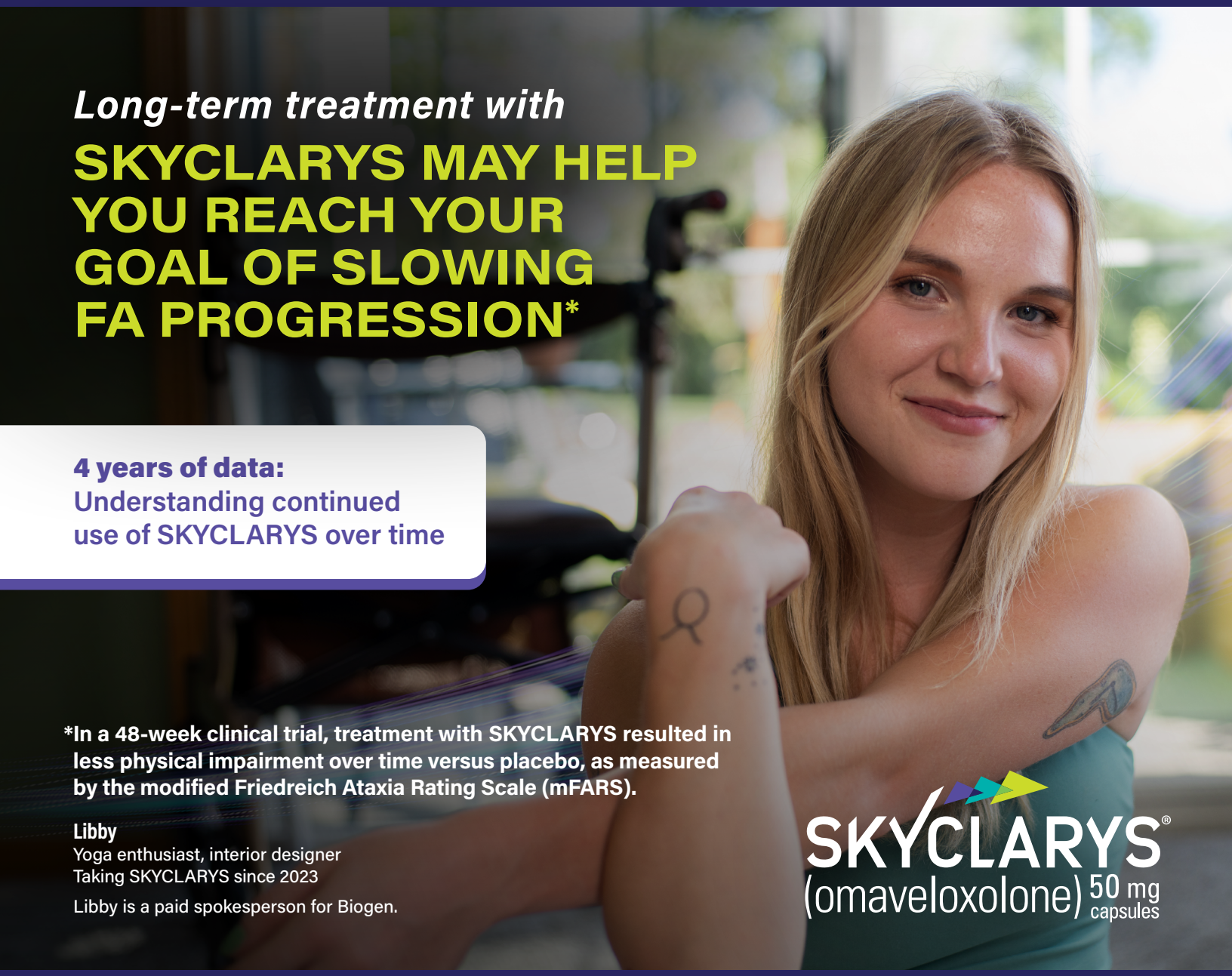
The first and only FDA-approved treatment for Friedreich ataxia (FA) in patients 16 years and older



Long-term treatment with

SKYCLARYS MAY HELP YOU REACH YOUR GOAL OF SLOWING FA PROGRESSION*

4 years of data:
Understanding continued use of SKYCLARYS over time

***In a 48-week clinical trial, treatment with SKYCLARYS resulted in less physical impairment over time versus placebo, as measured by the modified Friedreich Ataxia Rating Scale (mFARS).**

Libby
Yoga enthusiast, interior designer
Taking SKYCLARYS since 2023

Libby is a paid spokesperson for Biogen.

SKYCLARYS® (omaveloxolone) 50 mg capsules

WHAT IS SKYCLARYS?

- SKYCLARYS® (omaveloxolone) is used for the treatment of Friedreich ataxia in adults and children aged 16 years and older. It is not known if SKYCLARYS is safe and effective for use in children younger than 16 years of age

IMPORTANT SAFETY INFORMATION

What are the possible side effects of SKYCLARYS?
SKYCLARYS may cause serious side effects, including:

- **Increase in blood liver enzymes:** Some people taking SKYCLARYS have had an increase in the level of liver enzymes in their blood. Your healthcare provider will do liver function tests
  - before you start taking SKYCLARYS
  - every month for the first 3 months after starting your treatment with SKYCLARYS
  - during certain times as needed while taking SKYCLARYS

If your liver enzymes increase, your healthcare provider may change your dose, stop treatment for some time, or completely stop treatment with SKYCLARYS.

Please see Important Safety Information throughout and full Prescribing Information, including Patient Information.

ABOUT THE MOXIe TRIAL

SKYCLARYS® (omaveloxolone) 50 mg capsules

SKYCLARYS was shown to improve mFARS scores compared to an untreated population

The MOXIe trial included 103 people across 3 continents, aged 16 to 40 years old, with a genetically confirmed diagnosis of FA and a baseline modified Friedreich Ataxia Rating Scale (mFARS) score between 20 and 80. Patients were randomly assigned to either the SKYCLARYS or placebo treatment group. This clinical trial looked at changes in mFARS after 48 weeks of treatment with SKYCLARYS compared to untreated patients in the placebo group. Disease progression was measured by changes in mFARS scores for both SKYCLARYS and untreated patients.

How is FA progression measured?

In the MOXIe trial, the primary endpoint of the study was measured using the mFARS. The mFARS is a neurological exam commonly used in clinical trials to help physicians assess disease progression by **evaluating 4 key areas related to everyday activities:**



Mouth and throat function



Upper limb coordination



Lower limb coordination



Upright stability

The mFARS exam is scored on a scale of 0 to 93, with higher scores meaning greater physical impairment. While rates of progression depend on several factors and can vary from person to person, **people with FA typically progress at an average rate of ~2 points per year**.

There are many ways to measure FA disease progression. Your doctor will decide which is best for assessing your FA.

Ask your doctor what slowing FA progression may mean for you

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of SKYCLARYS? (cont'd)

SKYCLARYS may cause serious side effects, including (cont'd):

- **Increase in a blood protein called B-Type Natriuretic Peptide (BNP).** BNP tells how well your heart is working. Your healthcare provider will check your BNP levels before your treatment with SKYCLARYS. Tell your healthcare provider if you have signs and symptoms of your heart not working well such as too much fluid in your body (fluid overload). Signs and symptoms may include:
  - sudden weight gain (3 pounds or more of weight gain in 1 day, or 5 pounds or more of weight gain in 1 week)
  - swelling in your arms, hands, legs, or feet (peripheral edema)
  - fast heartbeat (palpitations)
  - shortness of breath

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LESS PHYSICAL IMPAIRMENT

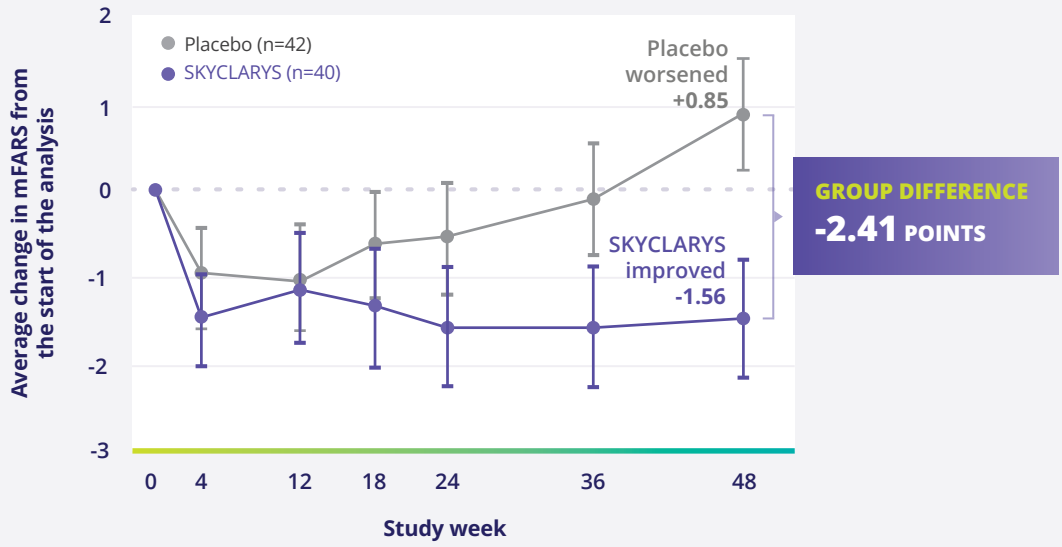
SKYCLARYS® (omaveloxolone) 50 mg capsules

SKYCLARYS was shown to slow FA progression

In the MOXIe trial, treatment with SKYCLARYS resulted in statistically lower mFARS scores compared with untreated patients at 48 weeks*

This means that, on average, patients taking SKYCLARYS had less physical impairment after 48 weeks of treatment compared with untreated patients.

Change in mFARS scores in the MOXIe study



*In the population of patients without pes cavus (high arch; n=82).

Set your sights on your long-term treatment goals

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of SKYCLARYS? (cont'd)

SKYCLARYS may cause serious side effects, including (cont'd):

If you have symptoms of fluid overload that is considered a side effect of SKYCLARYS, your healthcare provider may stop treatment with SKYCLARYS.

- **Changes in cholesterol levels.** Increases in low density lipoprotein cholesterol (LDL-C) or bad cholesterol and decreases in high density lipoprotein cholesterol (HDL-C) or good cholesterol have happened during treatment with SKYCLARYS. Your healthcare provider will check your cholesterol levels before and during your treatment with SKYCLARYS

The most common side effects of SKYCLARYS include: increased liver enzymes (ALT/AST), headache, nausea, stomach pain, tiredness, diarrhea, and muscle pain.

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SKYCLARYS® (omaveloxolone) 50 mg capsules

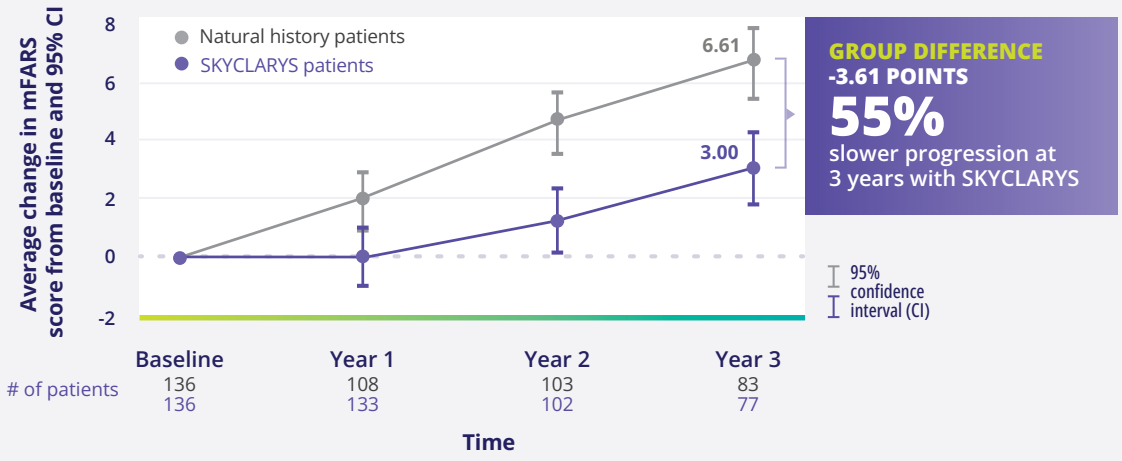
A look at the treatment effect of SKYCLARYS over time

At the end of the MOXIe trial, all patients who participated were given the option to continue in a longer-term study called an open-label extension. Before participating in the open-label extension study, patients were asked to temporarily stop taking their treatment. Then, all patients were given SKYCLARYS, including those who had not been on treatment in the clinical trial.

At Year 3, SKYCLARYS showed a sustained benefit by lessening physical impairment versus an untreated real-world population

After 3 years, researchers took the results from the open-label extension study and compared them with a matched set of untreated patients in the Friedreich Ataxia Clinical Outcome Measures Study (FA-COMS). FA-COMS is an ongoing natural history study that measures the progression of more than 1000 FA patients to determine just how the condition progresses.

Change in mFARS scores over 3 years in the MOXIe open-label extension



This kind of study is called an exploratory analysis and is not the same as a clinical trial. Because of that, there are some limitations to the study and the results should be interpreted cautiously

A 95% confidence interval (CI) means that if the study were repeated with a similar patient population and the same study design, the results would likely fall in this range 95% of the time.

With SKYCLARYS, people experienced less functional loss at 3 years compared with those who were untreated

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking SKYCLARYS, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have a history of heart problems, including heart failure
- have a high level of fat in your blood (high blood cholesterol)

Please see Important Safety Information throughout and full Prescribing Information, including Patient Information.

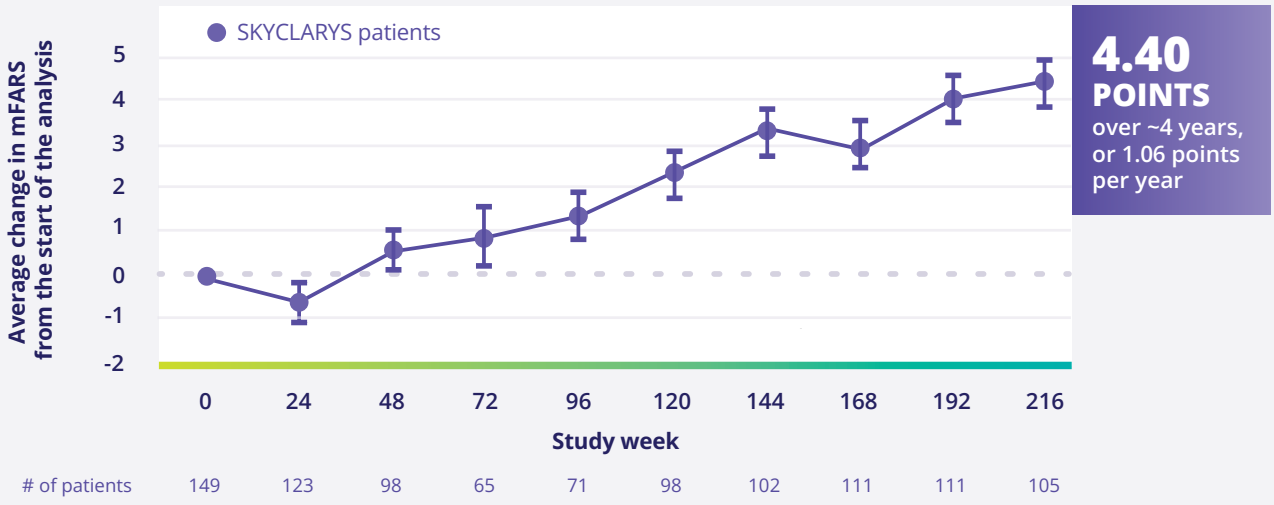
4-YEAR RESULTS

SKYCLARYS® (omaveloxolone) 50 mg capsules

The long-term treatment effect continued in patients who stayed on SKYCLARYS

Patients who were treated with SKYCLARYS saw their mFARS scores increase by 4.40 points over ~4 years, which is an average of 1.06 points per year

Change in mFARS score over ~4 years in the open-label extension



This kind of study is called an "open-label extension" and is not the same as a controlled clinical trial. Because of that, there are some limitations and the results should be interpreted cautiously

In the large FA-COMS study, people with FA who remained untreated saw their mFARS scores increase (worsen) by an average of ~2 points per year.

Check in on your long-term goals. Ask your doctor what your next milestone may look like with SKYCLARYS

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking SKYCLARYS, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- are pregnant or plan to become pregnant. It is not known if SKYCLARYS will harm your unborn baby. Women who use hormonal birth control should use another form of birth control such as a non-hormonal intrauterine system or an extra non-hormonal birth control such as condoms while using SKYCLARYS and for 28 days after stopping SKYCLARYS
- Pregnancy exposure registry: There is a pregnancy registry for women who are pregnant and are taking SKYCLARYS. The purpose of this registry is to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself by calling 1-866-609-1785 or by sending an email to SkyclarysPregnancySurveillance@ppd.com
- are breastfeeding or plan to breastfeed. It is not known if SKYCLARYS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take SKYCLARYS

Please see Important Safety Information throughout and full Prescribing Information, including Patient Information.

SAFETY AND MONITORING

SKYCLARYS® (omaveloxolone) 50 mg capsules

Regular testing will help your doctor monitor your progress

Lab tests are an important part of treatment, particularly over the first few months. Talk with your doctor's office to get these appointments scheduled as soon as possible.

Understanding possible side effects of SKYCLARYS

Some patients taking SKYCLARYS in the MOXIe trial saw an increase in liver enzymes, an increase in B-type natriuretic peptide (BNP, a protein that tells how well your heart is working), and changes in cholesterol levels.

Because of these possible side effects, your doctor will monitor:



Your liver function

- Before treatment
- Once a month for the first 3 months
- Periodically during treatment



Your cholesterol levels

- Before treatment
- Periodically during treatment



Your BNP levels and signs of fluid overload

- Before treatment

You will also need to look out for signs of fluid overload throughout your treatment and tell your healthcare provider if you have:

- Sudden weight gain of 3 pounds in a day or 5 pounds in a week
- Swelling in your arms, hands, legs, or feet
- Fast heartbeat
- Shortness of breath

In the MOXIe trial, the most common side effects* were:



Elevated liver enzymes



Headache



Nausea



Stomach pain



Tiredness

Some people also experienced diarrhea and muscle aches and pain. These are not all the possible side effects of SKYCLARYS. Call your doctor for medical advice about side effects.

*Defined as affecting at least 20% of patients and more patients on SKYCLARYS than untreated patients.

SAFETY AT 4 YEARS IN THE OPEN-LABEL EXTENSION

The majority of side effects experienced by patients taking SKYCLARYS were mild or moderate in severity

The most common side effects related to treatment were: nausea, elevated liver enzymes, headache, diarrhea, muscle spasms, tiredness, back pain, stomach pain, and flu.

The majority of severe side effects occurred in 2 or fewer patients. Those that occurred in more than 2 patients were: coronavirus infection (in 4 patients) and back pain (in 3 patients).

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DURATION OF SIDE EFFECTS

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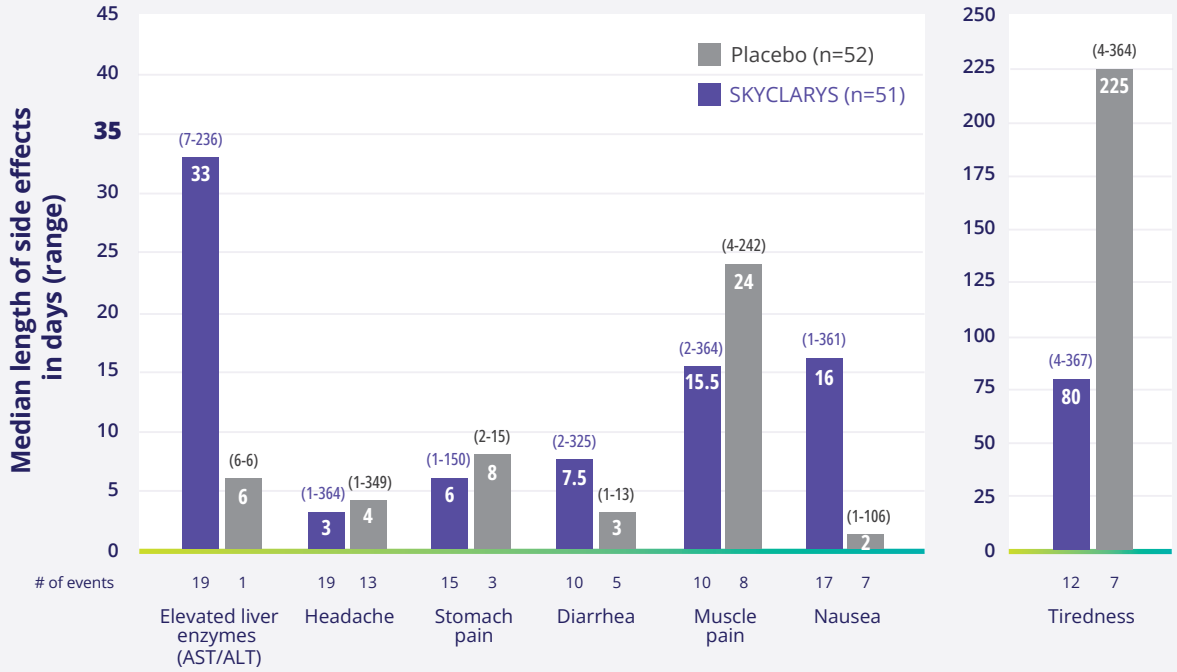
Know how long side effects may last

Most common side effects in the MOXIe trial were transient, meaning they typically lasted less than 35 days

The charts below show how long 51 patients taking SKYCLARYS and 52 patients taking placebo experienced some of the most common side effects reported in the MOXIe trial.

- The most common side effects were elevated liver enzymes (37%), headache (37%), nausea (33%), stomach pain (29%), tiredness (24%), diarrhea (20%), and muscle pain (20%)
- Side effects can occur at any time while taking SKYCLARYS

Median duration and range* of side effects reported in ≥20% of people in the 48-week MOXIe study



Liver enzyme elevations were generally transient, and no liver injury was reported in the clinical trial.

*The median is the middle value. Half of people had a shorter duration, and half had a longer duration. The range shows the lowest and highest number of days the side effect was observed in the group.

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

Talk with your doctor about how long potential side effects may last so you can prepare, adjust, and keep your long-term goals in focus

Please see Important Safety Information throughout and full Prescribing Information, including Patient Information.

Your long-term goals matter.

CHOOSE THE TREATMENT SHOWN TO SLOW FA PROGRESSION OVER TIME

SKYCLARYS® (omaveloxolone) 50 mg capsules



Week 48

PRIMARY RESULTS

SKYCLARYS was shown to improve mFARS scores, which measure mouth and throat function, upper and lower limb coordination, and upright stability

Year 3

OPEN-LABEL EXTENSION

People taking SKYCLARYS experienced less functional loss compared with those who were untreated in an exploratory analysis

Year 4

Patients saw a continued effect on mFARS scores with long-term treatment

Hear real stories from people like Libby, who has been taking SKYCLARYS since 2023

Libby is a paid spokesperson for Biogen.

IMPORTANT SAFETY INFORMATION (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements such as St. John's Wort.

- Taking SKYCLARYS with other medicines can cause serious side effects
- SKYCLARYS may affect the way other medicines work, and other medicines may affect how SKYCLARYS works
- Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine

What should I avoid while taking SKYCLARYS?

- Do not drink grapefruit juice or eat grapefruit. These may change the amount of SKYCLARYS in your blood

These are not all the possible side effects of SKYCLARYS. For more information, ask your healthcare provider or pharmacist.

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

Please see Important Safety Information throughout and full Prescribing Information, including Patient Information.

Intended for a US audience.

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225 Binney Street, Cambridge, MA 02142

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