

## Informed Consent Addendum for Continued Treatment for Trial Participants

<b>Study Title</b>	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
<b>Protocol No.</b>	M25-540
<b>EU CT No.</b>	2024-518998-33
<b>Sponsor</b>	AbbVie Deutschland GmbH & Co, KG, Knollstrasse 67061 Ludwigshafen, Germany
<b>Investigator</b>	Principal investigator name:..... Principal investigator address: ..... Phone number (daytime):..... Phone number (24-hour contact number):.....
<b>Study Site</b>	Study site name: .....
<b>Institutional Review Board</b>	Name: National Bioethics Committee for Medicines and Medical Devices Address: 6 Dr. Grozovici St., Colentina Hospital, Exterior Building C, District 2, Bucharest, Romania, 021105 Phone Number: +4 021.311.53.82 E-mail: secretariat@bioetica-medicala.ro Website: www.bioetica-medicala.ro

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

The purpose of this Informed Consent Addendum is to ask you if you would like to continue treatment with the 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 drug 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 drug 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.

## CONSENT

**Subject name:** \_\_\_\_\_

- I have read this Informed Consent Addendum, and the continued treatment has been explained to me. I have been given the chance to ask questions, and my questions have been answered.
- I will receive a copy of this Informed Consent Addendum after I sign and date it.
- I am not giving up any of my legal rights by signing this form.
- I agree to continue treatment with the study drug, Risankizumab, in the clinical study, M25-540, as described above.

\_\_\_\_\_  
Subject signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Conducting Informed Consent Discussion  
(Printed)

\_\_\_\_\_  
Signature of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Date