Dear FA Community,

As we reflect upon 2024, we are grateful for a year of meaningful growth and deepened connection with the FA community. We were inspired by your passion and participation in the many community events across the country and are thankful for the opportunity to learn about your experiences and share in your journey.

We were fortunate to have hundreds of impactful conversations with community members, advocates and leaders, which continue to help us learn and shape our priorities as we look ahead to 2025.

Through our engagements, we've been moved by your resilience and shared commitment to advancing care and awareness for FA. Your stories and advocacy fuel our mission to make meaningful progress in the care of FA.

We are thrilled for the opportunity to work alongside you and look forward to building on these efforts in 2025. In addition, we continue to expand and improve our U.S. patient services and financial assistance programs to enable greater access and support for individuals living with FA.

Together, we can continue to drive change and make a difference for people living with FA and their loved ones.

## Research Highlights

PASS Study

Together with FARA and leading experts in the field, Biogen worked to design the PASS study which will continue to monitor the real-world safety of SKYCLARYS that was established in our clinical trials.

The PASS study is a post-marketing registry that will collect data from SKYCLARYS-naïve individuals living with FA who are prescribed SKYCLARYS and treated per its approved label. The study aims to enroll 300 people living with FA aged 16 years and older, from 15 study sites in the U.S. and Europe.

We are also pleased to share that the first U.S. site for the PASS study, was activated in October 2024 at the Children's Hospital of Philadelphia, while the first European site was activated in early December at Tubingen University Hospital (Universitätsklinikum Tübingen) in Germany. Through this effort, we continue our commitment to improving the lives of those living with FA and their families.

## Commitment to Children with FA

We recognize the urgent need to advance potential pathways for access to therapy for children living with FA. In 2024, Biogen prioritized the initiation of the Phase 1 study of omaveloxolone, designed to identify the appropriate dose for the pediatric population living with FA. Use of omaveloxolone within the pediatric population for children younger than 16 years of age is considered investigational and not FDA approved.

Following the dose-finding portion of this study, participants have the opportunity to move into an ongoing open-label extension. After the appropriate dose of omaveloxolone for the pediatric population is identified, Biogen plans to conduct a Phase 3 study to comprehensively evaluate the safety and efficacy of omaveloxolone in pediatric patients, which we are on track to initiate this year.

We acknowledge the challenges faced by children and families awaiting a treatment option and recognize the unmet need for pediatric patients. This remains an important priority for Biogen, and we will share more details as they become available.

## Expanding Global Access to SKYCLARYS

2024 marked significant milestones in our efforts to expand access to SKYCLARYS. We are happy to share that there are 22 markets globally where access to SKYCLARYS is now available.

We also mentioned earlier this year that in addition to the U.S., SKYCLARYS was approved for the treatment of FA in adults and adolescents aged 16 years and older across all 27 European Union member states. We're actively working with local governments and reimbursement authorities to support access for eligible patients in these regions.

Additionally, we've submitted regulatory filings in other countries, including Brazil and Argentina, and are committed to continuing our global expansion efforts.

## Indication

SKYCLARYS® (omaveloxolone) is a prescription medicine used to treat Friedreich ataxia in adults and adolescents 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.

- **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

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.

**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)
- 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

**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 full Prescribing Information, including Patient Information.**

Sincerely,
Biogen Team