The PROGRESS-AD OLE Study

Participant Eligibility Checklist

Study number: 223646 Protocol Version: 21 Mar 2025

Site Number: _____

Principal Investigator: _____

Participant ID (PROGRESS-AD Study 219867): _____

Participant ID (PROGRESS-AD OLE Study 223646): _____

The Sections and Appendices referenced in this Checklist refer to the Protocol for Study 223646, Version 21Mar25.

Inclusion Criteria Participants are eligible to be included in the study only if all of the following criteria apply:	Comments (if applicable)	Yes	No
INC#1 **Completion of the Treatment Period in the parent study.** Participants may have missed doses during the Treatment Period or may be on a temporary dose suspension but must not have been permanently discontinued early from study intervention or withdrawn from the parent study.		☐	☐
INC#2 **Willing and able to give informed consent,** which includes compliance with the requirements and restrictions listed in the ICF and in this protocol. Where local regulations permit the inclusion of participants deemed not to have the capacity to provide informed consent, a legally authorized representative must provide informed consent on the participant's behalf, and the participant must provide assent, in accordance with the local and IRB/IEC regulations and guidelines. A participant's capacity to provide informed consent will be determined by the investigator in accordance with local and IRB/IEC regulations and guidelines.		☐	☐

Inclusion Criteria Participants are eligible to be included in the study only if all of the following criteria apply:	Comments (if applicable)	Yes	No
INC#3 **Availability of an adult person ("study partner")** who, in the investigator's opinion, has frequent and sufficient contact with the participant (e.g., at least 8 hours per week of in-person contact), is able to provide accurate information regarding the participant's cognitive and functional abilities, agrees to provide information at clinic visits (only those visits which require study partner input for efficacy assessments), and signs the study partner ICF. • The study partner must have sufficient cognitive capacity, in the investigator's opinion, to accurately report on the participant's behavior and cognitive and functional abilities throughout the study duration. The study partner must be in sufficiently good general health, in the investigator's opinion, to have a high likelihood of maintaining the same level of interaction with the participant and participation in study procedures. • Every effort should be made to have the same study partner from the parent study also participate in the OLE study and continue to participate throughout the duration of the OLE study. If the initial study partner can no longer continue in the study, a replacement study partner meeting the same criteria must be available for the participant to continue in the study. • The study partner does not have to live in the same residence as the participant. If the study partner does not reside with the participant, the investigator must be satisfied that the participant can access or contact the study partner readily. If in doubt about whether a participant's care arrangements are suitable for inclusion, the investigator should discuss this with the medical monitor for adjudication.		☐	☐
INC#4 **A female participant is eligible to participate if she is not pregnant or breastfeeding** and one of the following conditions applies: • Is a WONCBP as defined in Appendix 4 (Section 10.4) OR • Is a WOCBP as defined in Appendix 4 (Section 10.4) and is using a contraceptive method that is highly effective, with a failure rate of <1%, as described in Appendix 4 (Section 10.4) from at least 14 days prior to the first dose of study intervention until at least 12 weeks after the last administered dose of study intervention. • A WOCBP must have a negative, highly sensitive urine pregnancy test within 24 hours before the first dose of study intervention. Additional requirements for pregnancy testing during and after study intervention are provided in the SoA (See Section 1.3). • Contraceptive use by women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. • The investigator should evaluate the potential for contraceptive method failure (e.g., noncompliance, recently initiated in relationship to the first dose of study intervention). • The investigator is responsible for review of medical history, menstrual history and recent sexual activity to decrease the risk for inclusion of a woman with an early undetected pregnancy. Note: If the childbearing potential changes after start of the study or the risk of pregnancy changes (e.g., a female participant who is not heterosexually active becomes active), the participant must discuss this with the investigator, who should determine if a female participant must begin a highly effective method of contraception. If reproductive status is questionable, additional evaluation should be considered.		☐	☐

Inclusion Criteria Participants are eligible to be included in the study only if all of the following criteria apply:	Comments (if applicable)	Yes	No

INC#5
Male participants are eligible to participate if they agree to the following during the study and for at least 12 weeks after the last dose of study intervention, corresponding to the time needed to eliminate study intervention (5 terminal half-lives) plus an additional 90 days (a spermatogenesis cycle):
• Refrain from donating sperm.
PLUS either:
• Be abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent,
OR
• Must agree to use contraception/barrier if engaging in heterosexual intercourse with a woman of childbearing potential, as follows:
  • Agree to use a male condom; and
  • Female partner to use an additional highly effective contraceptive method with a failure rate of <1% per year as described in Appendix 4.
		☐	☐

INC#6 **Participant agrees not to donate blood or blood products for transfusion** for the duration of the study and for 12 weeks after the last dose of study intervention.		☐	☐

Exclusion criteria Participants are excluded from the study if any of the following criteria apply:	Comments (if applicable)	Yes	No
EXC#1 **QTc assessment at Day 1 (local read) that meets the stopping criteria** in Section 7.1.2.		☐	☐
EXC#2 **Participant is taking or will be starting a prohibited medication** as described in Section 6.9.		☐	☐
EXC#3 **Evidence of any ARIA or cerebral macrohemorrhage that meets the permanent discontinuation criteria** in Section 7.1.3.1. Note: Participants with an ARIA event (as reported from the most recent MRI scan) which does not require permanent discontinuation of study intervention by the criteria in the parent study are not excluded from the OLE, but their dosing will follow the guidelines in Section 8.7.4.2.		☐	☐
EXC#4 **Other newly identified intracranial hemorrhage aneurysm, vascular malformation, infective lesion, space occupying lesion or brain tumor, or other MRI findings contraindicating participation in the study** (e.g., subarachnoid hemorrhage).		☐	☐
EXC#5 **Newly identified infection(s) that may affect the CNS** (e.g., HIV, syphilis, neuroborreliosis, or viral or bacterial meningitis/encephalitis).		☐	☐
EXC#6 **New diagnosis of moderate to severe alcohol and/or substance use disorder** (according to the Diagnostic and Statistical Manual of Mental Disorders [DSM], 5th Edition).		☐	☐
EXC#7 **Change in participant's ability to tolerate MRI procedures** (e.g., due to anxiety or claustrophobia) **or participant has a contraindication to MRI** (e.g., the presence of pacemakers that are not MRI-compatible, aneurysm clips, artifical heart valves, ear implants, or foreign metal objects in the eyes, skin, or body that would contraindicate an MRI scan) or any other clinical history or examination finding that would pose a potential hazard in combination with MRI. Those who can tolerate MRI with intermittent use of sedative medication as per local practice do not need to be excluded.		☐	☐
EXC#8 **Newly diagnosed cancer,** except any of the following: • Surgically excised and not being actively treated with anticancer therapy or radiotherapy and is not likely to require treatment in the ensuing 3 years except for adjuvant hormonal therapy for localized breast cancer. • Localized prostate cancer with no treatment required. • Localized basal cell carcinoma or squamous cell carcinoma of skin that has been excised with clear margins (i.e., melanoma with metastases would be excluded).		☐	☐

Exclusion criteria Participants are excluded from the study if any of the following criteria apply:	Comments (if applicable)	Yes	No
EXC#9 **Newly identified severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric, human, or humanized antibodies or fusion proteins.**		☐	☐
EXC#10 **Newly identified genetic predisposition for clotting disorder or hemorrhagic disease.**		☐	☐
EXC#11 **Any other clinically significant change in health status** (based on medical history, neurological and physical examination, laboratory investigations, MRI, vital signs and ECGs) during the parent study which, in the opinion of the investigator, would make the participant unsuitable for participation in the OLE study. This includes a participant who permanently moved to a skilled nursing facility, convalescent home, or long-term care facility during the parent study and will not be able to be followed for efficacy and safety (in the opinion of the investigator) and/or does not continue to have a study partner who meets the minimum requirements mentioned above.		☐	☐
EXC#12 **Any other issue which, in the opinion of the investigator, would compromise participant safety or the integrity of the study data.**		☐	☐