FIRST AND ONLY FDA-APPROVED

oral medicine for children with pediatric low-grade glioma (pLGG) that returned or did not respond to treatment and who have certain changes in the BRAF gene

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

THIS CHILD HAS A BRAIN TUMOR

Sawyer, lives with pLGG, and Jordan, Sawyer's dad

Imagine what tumor shrinkage could do for your child

FDA=United States Food and Drug Administration.

INDICATION

What is OJEMDA™ (tovorafenib)?

OJEMDA is a prescription medicine used to treat certain types of brain tumors (cancers) called gliomas in patients 6 months and older:

- that is a pediatric low-grade glioma (LGG), **and**
- that has come back after previous treatment or has not responded to previous treatment **and**
- that has a certain type of abnormal "BRAF" gene.

IMPORTANT SAFETY INFORMATION

Before taking or giving OJEMDA, tell your healthcare provider about all of your or your child's medical conditions, including if you:

- have bleeding, skin, or liver problems
- are pregnant or plan to become pregnant. OJEMDA can harm your unborn baby.

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

Why consider OJEMDA?

First and only FDA-approved, once-weekly OJEMDA targets the most common BRAF gene changes in pLGG

The clinical study FIREFLY-1 found meaningful tumor shrinkage

51% of children (39 out of 76) experienced tumor shrinkage of at least 25%

Children experienced mostly mild to moderate side effects, with 74% of children (102 out of 137) staying on treatment

Serious side effects include bleeding problems, skin reactions, liver problems, and slowed growth in children.

Most children's growth rates returned to normal after taking a break from treatment. During treatment with OJEMDA, growth will be checked often.

The FIREFLY-1 main phase will conclude by the end of 2024, after which patients will be followed for longer-term observation.

Once-weekly oral dosing in tablet or liquid form that can be taken with or without food conveniently from home

Comprehensive patient support to help your child start and stay on treatment

What you'll find in this guide

This guide can help empower you to ask your care team about OJEMDA

Thank you from Day One

Day One Biopharmaceuticals would like to thank the clinical study participants, their families, pediatric cancer advocacy foundations, and investigators who have given us feedback along this journey. We are inspired by the strength of children and families impacted by pLGG. That's why we put kids first in everything we do and are dedicated to supporting the community from day one and every day after.

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Expand your knowledge of pLGG and its treatment options

If your child's pLGG is described as "relapsed or refractory," this means the tumor either came back or did not respond to previous treatment.

Up to 50% of children with pLGG have their tumors grow again after an initial treatment.

Knowing your child's pLGG tumor biology may lead to an appropriate treatment option

Up to **75%** of LGG tumors in children have some type of BRAF change*

*Incidence of BRAF changes varies across pLGG subtypes.

This means that some children's pLGG may have a change to a gene called BRAF (pronounced "Be-Raf"). This gene change can cause a tumor to grow uncontrollably.

Ask about OJEMDA if your child's tumor has returned or not responded to treatment and has certain changes in the BRAF gene

"When considering our treatment options, we look at everything from efficacy to safety to administration."

—Jordan, dad of Sawyer, living with pLGG

Breslyn, lives with pLGG, and Noelle, her sister

Get to know OJEMDA

OJEMDA is a targeted therapy for children

It is designed to shrink pLGG tumors with a BRAF fusion or a BRAF V600E mutation, 2 of the most common BRAF changes. A genomic test can show if your child's tumor has a BRAF change or not.

OJEMDA may block tumor growth caused by these BRAF changes.

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking or giving OJEMDA, tell your healthcare provider about all of your or your child's medical conditions, including: (cont'd)

Females who are able to become pregnant:

- You should use effective non-hormonal birth control (contraception) during treatment with OJEMDA and for 28 days after your last dose of OJEMDA.

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

ojemda™ (tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Designed for kids. Tested in kids.

OJEMDA was studied in the largest clinical trial of children with BRAF gene changes

The clinical study FIREFLY-1 evaluated children 6 months and older.

Who took OJEMDA in the clinical study?

- Children with BRAF fusion– or BRAF V600E–positive pLGG, whose tumors came back or did not respond to previous treatment like chemotherapy or targeted treatment

What were the 2 main goals of the OJEMDA study?

- Prove tumor shrinkage (efficacy)
- Understand side effects (safety)

The study did not compare OJEMDA to any other treatment or placebo (sugar pill). Because of this, every child in the study took OJEMDA.

Efficacy
76 children were evaluated, and they all had tumors that met the size requirements to measure tumor shrinkage.

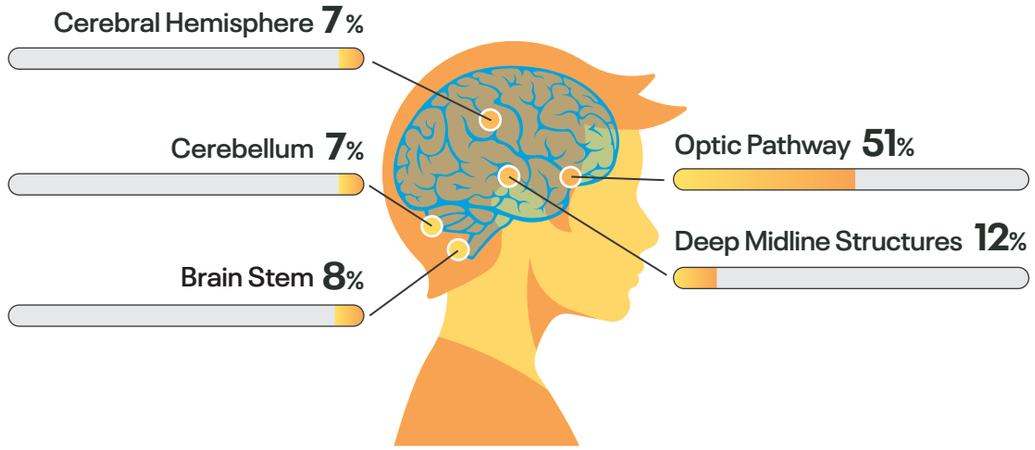
Safety
137 children were evaluated, and they all received at least 1 dose of OJEMDA.

FIREFLY-1 will conclude by end of 2024

Available results were reviewed in June 2023, and based on the review of efficacy and safety, OJEMDA received FDA approval. Full study results will be available by end of 2024.

Know who was in the clinical study

Most common tumor locations for children in the clinical study



One of the study's main goals was to see how many children had tumor shrinkage with OJEMDA

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking or giving OJEMDA, tell your healthcare provider about all of your or your child's medical conditions, including: (cont'd)

Males with female partners who are able to become pregnant should use effective non-hormonal birth control (contraception) during treatment with OJEMDA and for 2 weeks after your last dose of OJEMDA.

- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 2 weeks after your last dose of OJEMDA.

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

pLGG tumor shrinkage may be possible with once-weekly oral OJEMDA

Meaningful tumor shrinkage

51% of children saw their tumors shrink by at least 25%
(39 out of 76)

- 37% of children (28 out of 76) had tumor shrinkage of 50% or more
- No child had their tumor completely disappear

The FIREFLY-1 main phase will conclude by the end of 2024, after which patients will be followed for longer-term observation.

When did children see results in the clinical study?

46% of children (18 out of 39) saw tumor shrinkage on their MRI scan at **3 months***

50% of children (20 out of 39) saw tumor shrinkage at **5.3 months** after starting on OJEMDA

77% of children (30 out of 39) saw tumor shrinkage on their MRI scan at **6 months***

Results were measured with MRI scans every 3 months.

*These data were collected during the clinical study, and additional analyses were done. These results are not in the OJEMDA Prescribing Information.

How long did children maintain tumor shrinkage?

74% of children (102 out of 137) were still taking OJEMDA at the time of study evaluation on June 5, 2023.

At the time of review, half of the children who saw tumor shrinkage saw it for **13.8 months**

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking or giving OJEMDA, tell your healthcare provider about all of your or your child's medical conditions, including if you: (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

Hana, lives with pLGG, and Kibebew, her brother

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

"To think that there may be shrinkage in tumors is the most hopeful thing in the world."

—Clare, mom of Holmes, living with pLGG

IMPORTANT SAFETY INFORMATION (cont'd)

What should I avoid while taking OJEMDA?

Limit the amount of time you spend in sunlight. OJEMDA can make your skin sensitive to the sun (photosensitivity). Use sun protection measures, such as sunscreen, sunglasses and wear protective clothes that cover your skin during your treatment with OJEMDA.

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

What are the possible side effects?

OJEMDA may cause serious side effects, including:

Bleeding problems, such as nose bleeds or bleeding from the tumor

Call your child's doctor immediately if they have any symptoms including:

- Headache, dizziness, or feeling weak
- Coughing up blood or blood clots
- Vomiting blood or vomit looks like coffee grounds
- Red or black stools that look like tar

Skin reactions, including sensitivity to sunlight (photosensitivity)

Call your child's doctor if your child gets new or worsening skin reactions, including:

- Rash
- Bumps
- Acne
- Peeling, redness, or irritation
- Blisters

Liver problems

Your child's doctor will do blood tests to check your child's liver function before and during treatment with OJEMDA. Call your child's doctor right away if your child gets any of the following symptoms:

- Yellowing of skin or eyes
- Dark or brown (tea-colored) urine
- Nausea or vomiting
- Loss of appetite
- Tiredness
- Bruising
- Bleeding
- Pain in the upper right stomach area

Joseph, lives with pLGG

Slowing of growth (height)

- Your child's growth will be checked routinely during treatment with OJEMDA
- Rate of growth resumed after children took a break from OJEMDA

Other safety considerations

OJEMDA may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you.

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

What are the most common side effects?

Children mostly experienced mild to moderate side effects while taking OJEMDA

The most common side effects of OJEMDA include:

Side effect	Out of 137 children, how many experienced it?
Rash	77%
Hair color changes	76%
Fatigue (tiredness)	55%
Viral infection	55%
Vomiting	50%
Headache	45%
Fever	39%
Dry skin	36%
Constipation	33%
Nausea	33%
Acne	31%
Upper respiratory tract infection	31%

These are not all the possible side effects of OJEMDA. Talk to your child's care team for medical advice about side effects. They can determine if your child needs to change their dosage or stop treatment. You may report side effects to the FDA at 1-800-FDA-1088.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of OJEMDA?

OJEMDA may cause serious side effects, including:

- **bleeding problems (hemorrhage)** are common and can also be serious. Tell your healthcare provider if you develop any signs or symptoms of bleeding, including:
  - headache, dizziness or feeling weak
  - coughing up blood or blood clots
  - vomiting blood or your vomit looks like "coffee grounds"
  - red or black stools that look like tar

OJEMDA was generally well tolerated in the clinical study

When the results of the FIREFLY-1 trial were studied:

74% **of children were still taking OJEMDA**
(102 out of 137)

93% **of children did not stop taking OJEMDA due to side effects**
(128 out of 137)

The main side effects that caused 7% of children (9 out of 137) to stop taking OJEMDA were:

- Bleeding from the tumor (3 out of 137)
- Slowing of growth (2 out of 137)

If your child experiences any serious side effects during treatment with OJEMDA, your child's doctor may decrease dosage.

Download the What to Know When Starting OJEMDA guide at OJEMDA.com or scan the QR code for more details about getting started on OJEMDA

Scan

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Once-weekly oral dosing can mean fewer interruptions to your schedule

Give **OJEMDA once a week,** on the same day every week

With the flexibility to take **with or without food**

Can be taken **conveniently from home**

OJEMDA is available in 2 forms

Tablets

Oral suspension

Product images are not shown at actual size.

Each OJEMDA tablet is approximately 0.6 by 0.4 inches, about the size of a peanut.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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

- **skin reactions, including sensitivity to sunlight (photosensitivity).** OJEMDA can cause skin reactions that can become severe. Tell your healthcare provider if you get new or worsening skin reactions, including:
  - rash
  - bumps or tiny papules
  - acne
  - peeling, redness, or irritation
  - blisters

Important dosing reminders

1. OJEMDA is taken once a week, same day every week, with or without food
2. If a dose is missed by:
   - 3 days or less, the missed dose should be taken as soon as possible, and the next dose should be taken on its regularly scheduled day
   - More than 3 days, the missed dose should be skipped and the next dose should be taken on its regularly scheduled day
3. When giving your child OJEMDA, remove the tablets only when it's time for their dose. If using a liquid dose, make sure it's given within 15 minutes of preparing it
4. Continue giving OJEMDA as prescribed unless advised by your child's doctor
   - Do not change your child's dose or stop taking OJEMDA unless your child's doctor tells you to
5. If your child vomits right after taking a dose of OJEMDA, give them another dose. If you are not sure if you should repeat the dose, contact your child's care team

If your child has been prescribed the OJEMDA oral suspension, you will be given specific instructions on how to mix the powder with water to make the prescribed dose at home.

For specific liquid dose instructions, visit OJEMDA.com/step-by-step or scan this QR code

Scan

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Why convenient, once-weekly dosing matters

"We only have to think about OJEMDA once a week—which works for our busy schedules."

"My child has always struggled taking pills, so the liquid formulation was the obvious choice for us."

Holmes, lives with pLGG, and Clare, Holmes' mother

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Designed with your child in mind—EveryDay Support From Day One™

EveryDay Support From Day One is here to help your child start and stay on therapy for pLGG. Let us help work through the details, so you can focus on your child

EveryDay Support From Day One is a trusted partner for you and your care team. We provide help with:

Dedicated Patient Navigators

Our Patient Navigators will work directly with you to address your specific needs and coordinate with your child's care team to simplify the process of getting OJEMDA.

Coverage support

We work with your child's care team and health insurance plan to understand your benefits and help obtain coverage.

Financial assistance

We provide financial assistance programs to help eligible families pay for OJEMDA, including the OJEMDA Copay Program,* which can lower out-of-pocket costs to as little as $0 per month, and a program that may provide free medicine if you don't have health insurance or have limited insurance coverage for OJEMDA.†

Shipment & medication support

Our specialty pharmacy partners will ship OJEMDA directly to your home, help you learn about it, and teach you how to give it to your child.

Enroll today at EveryDaySupport.com, scan the QR code, or call us at 855-DAY1-BIO (855-329-1246)

Scan

*Restrictions and eligibility requirements apply. Not available for those with government insurance. Maximum benefit applies. Please see EveryDaySupport.com for full terms and conditions.

†Additional terms and conditions may apply.

Continued support from the pLGG community

Connecting with a community of others going through similar experiences can be a great source of comfort and knowledge.

Here are a few pediatric cancer advocacy foundations you can reach out to for support.

Children's Brain Tumor Foundation — Research • Community • Companionship

Pediatric Brain Tumor Foundation

Momcology

Team Jack Foundation

The Lilabean Foundation

These are only a few of the many pediatric cancer advocacy foundations in the US. Reach out to your child's care team for a more comprehensive list, including local groups.

"The brain tumor community is like family. They support you no matter what and understand things that nobody else can."

—Kendra, mom of Breslyn, living with pLGG

Please see Important Safety Information throughout and accompanying Patient Information, including Instructions for Use, for more information.

ojemda™ (tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Notes and questions

Use this page to write down questions or information to share with your child's care team.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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

- **liver problems.** Your healthcare provider will do blood tests to check your liver function before and during treatment with OJEMDA. Tell your healthcare provider right away if you develop any of the following symptoms:
  - yellowing of your skin or your eyes
  - dark or brown (tea-colored) urine
  - nausea or vomiting
  - loss of appetite
  - tiredness
  - bruising
  - bleeding
  - pain in your upper right stomach area
- **slowed growth in children.** Growth will be checked routinely during treatment with OJEMDA.

The most common side effects of OJEMDA include:

- rash
- hair color changes
- tiredness
- viral infection
- vomiting
- headache
- fever
- dry skin
- constipation
- nausea
- acne
- upper respiratory tract infection

OJEMDA may cause fertility problems in males and females, which may affect your ability to have children.

These are not all the possible side effects of OJEMDA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see accompanying full Patient Information, including Instructions for Use, for more information.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Help shrink your child's pLGG tumor with OJEMDA

The clinical study FIREFLY-1 found meaningful tumor shrinkage

51% of children (39 out of 76) experienced tumor shrinkage of at least 25%

Children experienced mostly mild to moderate side effects, with 74% of children (102 out of 137) staying on treatment

Serious side effects include bleeding problems, skin reactions, liver problems, and slowed growth in children.

Most children's growth rate returned to normal after taking a break from treatment. During treatment with OJEMDA, growth will be checked often.

FIREFLY-1 is an ongoing trial and will conclude by end of 2024.

Once-weekly oral dosing in tablet or liquid form that can be taken with or without food conveniently from home

Comprehensive patient support to help your child start and stay on treatment

Start the conversation about OJEMDA—scan the QR code or visit OJEMDA.com/get-resources to download the Doctor Discussion Guide

Scan

Please see Important Safety Information throughout and full Patient Information, including Instructions for Use, for more information..

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension