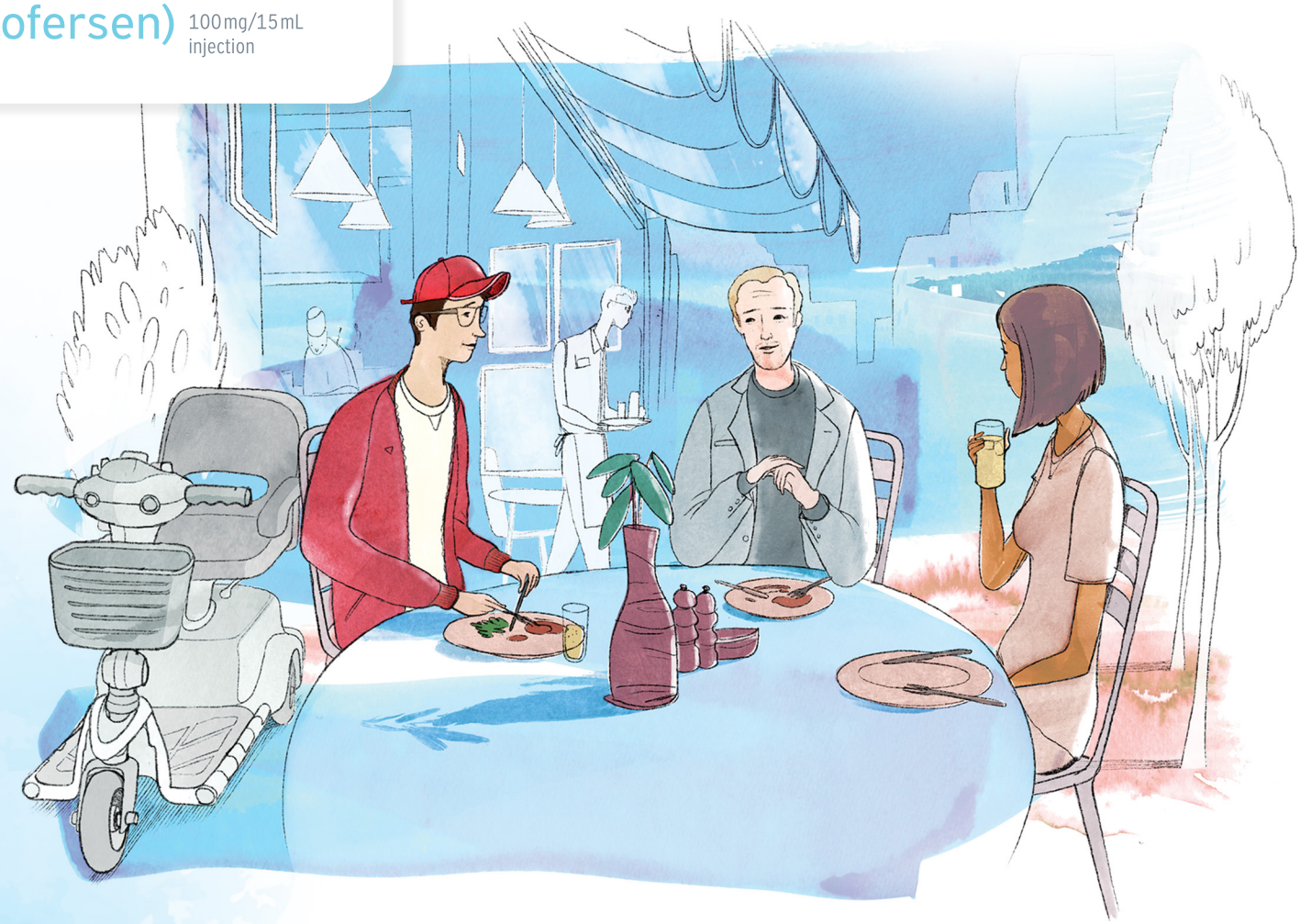
QALSODY®
(tofersen) 100 mg/15 mL injection



Treatment that targets a genetic cause of ALS is here

QALSODY® (tofersen) is a prescription medicine used to treat adults with amyotrophic lateral sclerosis (ALS) who have a mutation, or change, in the superoxide dismutase 1 *(SOD1)* gene. QALSODY is approved under accelerated approval based on reduction in neurofilament light chain (NfL) in the blood observed in patients treated with QALSODY. Continued approval of QALSODY may require verification of clinical benefit in a confirmatory study.

IMPORTANT SAFETY INFORMATION

What is the most important information that I should know about QALSODY?

QALSODY can cause serious side effects, including:

- **Inflammation of the spinal cord (myelitis) and/or irritation of the nerve roots (radiculitis),** including serious cases, have been reported in patients treated with QALSODY. Six patients treated with QALSODY experienced inflammation of the spinal cord or irritation of the nerve roots in the clinical studies. Two patients stopped treatment with QALSODY and their symptoms resolved with treatment. In the remaining 4 patients, symptoms resolved without stopping QALSODY. If you experience common symptoms such as abnormal sensations (pins and needles), numbness, or weakness, please contact your healthcare provider. Your healthcare provider can help you determine how to address symptoms, and may recommend that you stop taking QALSODY.

Please see additional Important Safety Information throughout and click for full Prescribing Information.

What is *SOD1*-ALS?

SOD1-ALS is a type of **genetic ALS** associated with a change or mutation in the *SOD1* gene

ALS is often categorized as either familial (fALS) or sporadic (sALS). **But anyone whose ALS has a genetic component is considered to have genetic ALS**—regardless of a known family history of the disease. People living with ALS whose genetic testing results reveal a mutation in *SOD1* are considered to have *SOD1*-ALS.

What is the role of neurofilament in *SOD1*-ALS?

The connection between *SOD1*, neurofilaments, and ALS

When a person has a mutation in the *SOD1* gene, it produces mutated SOD1 protein in the brain and spinal cord. Over time, the buildup of mutated SOD1 protein can kill nerve cells that control muscle movement. **This can result in the symptoms of *SOD1*-ALS.**

When nerve cells are damaged or destroyed, structural components called neurofilaments are released. The more that mutated SOD1 protein builds up, the more nerve cells are killed—leading to elevated neurofilament levels in cerebrospinal fluid (CSF) and blood. **Given these connections, the level of neurofilament is thought to be an important prognostic marker of disease progression in ALS.**

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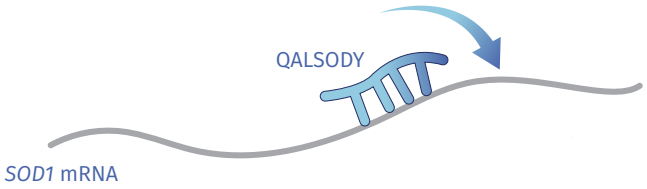
QALSODY is an FDA-approved treatment specifically for people with *SOD1*-ALS

Continued approval for this indication may depend upon confirmation of clinical benefit in additional trials.

QALSODY is a type of therapy called an antisense oligonucleotide (ASO). ASOs are able to bind directly to specific mRNA to change the amount of protein produced by the body.



QALSODY binds to *SOD1* mRNA, a molecule that carries instructions for making SOD1 protein

***SOD1* mRNA is degraded, which results in less SOD1 protein being made**

IMPORTANT SAFETY INFORMATION (cont.)

What is the most important information that I should know about QALSODY? (cont.)

QALSODY can cause serious side effects, including: (cont.)

- **Swelling of the optic nerve (papilledema) and increased pressure inside the skull (elevated intracranial pressure)**, including serious cases, have been reported in patients treated with QALSODY. The optic nerve connects the eyes with the brain and is responsible for vision. Four patients developed increased pressure inside the skull and/or swelling of the optic nerve. All patients received treatment from their healthcare provider that resolved these symptoms, and no events led to stopping QALSODY. If you experience common symptoms of swelling of the optic nerve such as blurred vision, double vision, or vision loss, please contact your healthcare provider. If you experience symptoms of increased pressure inside the skull, such as headache, vomiting, or numbness or weakness, please contact your healthcare provider.

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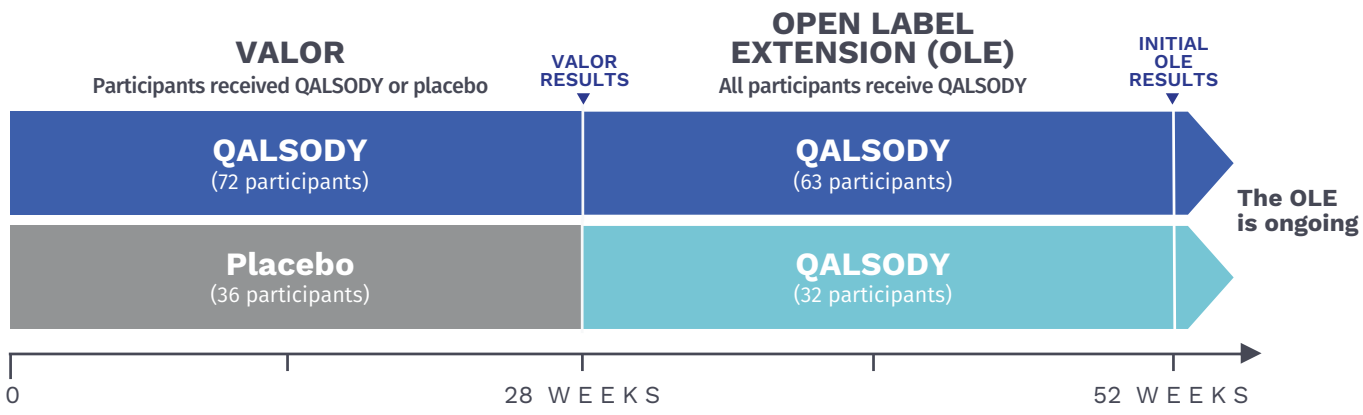
Clinical studies

The VALOR trial (Study 1 Part C) lasted 28 weeks, and the results were analyzed at the end of the study. At the end of VALOR, all remaining participants were given the opportunity to continue in the open-label extension (OLE) study. All participants enrolled in the OLE study were treated with QALSODY.

There was an initial analysis of the OLE study when all participants had the opportunity to complete 52 weeks of treatment. This allowed the researchers to compare results of participants who started QALSODY at the start of the VALOR study to those who only received QALSODY later during the OLE study.



IMPORTANT SAFETY INFORMATION (cont.)

What is the most important information that I should know about QALSODY? (cont.)

QALSODY can cause serious side effects, including: (cont.)

- **Inflammation of the brain linings (aseptic meningitis, also called chemical meningitis or drug-induced aseptic meningitis)**, including serious cases, have been reported in patients treated with QALSODY. One patient experienced a serious side effect of inflammation of the brain linings, which led to the patient stopping QALSODY. One patient experienced a serious side effect of inflammation of the brain linings, which did not lead to the patient stopping QALSODY. In addition, nonserious side effects that can be signs of inflammation or infection have also been reported with QALSODY, including increased white blood cells and increased protein in the cerebrospinal fluid (the fluid around the spinal cord and the brain). If you experience symptoms such as headache, fever, vomiting, neck stiffness, nausea or vomiting, please contact your healthcare provider.

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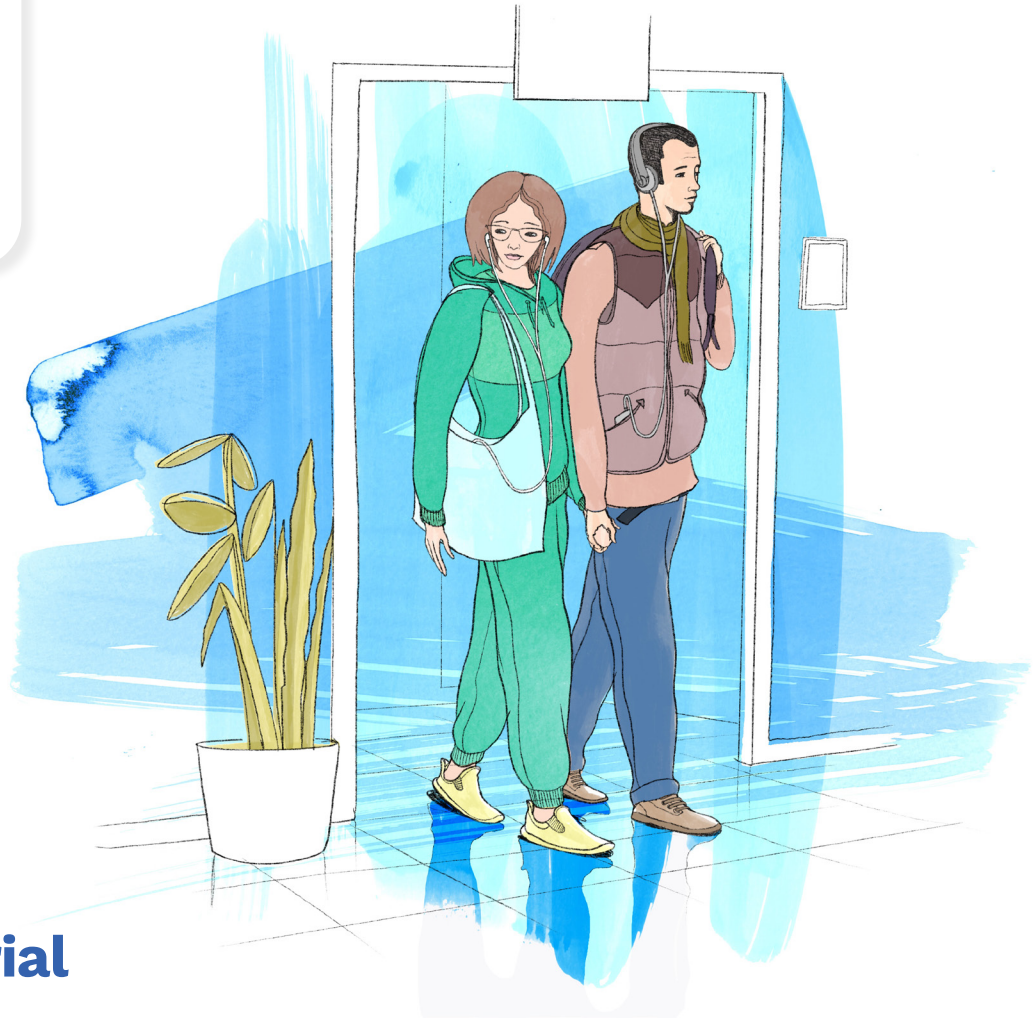

The VALOR trial

How was QALSODY studied in the VALOR trial?

- **Placebo controlled**, which means the study was designed to compare QALSODY to a placebo drug (an inactive substance that looks the same as, and is given the same as, an active drug being tested). Everything else in the study was the same for all participants. Then, researchers compare the effects in each group to determine whether the new treatment works. This allows researchers to understand if QALSODY had any effect on the study outcomes
- **Randomized 2:1**, which means that participants were randomly assigned to receive QALSODY or the placebo. Twice as many participants were given QALSODY as placebo
- **Double-blind**, which means neither the participants nor the study doctors or staff knew if the participants received QALSODY or the placebo

IMPORTANT SAFETY INFORMATION (cont.)

What should I tell my healthcare provider before I start using QALSODY?

Before taking QALSODY, tell your healthcare provider if you are pregnant, plan to become pregnant, or are breastfeeding or plan to breastfeed.

Please see additional Important Safety Information throughout and click for full Prescribing Information.

QALSODY® (tofersen) 100 mg/15 mL injection

Who participated in VALOR?

VALOR studied the effectiveness and safety of QALSODY compared to placebo in people with weakness due to ALS who have a mutation, or change, in the superoxide dismutase 1 *(SOD1)* gene.

A total of 108 people with *SOD1*-ALS participated in VALOR

- **72 participants received QALSODY 100 mg**
- **36 participants received placebo**

Participants received treatment for 24 weeks (3 loading doses followed by 5 maintenance doses).

Participants were allowed to also take riluzole and/or edaravone during the study.

VALOR participants were determined to either have faster progressing *SOD1*-ALS or slower progressing *SOD1*-ALS

The faster progressing group was the *Primary analysis population* that included 60 participants who met the following conditions:

- Had a slow vital capacity, or SVC, (a measure of breathing function) ≥65% of percent ***Predicted value***
- Exhibited more rapid decline based on the ***ALSFRS-R*** before the start of the study
- Had a specific type of *SOD1* mutation associated with faster disease progression

The slower progressing group included 48 participants who met the following criteria:

- Had an SVC (a measure of breathing function) ≥50% of ***Predicted value***
- Did not meet criteria for inclusion in the ***Primary analysis population***

GLOSSARY

Primary analysis population is made up of the participants in the trial who are chosen to have their results studied based on the criteria they met before the trial began. In VALOR, the results for this group of people are what the researchers used to answer their main question about the effectiveness of QALSODY (the primary endpoint).

Predicted value compares the volume (amount) of air a person breathes out while relaxed to an average of the normal volume for a person of the same sex, height, and age. This is shown as a percentage, with normal test values falling between 80% and 120% of the average (predicted) values.

ALSFRS-R measures 12 aspects of physical function, ranging from one's ability to swallow and use utensils to climbing stairs and breathing. Each function is scored from 4 (normal) to 0 (no ability), with a maximum total score of 48 and a minimum total score of 0.

IMPORTANT SAFETY INFORMATION (cont.)

What are the possible side effects of QALSODY?

QALSODY can cause serious side effects. See "What is the most important information I should know about QALSODY?" in the full Important Safety Information on page 15.

Please see additional Important Safety Information throughout and click for full Prescribing Information.

QALSODY®
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The VALOR trial

What were participants' baseline characteristics?

Baseline disease characteristics

- ***Baseline disease characteristics*** were generally similar between those treated with QALSODY and those who received placebo. However, the QALSODY group had:
  - Slightly shorter time from when symptoms began
  - Higher blood levels of neurofilament (a blood-based marker of nerve damage and deterioration) at the start of the study
- 62% of participants were taking riluzole, and 8% of participants were taking edaravone
- The average ***ALSFRS-R*** score at the start of the study was 36.9 in the QALSODY treatment group and 37.3 in the placebo group
- The average time from symptoms beginning was 49.5 weeks in the QALSODY treatment group and 63.4 weeks in the placebo group

What question was VALOR designed to answer?

The primary outcome, or main question VALOR was designed to answer, was:

In participants who met the criteria for faster progressing disease, how much did their *ALSFRS-R* scores change at 28 weeks compared to the start of the study?

- These results were examined using statistical methods to reduce the risk of bias or unsupportable conclusions that may have been caused by patient deaths during the trial, as well as to account for missing data (for withdrawals other than death)

GLOSSARY

Baseline characteristics are information about a study participant such as demographics (such as age, gender, race) or medical information (such as lab results or measures of function or abilities) that are collected at the beginning of a study. This helps researchers understand how similar study participants are to the broader population of people living with a condition, whether there were major differences between the active treatment and placebo study groups, and how a person's disease status and functioning may have changed after they received the treatment being studied (QALSODY or placebo).

ALSFRS-R measures 12 aspects of physical function, ranging from one's ability to swallow and use utensils to climbing stairs and breathing. Each function is scored from 4 (normal) to 0 (no ability), with a maximum total score of 48 and a minimum total score of 0.

IMPORTANT SAFETY INFORMATION (cont.)

What are the possible side effects of QALSODY? (cont.)

The most common side effects reported in patients treated with QALSODY were pain (back pain, pain in arms or legs), feeling tired, joint pain, increased white blood cell count in the cerebrospinal fluid (CSF), and muscle pain.

Please see additional Important Safety Information throughout and click for full Prescribing Information.

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VALOR results

What were the results of VALOR?

Participants who received QALSODY experienced less decline in average *ALSFRS-R* scores compared to the placebo group, but the results *were not Statistically significant* (QALSODY-placebo *Adjusted mean difference [95% CI]*: 1.2 [-3.2, 5.5]).

Other secondary clinical outcomes were also studied in VALOR. These are other questions that may help researchers learn more about the main question or provide new answers in the study. These secondary outcomes in the QALSODY group *were not Statistically significant*.

GLOSSARY

ALSFRS-R measures 12 aspects of physical function, ranging from one's ability to swallow and use utensils to climbing stairs and breathing. Each function is scored from 4 (normal) to 0 (no ability), with a maximum total score of 48 and a minimum total score of 0.

Statistically significant is a mathematical term used to describe an outcome that is likely to be due to the treatment rather than occurring by chance. If a result is not statistically significant, it means that a result is not likely to be due to a treatment.

Adjusted mean difference is the average difference between the QALSODY group and the placebo group. The averages are adjusted for variables that may be related to the results of the study, including the level of disease before starting treatment, the duration of disease, and if participants had used riluzole or edaravone or not.

95% CI, or confidence interval, means that if the study were run again with a similar patient population and the same study design, the results would be likely to fall within this range. In VALOR, researchers were 95% confident that the average change in ALSFRS-R scores would fall between a 3.2-point decline and a 5.5-point improvement.

IMPORTANT SAFETY INFORMATION (cont.)

What are the possible side effects of QALSODY? (cont.)

These are not all the possible side effects of QALSODY. Please talk to your healthcare provider if you experience any of these symptoms, or other new symptoms that concern you.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

This information is not intended to replace discussions with your healthcare provider.

Please see additional Important Safety Information throughout and click for full Prescribing Information.

QALSODY® (tofersen) 100 mg/15 mL injection

VALOR results (continued)

Why was QALSODY approved?

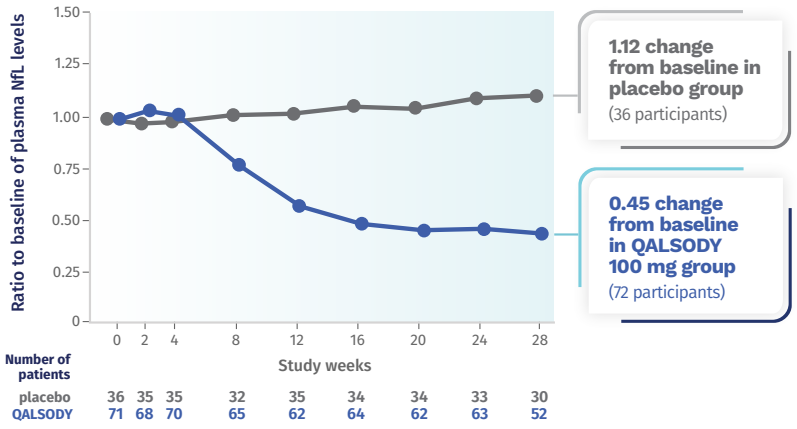
Neurofilament light chain, or NfL, is a blood-based biomarker of nerve damage and deterioration.

QALSODY® (tofersen) is a prescription medicine used to treat adults with amyotrophic lateral sclerosis (ALS) who have a mutation, or change, in the superoxide dismutase 1 *(SOD1)* gene. QALSODY is approved under accelerated approval based on reduction in NfL in the blood observed in patients treated with QALSODY. Continued approval for QALSODY may depend on results of additional studies to confirm that there is a clinical benefit.

After 28 weeks, NfL levels in the blood decreased an average of 55% (***Geometric mean ratio to baseline***) from the start of the study in the QALSODY-treated participants and increased by 12% (***Geometric mean ratio to baseline***) from the start of the study in the placebo group. The ***Difference in geometric mean ratios*** between the QALSODY-treated participants and the placebo group was 60%.

NfL levels in the blood declined for approximately 113 days, then the reductions leveled off.

Blood NfL adjusted Geometric mean ratio to baseline levels for all participants in VALOR



Placebo group (36 participants)
12% INCREASE from the start of the study to Week 28

QALSODY group (72 participants)
55% DECREASE from the start of the study to Week 28

Difference in geometric mean ratios: **60% (95% CI): (0.33, 0.49).**

Continued approval for QALSODY may depend on results of additional studies to confirm that there is a clinical benefit.

GLOSSARY

Geometric mean ratio to baseline measures the change in the average NfL levels in each study group at the time of analysis at Week 28 compared to each study group's NfL measurement at baseline (the start of the study).

Difference in geometric mean ratios is the difference between the ***Geometric mean ratios to baseline*** (see definition) between the QALSODY group and the placebo group.

What is QALSODY?

QALSODY® (tofersen) is a prescription medicine used to treat adults with amyotrophic lateral sclerosis (ALS) who have a mutation, or change, in the superoxide dismutase 1 *(SOD1)* gene. QALSODY is approved under accelerated approval based on reduction in neurofilament light chain (NfL) in the blood observed in patients treated with QALSODY. Continued approval of QALSODY may require verification of clinical benefit in a confirmatory study.

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QALSODY® (tofersen) 100 mg/15 mL injection

Safety and side effects

QALSODY can cause serious side effects, including the following

- **Inflammation of the spinal cord (myelitis) and/or irritation of the nerve roots (radiculitis)**, including serious cases, have been reported in patients treated with QALSODY
- Six patients treated with QALSODY experienced inflammation of the spinal cord or irritation of the nerve roots in the clinical studies
- Two patients stopped treatment with QALSODY and their symptoms resolved with treatment. In the remaining 4 patients, symptoms resolved without stopping QALSODY
- If you experience common symptoms such as abnormal sensations (pins and needles), numbness, or weakness, please contact your healthcare provider
- Your healthcare provider can help you determine how to address symptoms, and may recommend that you stop taking QALSODY
- **Swelling of the optic nerve (papilledema) and increased pressure inside the skull (elevated intracranial pressure)**, including serious cases, have been reported in patients treated with QALSODY
- The optic nerve connects the eyes with the brain and is responsible for vision
- Four patients developed increased pressure inside the skull and/or swelling of the optic nerve
- All patients received treatment from their healthcare provider that resolved these symptoms, and no events led to stopping QALSODY
- If you experience common symptoms of swelling of the optic nerve such as blurred vision, double vision, or vision loss, please contact your healthcare provider
- If you experience symptoms of increased pressure inside the skull, such as headache, vomiting, or numbness or weakness, please contact your healthcare provider
- **Inflammation of the brain linings (aseptic meningitis, also called chemical meningitis or drug-induced aseptic meningitis)**, including serious cases, have been reported in patients treated with QALSODY
- One patient experienced a serious side effect of inflammation of the brain linings, which led to the patient stopping QALSODY
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- In addition, nonserious side effects that can be signs of inflammation or infection have also been reported with QALSODY, including increased white blood cells and increased protein in the cerebrospinal fluid (the fluid around the spinal cord and the brain)
- If you experience symptoms such as headache, fever, vomiting, neck stiffness, nausea or vomiting, please contact your healthcare provider

IMPORTANT SAFETY INFORMATION

What is the most important information that I should know about QALSODY?

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Safety and side effects (continued)

It is important to talk with your doctor about the potential benefits and risks of any medication

Most common side effects associated with QALSODY seen in VALOR were:	
Side effect	**Percentage of patients**
Pain (back pain, pain in the arms or legs)	42%
Feeling tired	17%
Joint pain	14%
Increased white blood cell count in the cerebrospinal fluid (CSF)	14%
Muscle pain	14%

Talk to your doctor for more information about QALSODY

IMPORTANT SAFETY INFORMATION (cont.)

What is the most important information that I should know about QALSODY? (cont.)

QALSODY can cause serious side effects, including: (cont.)

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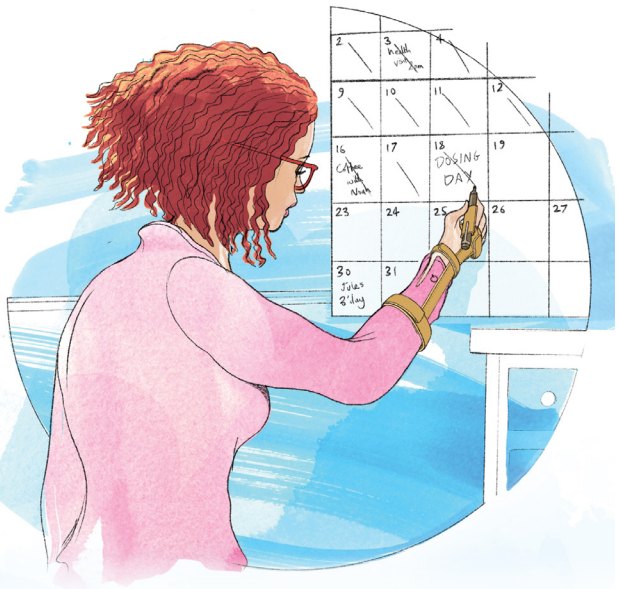
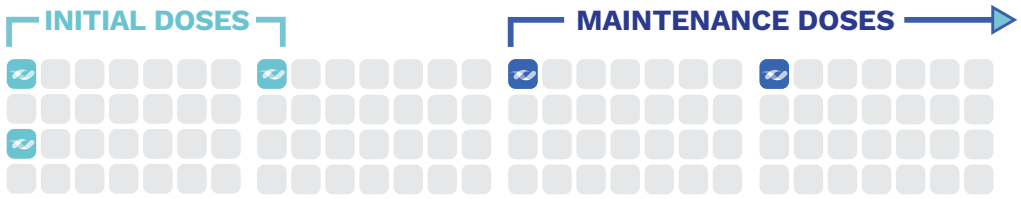


Taking QALSODY

The initial QALSODY doses are administered as loading doses. These are given **14 days apart** to build up levels of QALSODY in the body. This level is then maintained with the maintenance doses, which are more spaced out (**28 days apart**).

After an initial dosing period, QALSODY is administered once every 28 days



Loading doses are administered at **14-day intervals**
(Doses 1 through 3)

Maintenance doses are given once **every 28 days** thereafter
(Dose 4 and onward)

QALSODY is an intrathecal injection, or an injection into the fluid of the spine, given by a healthcare provider experienced in performing lumbar punctures.

IMPORTANT SAFETY INFORMATION (cont.)

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Support and resources

Biogen Support Services is here to support patients receiving QALSODY

As soon as you're prescribed QALSODY, we can provide help with financial, insurance, or treatment education. Remember, your healthcare team is always your best source of information.

Biogen Support Coordinators

Get one-on-one phone support, access to resources, and helpful information.

Financial and insurance assistance

From understanding insurance coverage to exploring financial assistance options, we will connect you with the appropriate support.

Resources

Access additional resources to learn more about QALSODY.

To get started, call 1-877-725-7639 Monday-Friday, 8:30 AM to 8:00 PM ET

Is there a Copay Program for QALSODY that may help reduce out-of-pocket costs?

There are 2 ways in which you may be eligible for financial assistance from Biogen's Copay Program: for QALSODY itself and for some of the treatment costs to the administration of QALSODY. These are 2 different programs and if eligible, you must enroll separately.

- Generally, all US residents who are prescribed QALSODY who have coverage through non-government insurance are eligible, regardless of income, subject to Biogen's terms and conditions. Insurance will be billed first and must pay before copay assistance will be applicable
- Individuals receiving coverage from Medicare, Medicaid, the VA/DoD, TRICARE®,* or any other governmental or pharmaceutical assistance may not be eligible

Patients may be eligible if:

- You're not a resident of Massachusetts, Minnesota, or Rhode Island
- Your healthcare provider submits a request for treatment using an approved procedure code for anesthesia, imaging procedures, and/or surgical procedure or drug administration. Only codes approved by Biogen shall be eligible under the program. There would likely be other administration costs not covered by the program

Administration Copay Program will cover only specific, approved billing codes that relate to anesthesia, imaging procedures, and/or surgical procedure or drug administration. The program does not cover lab work, observation, surgical supplies, facility/room costs, or other miscellaneous costs that may be associated with the administration of QALSODY.

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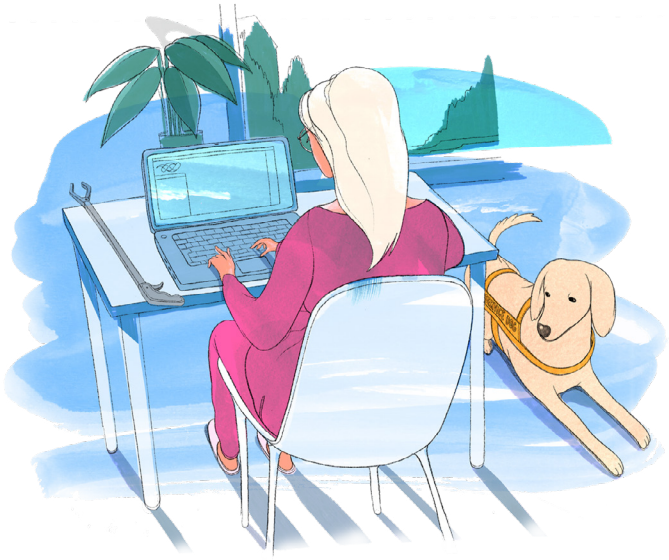

Glossary

Helpful explanations of important terms used throughout this piece

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Indication and Important Safety Information

What is QALSODY?

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QALSODY can cause serious side effects, including:

- **Inflammation of the spinal cord (myelitis) and/or irritation of the nerve roots (radiculitis)**, including serious cases, have been reported in patients treated with QALSODY. Six patients treated with QALSODY experienced inflammation of the spinal cord or irritation of the nerve roots in the clinical studies. Two patients stopped treatment with QALSODY and their symptoms resolved with treatment. In the remaining 4 patients, symptoms resolved without stopping QALSODY. If you experience common symptoms such as abnormal sensations (pins and needles), numbness, or weakness, please contact your healthcare provider. Your healthcare provider can help you determine how to address symptoms, and may recommend that you stop taking QALSODY.
- **Swelling of the optic nerve (papilledema) and increased pressure inside the skull (elevated intracranial pressure)**, including serious cases, have been reported in patients treated with QALSODY. The optic nerve connects the eyes with the brain and is responsible for vision. Four patients developed increased pressure inside the skull and/or swelling of the optic nerve. All patients received treatment from their healthcare provider that resolved these symptoms, and no events led to stopping QALSODY. If you experience common symptoms of swelling of the optic nerve such as blurred vision, double vision, or vision loss, please contact your healthcare provider. If you experience symptoms of increased pressure inside the skull, such as headache, vomiting, or numbness or weakness, please contact your healthcare provider.
- **Inflammation of the brain linings (aseptic meningitis, also called chemical meningitis or drug-induced aseptic meningitis)**, including serious cases, have been reported in patients treated with QALSODY. One patient experienced a serious side effect of inflammation of the brain linings, which led to the patient stopping QALSODY. One patient experienced a serious side effect of inflammation of the brain linings, which did not lead to the patient stopping QALSODY. In addition, nonserious side effects that can be signs of inflammation or infection have also been reported with QALSODY, including increased white blood cells and increased protein in the cerebrospinal fluid (the fluid around the spinal cord and the brain). If you experience symptoms such as headache, fever, vomiting, neck stiffness, nausea or vomiting, please contact your healthcare provider.

What should I tell my healthcare provider before I start using QALSODY?

Before taking QALSODY, tell your healthcare provider if you are pregnant, plan to become pregnant, or are breastfeeding or plan to breastfeed.

What are the possible side effects of QALSODY?

QALSODY can cause serious side effects. See "What is the most important information I should know about QALSODY?" above.

The most common side effects reported in patients treated with QALSODY were pain (back pain, pain in arms or legs), feeling tired, joint pain, increased white blood cell count in the cerebrospinal fluid (CSF), and muscle pain.

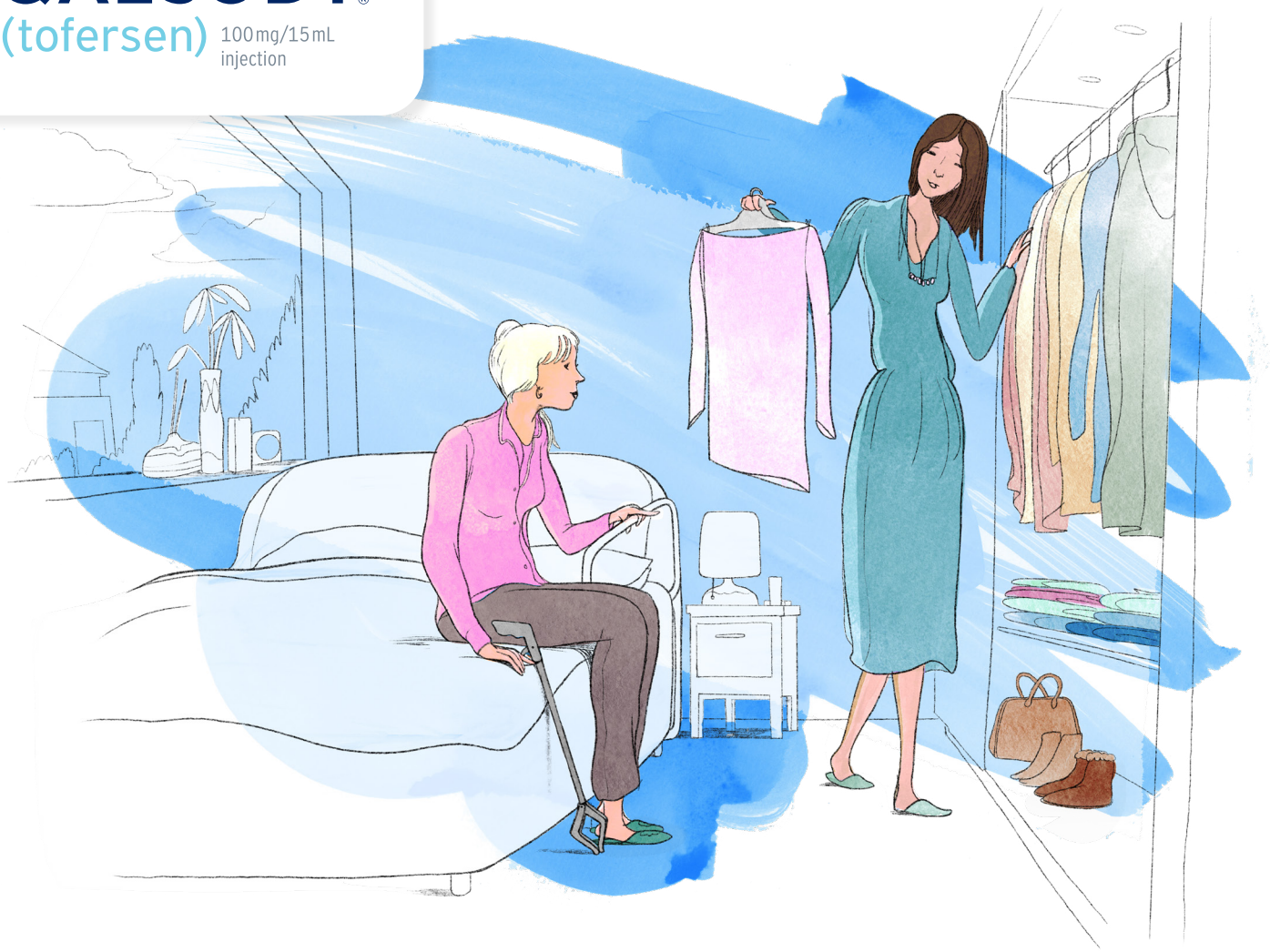
These are not all the possible side effects of QALSODY. Please talk to your healthcare provider if you experience any of these symptoms, or other new symptoms that concern you.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

This information is not intended to replace discussions with your healthcare provider.

Please see additional Important Safety Information throughout and click for full Prescribing Information.

QALSODY®
(tofersen) 100 mg/15 mL injection



If you have *SOD1*-ALS, talk to your doctor about treatment with QALSODY

Learn more about QALSODY. Visit QALSODY.com

IMPORTANT SAFETY INFORMATION (cont.)

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Biogen