

**WELCOME
TO THE
1002-CL-0101
STUDY**



A Study Visit Guide



1002-CL-0101
STUDY



Thank You for Participating in the 1002-CL-0101 Study


This visit guide was created to help you through this study. It outlines important information like what you can expect during upcoming visits, as well as how long these visits may be.

You will also find important **Study Contact Information** on the back of this guide.

While participating in the 1002-CL-0101 study, and as stated in the Informed Consent Form:

- Participation in the study is completely voluntary.
- You can end your participation at any time, for any reason.
- If you decide not to participate in this study, or if you stop taking part, your medical care now or in the future will not be affected.

Please tell your current doctors that you are participating in this study. This guide does not replace talking with your doctors or the study staff.

 **Reminder:** The details of all tests and procedures required for the study are available in the Informed Consent Form.

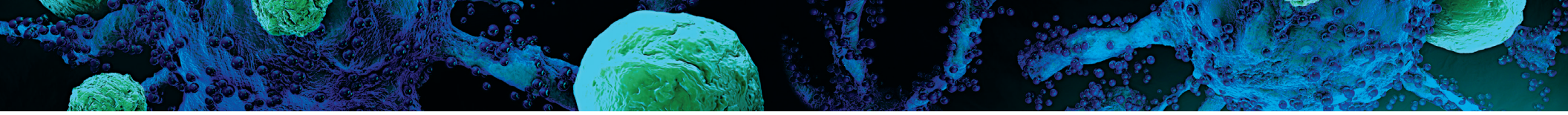
If you have questions about how to use this study visit guide, please ask your study staff. For your convenience, you may jot down any notes or questions you may have in the “Notes” section on page 15 of this guide.

If you have any changes in your health during this study, please be sure to tell the study doctor. You may use the “Health Changes” section on page 14 of this guide to make note of those changes.

Overview of the 1002-CL-0101 Study

This study includes three periods:

- I. Screening:** (up to 4 weeks): to see if this study is right for you
- II. Treatment:** (up to 2 years or more): includes weekly visits to the study site to receive treatment
 - **End of Treatment:** within 7 days of the last dose of ASP1002
- III. Follow-up:** (at study end): includes the following visits to monitor your health as a follow-up to your participation (the site will send you a letter/email for a questionnaire to complete):
 - **Safety Follow-up:** 1 month and 3 months after the last dose of ASP1002
 - **Post-treatment Follow-up (as needed):** may include some lab tests and/or tumor imaging every 9 weeks for up to one year
 - **Long-term Follow-up:** may be every 3 months for up to one year after the final safety follow-up



The Screening Period (up to 4 weeks)

The screening period involves several tests, procedures, and assessments to determine your eligibility for the 1002-CL-0101 study.

During the screening period, you will:

- Have your medical and disease history reviewed
- Discuss the medications you are taking
- Have a physical examination, your vital signs taken and your weight and height measured
- Have your day-to-day living skills evaluated
- Have an electrocardiogram
- Provide blood and urine samples for testing
- Take a pregnancy test, if appropriate
- Asking you how you feel on a day-to-day basis

You may also have had the following assessments at an outside facility:

- Echocardiogram
- Tumor imaging scans, such as CT or MRI
- Tumor biopsy, if needed

The Treatment Period

What to Expect When Treatment Begins

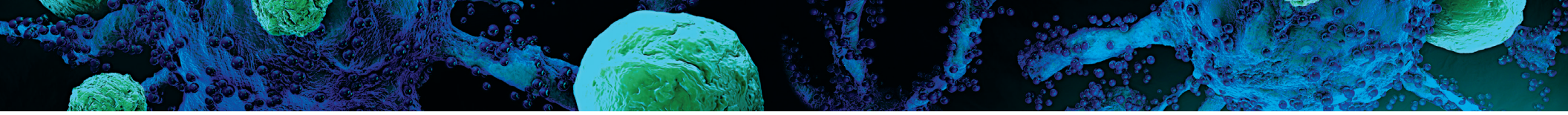
The treatment period may last up to 2 years. Please note that Cycles 1 and 2 will have more frequent visits to the study site, with some of the visits not requiring treatment (assessments only). Each cycle is 3 weeks, or 21 days.

You will have treatment visits every week. The study medication will be given to you through an IV (in the vein) infusion. After your infusion, the study team will observe you and how you are reacting to the infusion. The observation period for Cycles 1 and 2 is 4 hours and then 2 hours for all later cycles.

During the study you will need to have tumor imaging like CT and/or MRI scans every 9 weeks. Your doctor may request additional procedures like echocardiograms, imaging, and tumor biopsies, if needed.

All visits will include a discussion on your current/changes to your medications and how you are feeling.

The following pages will detail what is performed at each treatment cycle. If you have questions about the treatment period, please ask your study doctor.



Cycle 1

Cycle 1, Day 1: Appointment Date and Time: _____

- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken and weight measured
- Have your day-to-day living skills evaluated
- Provide blood and urine samples for laboratory testing
- Have electrocardiograms
- Take a pregnancy test, if applicable
- Receive the study medication

Cycle 1, Day 2: Appointment Date and Time: _____

- Have your vital signs taken
- Provide blood samples
- Have electrocardiograms

Cycle 1, Day 4: Appointment Date and Time: _____

- Have a physical examination and your vital signs taken
- Provide blood and urine samples for laboratory testing
- Have electrocardiograms

Cycle 1, Day 8: Appointment Date and Time: _____

- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken
- Provide blood and urine samples for laboratory testing
- Have electrocardiograms
- Receive the study medication

Cycle 1, Day 11: Appointment Date and Time: _____

- Have your vital signs taken
- Provide blood and urine samples for laboratory testing

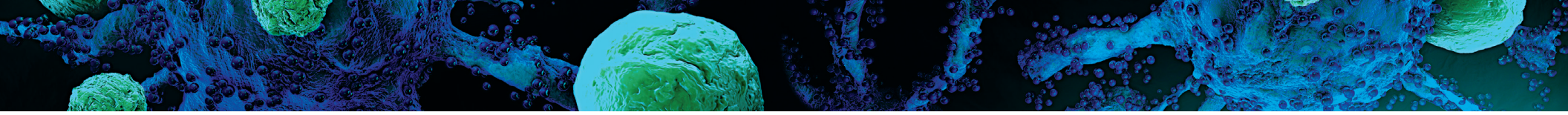
Cycle 1, Day 15: Appointment Date and Time: _____

- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken
- Provide blood and urine samples for laboratory testing
- Have electrocardiograms
- Receive the study medication

Cycle 2

Cycle 2, Day 1: Appointment Date and Time: _____

- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken and weight measured
- Have your day-to-day living skills evaluated
- Provide blood and urine samples for laboratory testing
- Have electrocardiograms
- Take a pregnancy test, if applicable
- Receive the study medication



Cycle 2 (cont.)

Cycle 2, Day 2: Appointment Date and Time: _____

- Have your vital signs taken
- Have blood samples taken
- Have electrocardiograms

Cycle 2, Day 4: Appointment Date and Time: _____

- Have your vital signs taken
- Have blood samples taken
- Have electrocardiograms

Cycle 2, Day 8: Appointment Date and Time: _____

- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken
- Provide a tumor tissue sample
- Provide blood and urine samples for laboratory testing
- Have electrocardiograms
- Receive the study medication

Cycle 2, Day 15: Appointment Date and Time: _____

- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken
- Provide blood and urine samples for laboratory testing
- Have electrocardiograms
- Provide a tumor tissue sample
- Receive the study medication

Cycle 3 and later cycles

Cycle 3, Day 1: Appointment Date and Time: _____

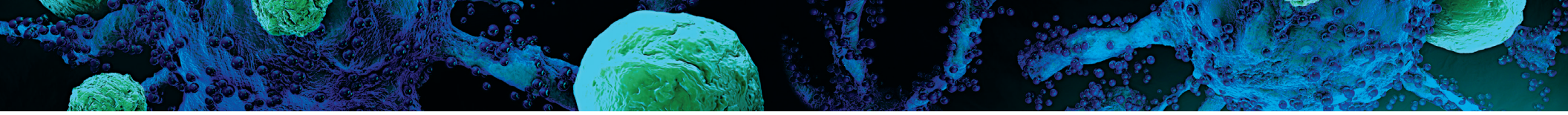
- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken and weight measured
- Have your day-to-day living skills evaluated
- Provide blood and urine samples for laboratory testing
- Have an electrocardiogram(s)
- Take a pregnancy test, if applicable
- Receive the study medication

Cycle 3, Day 8: Appointment Date and Time: _____

- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken
- Have an electrocardiogram(s)
- Receive the study medication

Cycle 3, Day 15: Appointment Date and Time: _____

- Have a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and your vital signs taken
- Have an electrocardiogram(s)
- Receive the study medication



Appointments beyond Cycle 3

Cycle 4, Day 1: Appointment Date and Time: _____

Cycle 4, Day 8: Appointment Date and Time: _____

Cycle 4, Day 15: Appointment Date and Time: _____

Cycle 5, Day 1: Appointment Date and Time: _____

Cycle 5, Day 8: Appointment Date and Time: _____

Cycle 5, Day 15: Appointment Date and Time: _____

Cycle 6, Day 1: Appointment Date and Time: _____

Cycle 6, Day 8: Appointment Date and Time: _____

Cycle 6, Day 15: Appointment Date and Time: _____

Later cycles/appointment dates will be provided by study team.

End of Treatment: Appointment Date and Time: _____

What to Expect When Treatment Ends

You will be asked to complete an End of Treatment visit within 7 days of completing the study treatment or if you choose to leave the study before the end of the treatment period.

During this visit your study team will:

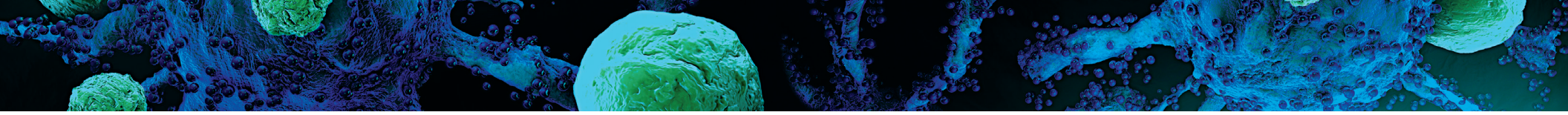
- Review past and current medications
- Discuss any side effects you may be experiencing
- Evaluate your daily activities and physical abilities
- Have an electrocardiogram

Your study team may also:

- Conduct a physical exam, including an evaluation of your mental status, reflexes, coordination and movements (may include imaging), and measure your vital signs and weight
- Take blood and urine samples for testing
- Give you a pregnancy test, if applicable
- And, if needed or requested:
 - Perform a CT and/or MRI
 - Conduct chest x-rays and/or echocardiogram
 - Collect a tumor biopsy

You will also be invited to respond to an optional Study Participant Feedback Questionnaire regarding your experience participating in this study. The study staff will provide you with a letter from Astellas with instructions.

If you have questions about the end of treatment/early termination visit, please ask your study doctor.



What to Expect During the Follow-up Period

Follow-up Period:

- **Safety Follow-up:** 1 month and 3 months after the last dose of ASP1002
- **Post-treatment Follow-up (as needed):** may include some lab tests and/or tumor imaging every 9 weeks for up to one year
- **Long-term Follow-up:** may be every 3 months for up to one year after the final safety visit

Safety Follow-up visits are required for your safety and will occur 1 month and 3 months after the last dose of ASP1002.

1 Month Safety Follow-up Visit Appointment Date and Time: _____

3 Month Safety Follow-up Visit Appointment Date and Time: _____

During these visits you will:

- Talk about how you are feeling and any side effects you may be experiencing
- Discuss the medications you are taking
- Have your vital signs taken
- Have your day-to-day living skills evaluated
- Have electrocardiograms
- Provide blood and urine samples for testing

If needed or requested you may also have:

- Tumor imaging (every 9 weeks for up to one year) and/or follow-up neurologic scans
- Chest x-rays and/or echocardiogram
- Central nervous system imaging

Post-treatment Follow-up visits are only required if needed. These visits may include lab tests, tumor imaging every 9 weeks for up to one year, and/or follow-up neurologic scans.

Appointment Date and Time: _____

Appointment Date and Time: _____

Appointment Date and Time: _____

Appointment Date and Time: _____

Appointment Date and Time: _____

Appointment Date and Time: _____

Long-term Follow-up: A member of the study team will call you every 3 months for up to 1 year to see how you are doing.

Appointment Date and Time: _____

Appointment Date and Time: _____

Appointment Date and Time: _____

Appointment Date and Time: _____



STUDY SITE CONTACT INFORMATION

*If you are experiencing a medical emergency,
please call emergency services in your country.*



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