



For people with relapsing multiple sclerosis (RMS).



"I couldn't believe that there was an option for a 1-hour infusion twice per year. With BRIUMVI's dosing schedule, I don't have to think about my MS medication everyday."

 Danté C. has taken BRIUMVI since 2023

Individual results may vary.

<sup>a</sup>Following the starting dose.

Click here to visit the BRIUMVI patient website

#### INDICATION

BRIUMVI is a prescription medication used to treat adults with relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. It is not known if BRIUMVI is safe or effective in children.

#### IMPORTANT SAFETY INFORMATION

#### Who should not receive BRIUMVI?

**Do not** receive BRIUMVI if you have an active hepatitis B virus (HBV) infection.

**Do not** receive BRIUMVI if you have had a life-threatening allergic reaction to BRIUMVI. Tell your healthcare provider if you have had an allergic reaction to BRIUMVI or any of its ingredients in the past.

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#### IMPORTANT SAFETY INFORMATION

**Infusion reactions:** Infusion reactions are one of the most common side effects of BRIUMVI, which can be serious and may require you to be hospitalized. You will be monitored during your infusion and may be monitored after each infusion of BRIUMVI for signs and symptoms of an infusion reaction.

### What is BRIUMVI?

The only B-cell therapy\*
approved for relapsing
multiple sclerosis (RMS)
that is administered in a
1-hour infusion, twice per year



Proven results in 2 clinical studies



Well-studied safety profile

<sup>a</sup>Following the starting dose. Day 1 infusion is 150 mg over 4 hours; day 15 infusion is 450 mg over 1 hour; subsequent infusions are 450 mg over 1 hour, every 24 weeks.

\*Other approved B-cell therapies are OCREVUS® and KESIMPTA®. OCREVUS® is a registered trademark of Genentech. KESIMPTA® is a registered trademark of Novartis AG.



# BRIUMVI is an FDA-approved B-cell depletion treatment for relapsing multiple sclerosis (RMS)

In MS, B-cells are known to play an important role in the destruction of myelin. Myelin is the protective nerve covering that helps maintain the signals carried by the nerves in the central nervous system.

Although it's not known exactly how BRIUMVI works in relapsing MS, it is thought to target and deplete certain types of B-cells. Removing those B-cells plays a very important role in the treatment of RMS.

Medications that target B-cells have been available to treat diseases for more than 20 years and are the most highly prescribed type of medication to treat RMS.

#### IMPORTANT SAFETY INFORMATION

Tell your healthcare provider if you get any of these symptoms:

- fever
- chills
- headache
- flu-like symptoms
   swelling of tongue
   throat irritation
- fast heartbeat
- hives
- itchy skin
- dizzinessfeeling faintswelling of tongue or throat
- trouble breathing
- wheezing
- nausea
- abdominal pain
- throat irritation
   redness of the face or skin

These infusion reactions can happen over 24 hours after your infusion. It is important that you call your healthcare provider right away if you get any of the signs or symptoms listed above after each infusion. If you get an infusion reaction, your healthcare provider may need to stop or slow down the rate of your infusion.

# BRIUMVI was tested against teriflunomide\* in 2 separate, 2-year clinical studies of people with RMS



BRIUMVI was shown to be safe and effective compared to another approved MS medication in 2 clinical studies.



The clinical studies **each lasted 2 years.** 



More than 1,000 people were studied.

(546 assigned to receive BRIUMVI, 548 assigned to receive teriflunomide)

- A wide age range of people with RMS, 18-55 years of age
- People included in the studies had active disease:
  - » greater than or equal to 1 relapse within the prior year

#### OR

» greater than or equal to 2 relapses in prior 2 years

#### AND/OR

» greater than or equal to 1 gadolinium-enhanced T1 magnetic resonance imaging (MRI) lesion in the prior year

<sup>\*</sup>teriflunomide is the active ingredient in AUBAGIO®. AUBAGIO® is a registered trademark of Sanofi or an affiliate.



# BRIUMVI® (ublituximab-xiiy) reduced relapses by up to 59%



with BRIUMVI compared to teriflunomide\*

Study 1: ARR was 0.076 for BRIUMVI and 0.188 for teriflunomide



with BRIUMVI compared to teriflunomide\*

Study 2: ARR was 0.091 for BRIUMVI and 0.178 for teriflunomide

ARR=Annualized Relapse Rate

\*teriflunomide is the active ingredient in AUBAGIO<sup>®</sup>. AUBAGIO<sup>®</sup> is a registered trademark of Sanofi or an affiliate.

#### IMPORTANT SAFETY INFORMATION

**Hepatitis B virus (HBV) reactivation:** Before starting treatment with BRIUMVI, your healthcare provider will do blood tests to check for hepatitis B viral infection. If you have ever had hepatitis B virus infection, the hepatitis B virus may become active again during or after treatment with BRIUMVI. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure or death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop receiving BRIUMVI.

# People taking BRIUMVI had fewer relapses





86%

of people taking BRIUMVI had ZERO RELAPSES

compared to 74% for teriflunomide\*

#### STUDY 2



87%

of people taking BRIUMVI had ZERO RELAPSES

compared to 72% for teriflunomide\*

<sup>\*</sup>teriflunomide is the active ingredient in AUBAGIO®. AUBAGIO® is a registered trademark of Sanofi or an affiliate.



# BRIUMVI® (ublituximab-xiiy) showed near complete suppression of lesions

Healthcare providers look to 2 different types of lesions to track the effect of treatment in relapsing MS.



T1 Gd+ lesions are areas of active inflammation, which causes damage.



T2 lesions are areas that indicate long-term impact of MS on the brain. They can either be new lesions or lesions that have gotten bigger.

STUDY 1 & 2

97%



#### **FEWER T1 Gd+ LESIONS**

with BRIUMVI compared to teriflunomide\*
On average per MRI over 2 years

Study 1: 0.016 lesions with BRIUMVI vs. 0.491 lesions with teriflunomide Study 2: 0.009 lesions with BRIUMVI vs. 0.250 lesions with teriflunomide

STUDY 1 & 2

# **UP TO 92%**



#### **FEWER T2 LESIONS**

with BRIUMVI compared to teriflunomide\* On average per MRI over 2 years

Study 1: 0.213 lesions with BRIUMVI vs. 2.789 lesions with teriflunomide Study 2: 0.282 lesions with BRIUMVI vs. 2.831 lesions with teriflunomide

\*teriflunomide is the active ingredient in AUBAGIO®. AUBAGIO® is a registered trademark of Sanofi or an affiliate.

#### IMPORTANT SAFETY INFORMATION

**Weakened immune system:** BRIUMVI taken before or after other medicines that weaken the immune system could increase your risk of getting infections.

# Most people experienced no confirmed progression of physical disability<sup>a</sup>

Physical disability progression was measured at 3 months in people taking BRIUMVI and those who took teriflunomide.



When taking BRIUMVI or teriflunomide, more than 9 out of 10 people experienced NO CONFIRMED PROGRESSION OF PHYSICAL DISABILITY

There was no significant difference in confirmed disability progression between people who took BRIUMVI (5.2% had confirmed disability progression) and those who took teriflunomide (5.9% had confirmed disability progression). Physical disability progression was measured at 3 months and combined from both studies.

<sup>a</sup> Disability progression was considered to be confirmed if it was present 12 weeks after it was initially documented.



# BRIUMVI has a well-studied safety profile

#### **IMPORTANT SAFETY INFORMATION**

#### Who should not receive BRIUMVI?

**Do not** receive BRIUMVI if you have an active hepatitis B virus (HBV) infection.

**Do not** receive BRIUMVI if you have had a lifethreatening allergic reaction to BRIUMVI. Tell your healthcare provider if you have had an allergic reaction to BRIUMVI or any of its ingredients in the past.

#### SAFETY PROFILE OF BRIUMVI

Side effects with an incidence of at least 5% and greater than teriflunomide

Side effects	<b>BRIUMVI</b> (n=545) %	Teriflunomide (n=548) %
Infusion reactions	48	12
Upper respiratory tract infections	45	41
Lower respiratory tract infections	9	7
Herpes virus-associated infections	6	5
Pain in extremity	6	4
Insomnia	6	3
Fatigue	5	4

- The BRIUMVI safety profile was based on 2 clinical trials
- Overall infection rates of BRIUMVI (56%) & teriflunomide (54%) were similar. Most were mild to moderate in severity and consisted of upper respiratory tract infection (45%) and urinary tract infection (10%)
- ~90% of people remained on treatment throughout both clinical studies. This was similar for people taking BRIUMVI and people taking teriflunomide

**Infusion reactions:** Infusion reactions are one of the most common side effects of BRIUMVI, which can be serious and may require you to be hospitalized. You will be monitored during your infusion and may be monitored after each infusion of BRIUMVI for signs and symptoms of an infusion reaction. Tell your healthcare provider if you get any of these symptoms:

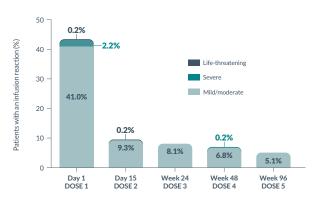
- fever
- o chills
- headache
- flu-like symptoms
- fast heartbeat
- hives
- itchy skin
- dizziness

- feeling faint
- swelling of tongue or throat
- trouble breathing
- wheezing
- nausea
- abdominal pain
- throat irritation
- redness of the face or skin

These infusion reactions can happen over 24 hours after your infusion. It is important that you call your healthcare provider right away if you get any of the signs or symptoms listed above after each infusion. If you get an infusion reaction, your healthcare provider may need to stop or slow down the rate of your infusion.

#### Infusion reactions with BRIUMVI

Infusion reactions were primarily mild to moderate in severity and decreased with each infusion.



95% of all BRIUMVI 1-hour infusions were completed in 1 hour<sup>†</sup>

†± 5 minutes

briumvi ublituximab-xiiy <sup>50,my6 nd.</sup>

## BRIUMVI is a 1-hour infusion, twice per year after the starting dose

BRIUMVI is an infusion therapy that is administered by a healthcare provider (such as a doctor or nurse) through a needle placed in a vein in your arm, also known as an intravenous (IV) infusion. Your healthcare provider is there to support you by reviewing the overall treatment process, answering any questions you may have, and monitoring for potential infusion-related reactions. Please allow enough time in your schedule for your infusion treatments.

#### A dosing schedule that provides more time for you and less time for your infusion



- Your first infusion of BRIUMVI will last. about 4 hours<sup>a</sup>
- Your second infusion will be given 2 weeks after your first dose—this infusion will last about 1 houra
- Your third infusion and beyond of BRIUMVI will be given as 1 infusion every 24 weeks (approx. 6 months) after the first infusion. These infusions will also last about 1 houra

#### IMPORTANT SAFETY INFORMATION

Low immunoglobulins: BRIUMVI may cause a decrease in some types of antibodies. Your healthcare provider will do blood tests to 12 check your blood immunoglobulin levels.

<sup>&</sup>lt;sup>a</sup>Infusion duration may take longer if the infusion is interrupted or slowed.

## What to expect on a typical BRIUMVI infusion day

Your healthcare team is there for you. Prior to your first BRIUMVI infusion, your healthcare provider can answer any questions you may have and review the overall process of receiving treatment. During your infusion, your healthcare team will monitor you through the full process to ensure you are comfortable and in case you have an infusion reaction.

#### Pre-infusion: 30 minutes - 60 minutes

- Prior to every infusion, your healthcare provider will evaluate your overall health and answer any questions you have about your infusion treatment
- Pre-infusion medication to help reduce possible infusion reactions may be given to you approximately 30-60 minutes prior to your infusion and can be given orally or intravenously (IV)

#### **During infusion:** 1 hour

- Once you are comfortably settled in the infusion chair and ready for treatment, your healthcare provider will begin your infusion
- Infusions (following the starting dose) will typically take 1 hour

#### **Post-infusion**

- Post-infusion monitoring is at your healthcare provider's discretion and is not required after your first 2 infusions (unless you have experienced an infusion reaction and/ or signs of hypersensitivity with the current or any prior infusions)
- For your first 2 infusions, your healthcare provider will observe you for 1 hour after your infusion is completed

# 95% of all BRIUMVI 1-hour infusions were completed in 1 hour<sup>†</sup>

†± 5 minutes

briumvi ublituximab-xiiy injector feriv

## BRIUMVI® (ublituximab-xiiy), the only 1-hour infusion, twice per year<sup>a</sup>

When it comes to your MS treatment, consider the dosing and administration options available and discuss with your healthcare provider what option might work best for you

#### Summary of Select RMS Maintenance Treatments<sup>†</sup>

Frequency	Treatment	Administration
2x per year	BRIUMVI® (ublituximab)	1-hour infusion, every 24 weeks (approx. 6 months)
	OCREVUS® (ocrelizumab)	Approx. 2-3.5 hour infusion‡ every 6 months
12x per year	TYSABRI® (natalizumab)	1-hour infusion, every 4 weeks
	KESIMPTA® (ofatumumab)	Self-injection, once a month
365x per year (or 156)	COPAXONE® (glatiramer acetate injection)	Self-injection, once a day or 3 times per week <sup>‡</sup>
365x per year	AUBAGIO® (teriflunomide)	1 pill, once a day
730x per year	VUMERITY® (diroximel fumarate)	1 pill, twice a day

The comparison pertains only to differences in dosing and administration and should not be considered a comparison of efficacy or safety.

This is not a complete list of all the available treatments for RMS.

Trademarks are the property of their respective owners.

Please see each product's respective Prescribing Information for additional information including indication, dosing, and safety.

#### IMPORTANT SAFETY INFORMATION

#### Before receiving BRIUMVI, tell your healthcare provider about all of your medical conditions, including if you:

- have or think you have an infection.
- take or plan to take medicines that affect your immune system.
   These medicines may increase your risk of getting an infection.
- have ever had hepatitis B or are a carrier of the hepatitis B virus.
- have had a recent vaccination or are scheduled to receive any vaccinations.

<sup>&</sup>lt;sup>a</sup>Following the starting dose.

<sup>&</sup>lt;sup>†</sup>Does not include starting dose(s). Includes BRIUMVI and the top 6 FDA-approved RMS treatments for patients starting or switching to a new MS treatment (Q4 2021 to Q1 2022 Komodo claims), combining both generic and branded formulations. Fumarate class includes VUMERITY, Tecfidera, and generic Tecfidera.

<sup>&</sup>lt;sup>‡</sup>Depending on dose or option.

# BRIUMVI patient support focuses on what matters most

A flexible program designed to support your treatment journey in a way that works best for you.





#### **Dedicated Case Manager**

Your single point of contact to support your treatment journey.

To speak with a Case Manager, call 1-833-BRIUMVI (1-833-274-8684) (Mon-Fri, 8 AM to 8 PM ET)



#### **Insurance Support**

Information to help you understand your insurance coverage and locate a nearby infusion center that accepts your insurance.



#### **Financial Assistance**

Options that may help assist you with the cost of BRIUMVI, including the BRIUMVI Copay Assistance Program where eligible patients may pay as little as \$0 copay per BRIUMVI treatment\*, as well as help covering infusion related costs.

Visit www.briumvi.com or call 1-833-BRIUMVI (1-833-274-8684) to speak with a BRIUMVI Patient Support Case Manager

Visit www.briumvicopayterms.com for full terms and conditions



<sup>\*</sup>For commercially insured patients only. Other eligibility requirements apply.

## Discover advocacy groups

A large network of advocacy organizations is ready to help you navigate life with MS. Explore the websites below to access helpful resources, services, and support.

#### MyMSAA.org

Offers a variety of support services, such as a toll-free helpline with experienced specialists, educational resources, and their MRI Access Program. Visit the site listed above or call 1-800-532-7667.

### nationalMSsociety.org



Serves the MS community by offering different platforms to connect, such as educational programs and local support groups, while also sharing information on all things MS. Visit the site listed above or call 1-800-344-4867.

### CanDo-MS.org CAN DO

Can Do MS offers health and wellness programs and resources to help people with MS and their loved ones thrive. Discover practical solutions to manage MS symptoms, receive personalized guidance to overcome challenges, find the motivation to make real change, and connect with other to build a positive support network. Visit the site listed above or call 1-800-367-3101.

## MSViews.org MS



MS Views and News keeps people affected by MS up to date with free educational information, resources, and the latest research, plus live and online educational programs. Visit the site listed above or call 1-888-871-1664.

#### **MSFocus.org**



MS Focus provides services that address the critical needs of people with MS and their families. The organization's primary focus is on helping individuals with MS to access what they need to maintain their health and well-being. MS Focus charges no membership fees and all services are free to people with MS and their families. Visit the site listed above or call 1-888-673-6287.

\*TG Therapeutics is not affiliated with these independent organizations and does not recommend one organization over the other. Please note that the content of these websites is the sole responsibility of the website providers. TG Therapeutics does not control, review, edit, or influence this third-party content in any manner and makes no warranty as to the services offered by any organization listed here.

#### IMPORTANT SAFETY INFORMATION

#### Who should not receive BRIUMVI?

**Do not** receive BRIUMVI if you have an active hepatitis B virus (HBV) infection.

**Do not** receive BRIUMVI if you have had a life-threatening allergic reaction to BRIUMVI. Tell your healthcare provider if you have had an allergic reaction to BRIUMVI or any of its ingredients in the past.

# What is the most important information I should know about BRIUMVI?

#### BRIUMVI can cause serious side effects, including:

- Infusion reactions: Infusion reactions are one of the most common side effects of BRIUMVI, which can be serious and may require you to be hospitalized. You will be monitored during your infusion and may be monitored after each infusion of BRIUMVI for signs and symptoms of an infusion reaction. Tell your healthcare provider if you get any of these symptoms:
  - fever
  - chills
  - headache
  - flu-like symptoms
  - fast heartbeat
  - hives
  - itchv skin
  - dizziness

- feeling faint
- swelling of tongue or throat
- trouble breathing
- wheezing
- nausea
- abdominal pain
- throat irritation
- redness of the face or skin

These infusion reactions can happen over 24 hours after your infusion. It is important that you call your healthcare provider right away if you get any of the signs or symptoms listed above after each infusion. If you get an infusion reaction, your healthcare provider may need to stop or slow down the rate of your infusion.

#### • Infection:

- Infections are a common side effect, and upper respiratory tract infections are one of the most common side effects of BRIUMVI. BRIUMVI increases your risk of getting infections caused by bacteria or viruses that may be life-threatening or cause death. Tell your healthcare provider if you have an infection or have any of the following signs of infection including fever, chills, a cough that does not go away, or painful urination. Your healthcare provider should delay your treatment with BRIUMVI until your infection is gone.
- Hepatitis B virus (HBV) reactivation: Before starting treatment with BRIUMVI, your healthcare provider will do blood tests to check for hepatitis B viral infection.
   If you have ever had hepatitis B virus infection, the

hepatitis B virus may become active again during or after treatment with BRIUMVI. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure or death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop receiving BRIUMVI.

- Weakened immune system: BRIUMVI taken before or after other medicines that weaken the immune system could increase your risk of getting infections.
- Progressive Multifocal Leukoencephalopathy (PML):
   PML may happen with BRIUMVI. PML is a rare, serious brain infection caused by a virus that may get worse over days or weeks. PML can result in death or severe disability. Tell your healthcare provider right away if you have any new or worsening neurologic signs or symptoms. These symptoms may include weakness on one side of your body, loss of coordination in arms and legs, vision problems, changes in thinking and memory which may lead to confusion, and personality changes.
- Low immunoglobulins: BRIUMVI may cause a decrease in some types of antibodies. Your healthcare provider will do blood tests to check your blood immunoglobulin levels.

# Before receiving BRIUMVI, tell your healthcare provider about all of your medical conditions, including if you:

- have or think you have an infection.
- take or plan to take medicines that affect your immune system. These medicines may increase your risk of getting an infection.
- have ever had hepatitis B or are a carrier of the hepatitis B virus.
- have had a recent vaccination or are scheduled to receive any vaccinations.
  - You should receive any required 'live' or 'live-attenuated' vaccines at least 4 weeks before you start treatment with BRIUMVI. You should not receive 'live' or 'live-attenuated' vaccines while you are being treated with BRIUMVI and until your healthcare provider tells you that your immune system is no longer weakened.
  - When possible, you should receive any 'non-live' vaccines at least 2 weeks before you start treatment with BRIUMVI. If you would like to receive any non-live vaccines while you are being treated with BRIUMVI, talk to your healthcare provider.
  - If you have a baby and you received BRIUMVI during your pregnancy, it is important to tell your baby's healthcare provider about receiving BRIUMVI

so they can decide when your baby should be vaccinated.

- are pregnant, think that you might be pregnant, or plan to become pregnant. BRIUMVI may harm your unborn baby. You should use birth control (contraception) during treatment with BRIUMVI and for at least 6 months after your last infusion of BRIUMVI. Talk with your healthcare provider about what birth control method is right for you during this time.
- are breastfeeding or plan to breastfeed. It is not known
  if BRIUMVI passes into your breast milk. Talk to your
  healthcare provider about the best way to feed your baby if
  you take BRIUMVI.

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

# What are the possible side effects of BRIUMVI? The most common side effects of BRIUMVI include:

 Infusion reactions, upper and lower respiratory tract infections, herpes infections, extremity pain, insomnia, and fatigue.

These are not all the possible side effects of BRIUMVI. Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**. You may also report side effects to TG Therapeutics at **1-877-TGTXINC** (1-877-848-9462).

For more information, go to <u>www.briumvi.com</u> or call **1-833-BRIUMVI** (**1-833-274-8684**).



# brb be right back with BRIUMVI® (ublituximab-xiiy)



#### **Proven results in 2 clinical studies**

- Reduced relapses by up to 59% in Study 1 (in Study 2 by 49%) compared to teriflunomide
- Up to 87% of people had no relapses
- Significantly reduced brain lesions on magnetic resonance imaging (MRI)



#### Well-studied safety profile

- Tested in 2 clinical studies with more than 1,000 people, almost half of whom were given BRIUMVI
- Overall infection rates of BRIUMVI & teriflunomide were similar. Most were mild to moderate and consisted of upper respiratory tract infections and urinary tract infections



# The only 1-hour, twice per year\* infusion option

- Shortest available B-cell infusion in just 1-hour, twice per year\*
- Post-infusion monitoring is at your healthcare provider's discretion and is not required after your first 2 infusions (unless you have experienced an infusion reaction and/or signs of hypersensitivity with the current or any prior infusions)

Visit www.briumvi.com or call 1-833-BRIUMVI (1-833-274-8684)

#### IMPORTANT SAFETY INFORMATION

The most common side effects of BRIUMVI include: Infusion reactions, upper and lower respiratory tract infections, herpes infections, extremity pain, insomnia, and fatigue.

Please see full Important Safety Information on page 17 and full Prescribing Information for BRIUMVI <u>here</u>.

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<sup>\*</sup>Following the starting dose.