a blood pregnancy test will be performed in a local laboratory to confirm if you are pregnant.

If you prematurely discontinue your participation, a 140-day follow-up visit (or phone call if a visit is not possible) will be arranged by your study doctor, if applicable.

The Activities Table below will specify the procedures performed during each visit.

Schedule of Activities for Continued Treatment for Trial Participants

Activity	Every 24 Weeks starting at Week 52	PTE Withdrawal/ Completion Visit	Unscheduled Visit	140-Day Follow-Up Call
Informed Consent	X			
Prior/concomitant therapy	X	X	X	X
Adverse Event Assessment	X	X	X	X
Dispense and/or review subject Paper pregnancy and Dosing Diary cards	X	X	X	
Dispense urine pregnancy tests for home testing (for all female subjects of childbearing potential)	X			
Urine Pregnancy Test (for all female subjects of childbearing potential/individuals of childbearing potential)	X	X		
Dispense/administer Study treatment	X			

The study drug will be provided for this purpose until either (i) study drug is approved by the regulatory authority in the country where you participated in the study, and you have reasonable access to it (such as through insurance or your local health system) or (ii) up until approximately Week 196 visit whichever happens first.

Your access to the study drug for continued treatment in this study could be stopped early if:

- Your study doctor determines that you are no longer benefiting from the study drug
- You do not follow your study doctor's instructions
- AbbVie stops developing the study drug
- The research results about how well the study drug works or its safety make ongoing treatment inappropriate; or
- The regulatory authority in the country where you participated in the clinical study does not approve the study drug

Patient Initials:_____ Patient number:_____

CONSENT FORM

Study Title: M25-540: A Phase 3b, Multicenter, Randomized, Open-Label Study of Risankizumab Compared to Vedolizumab for the Treatment of Adult Subjects With Moderate to Severe Ulcerative Colitis Who are Naïve to Targeted Therapies

Principal Investigator: <INSERT NAME>		Please initial each box
1	I confirm that I have read this Ireland CTE ICF Addendum v1.0 22May2025 and all my questions regarding participation in this continued treatment have been answered.	
2	I understand that I *or my Witness* will receive a copy of this signed and dated Patient Information Sheet and Consent Form.	
3	I understand that my participation in this continued treatment is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.	
4	I agree to my GP being informed that I am taking part in this continued treatment and for my GP to provide personal health information that is relevant to my participation in this continued treatment, such as other medicines I am taking.	
5	I agree to continue treatment with the study drug, Risankizumab in the clinical study M25-540.	

_____	____/____/____	_____
Patient Name (print) [or Witness]	Date	Patient Signature [or Witness]

I have fully informed and discussed with the participant this continued treatment. The patient has been given enough time to read the information and appears to understand the nature and purpose of this continued treatment.

_____	____/____/____	_____
Investigator Name (print) (Investigator conducting informed consent discussion)	Date	Investigator Signature

Additional Signature if applicable:

Add role and reason for additional signature requirement (eg. Translator, impartial witness)

Name (print)	Date	Signature
_____ __	__/____/____	_____

When completed; 1 for patient [or 1 for Witness]; 1 for medical notes; original to be kept in Investigator Site File