ZELTASIA (litifimod) 0.92 mg capsules | SUPPORT PROGRAM

START FORM

☐ New patient ☐ Restarting treatment (after missing 14 or more consecutive doses)

PATIENT:

Please provide all information in the blue sections (1 through 4) below.
(!) Indicates a field that MUST be completed for this form to be processed.

1 PATIENT INFORMATION

☐ Male ☐ Female ☐ Other

(!) **First name** _____ **MI** _____ (!) **Last name** _____ (!) **Date of birth** ____/____/_____

Address *(No PO Box)* _____ **City** _____

State _____ **ZIP** _____ **E-mail address** _____

(!) **Mobile phone** _____ **Home phone** _____ ☐ OK to leave voicemail

Preferred contact number: ☐ Mobile ☐ Home **Preferred time:** ☐ Morning ☐ Afternoon ☐ Evening

Primary language: ☐ English ☐ Spanish ☐ Other _____

Name of care partner/alternate contact* _____

Care partner/alternate contact phone _____ ☐ OK to leave voicemail

*By providing the name and contact information of this individual, I am authorizing the disclosure of my health information to him/her.

2 MEDICAL INSURANCE COVERAGE

(!) **Primary insurance carrier** _____ (!) **Policy #** _____

Group # _____ **Insurance phone** _____ **Policyholder name (First, Last)** _____

☐ Patient has no insurance

Secondary insurance carrier _____ **Policy #** _____

Group # _____ **Insurance phone** _____ **Policyholder name (First, Last)** _____

3 PRESCRIPTION INSURANCE COVERAGE

Prescription insurance carrier _____ **Rx Member ID** _____ **Insurance phone** _____

Rx PCN (if applicable) _____ **Rx Group ID** _____ **Rx BIN (if applicable)** _____

☐ Patient has no insurance

4 PATIENT APPROVAL

☐ **If eligible, I would like to enroll in the ZELTASIA (litifimod) co-pay program.**
I have read and agreed to the program terms and conditions on page 5, and understand that co-pay assistance is only available for commercially insured patients and does not apply if I have prescription drug coverage through a federal, state, VA, or similar program.

☐ **I would like to receive text messages and calls.**
I have read and agreed to receive text messages and calls as explained in the Consent for autodialed calls & texts (see page 4).

I have read and agreed to the Patient Authorization and Agreement to Share Health Information on pages 3 and 4 of this form.

(!) **Patient or patient's personal representative's signature:** X _____ (!) **Date (MM/DD/YY)** _____/_____/_____

(If signed by patient's personal representative, please explain authority to act on behalf of the patient.) _____

TO HEALTHCARE PROVIDER: Fax the completed Start Form, a copy of insurance card, AND pharmacy benefit card (both sides of each) to **833-XXX-XXXX** or enroll online at **www.ZELTASIAportal.com**

Patient: First name _____ **Last name** _____ **Date of birth** ____/____/____

HEALTHCARE PROVIDER:

Please provide all information in the red sections (5 through 7) below. (!) Indicates a field that must be completed for this form to be processed. If you need help, please visit www.ZELTASIAportal.com or call ZELTASIA Support Progam at 1-833-ZELTASIA (833-XXX-XXXX).

5 PRESCRIBER INFORMATION

(!) **First name** _____ (!) **Last name** _____ **Facility name** _____

Address _____ **City** _____ **State** _____ **ZIP** _____

(!) **Phone** _____ **Fax** _____ **NPI #** _____ **State medical license #** _____

E-mail address _____ **Office contact name** _____ **Best time to contact:** ☐ Morning ☐ Afternoon

6 ASSESSMENT ASSISTANCE REQUESTED FROM ZELTASIA SUPPORT PROGRAM

Check boxes to request assistance*:

Blood tests:
- ☐ CBC
- ☐ LFTs
- ☐ VZV antibody serology

Screenings:
- ☐ In-home ECG
- ☐ Loaner ECG requested for in-office use†
- ☐ Help scheduling an ME screening‡

FDO:
- ☐ Request in-home first dose observation (FDO).§ Required for patients with certain preexisting cardiac conditions‖

*Available for on-label commercially insured patients only. This offer is not valid for medical assessments for which payment may be made in whole or in part under federal or state health programs, including but not limited to Medicare or Medicaid, and for residents in MA, MI, MN, and RI. This program is subject to termination or modification at any time.
†The loaner ECG equipment may be used only for the cardiac evaluation and/or FDO of ZELTASIA patients. Not available in all states. Restrictions apply.
‡Macular edema screening is available in select areas.
§Patient will be scheduled for FDO, but FDO will not be completed until prescriber has determined that all baseline tests are complete and satisfactory.
‖Sinus bradycardia, first- or second-degree (Mobitz type 1) AV block, or a history of myocardial infarction or heart failure.

No assistance required and I confirm:

☐ Blood tests above and ECG completed or not required ☐ FDO is not required ☐ Provider to conduct FDO

7 TREATMENT INFORMATION AND PRESCRIBER AUTHORIZATION¶ (COMPLETE ALL PARTS THAT APPLY)

PRESCRIBER AUTHORIZATION

By signing one or more of the prescriptions below, I certify that I have (1) prescribed ZELTASIA (litifimod) based on my professional judgment of medical necessity and that I will supervise the patient's medical treatment; (2) I have the authority to disclose this patient's information to Company X and its respective agents and service providers, including the dispensing pharmacy, and I have obtained this patient's authorization for the disclosure, if required by HIPAA or other applicable privacy laws; (3) the information provided is accurate to the best of my knowledge; and (4) I will not seek reimbursement for any free product provided to the patient. I authorize the ZELTASIA Support Program to transmit the prescription(s) below to the appropriate dispensing pharmacy.

¶If required by applicable law, please attach copies of all prescriptions on official state prescription forms.

(!) **Primary diagnosis:** ☐ ICD-10: G35 ☐ Other _____ **Current/most recent MS therapy:** _____ (MM/YY) ____/____ to ____/____

Other MS therapy: _____ (MM/YY) ____/____ to ____/____

(!) Initiation Rx:

Days 1-4: ZELTASIA 0.23 mg by mouth once daily
Days 5-7: ZELTASIA 0.46 mg by mouth once daily
Day 8 and thereafter: ZELTASIA 0.92 mg by mouth once daily

Following assessments noted in Section 6 above, prescriber provided sample or will provide patient with Starter Kit.

- ☐ Dispense Starter Kit#
  7-day Starter Pack, followed by 30-day supply, 0 refills
- ☐ Prescriber Provided Patient With Sample Kit
  7-day Pack, followed by 30-day supply, 0 refills

Date (MM/DD/YY) ____/____/____

#Starter Kit Rx is only for on-label patients who will not receive a sample from their prescriber.

Starter Kit should be sent to:

☐ Prescriber address (see above) ☐ Prescriber FDO site on file

If FDO is not required and confirmed in Section 6 above:

☐ Patient address (see page 1) ☐ Alternate patient address (provide below):

Address _____

City _____ **State** _____

ZIP _____ **Phone** _____

(!) **Prescriber signature:** _____

(!) **Date (MM/DD/YY)** ____/____/____

(!) Maintenance Rx (check one):

ZELTASIA 0.92 mg by mouth once daily

- ☐ Dispense 30-day supply followed by 11 refills or ___ refills
- ☐ Dispense 90-day supply followed by 3 refills or ___ refills

Rx to be dispensed at commercial specialty pharmacy

☐ Transmit Rx to specialty pharmacy (provide name of specialty pharmacy): _____

Additional notes: _____

(!) **Prescriber signature:** _____

(!) **Date (MM/DD/YY)** ____/____/____

Bridge Supply Rx** (optional for commercially insured patients):

ZELTASIA 0.92 mg by mouth once daily

☐ Dispense 30-day supply followed by up to 11 refills

**Bridge Supply Rx is available at no cost for eligible commercially insured, on-label diagnosed new patients, and is not contingent on purchase requirements of any kind. Bridge Supply Rx is not available to patients who have Medicare, Medicaid, and other federal and state programs in MA and MI, but would be available for no more than 6 months (180 days) to patients in MN and RI. Program is intended to support continuation of prescribed therapy if there is a delay in determining whether commercial prescription coverage is available. Authorization must be sought within 30 days, and appeal of any denial must be made within 90 days, to remain in the Program. Eligibility will be re-verified in January for patients continuing into the following year, and may be at other times during Program participation. Up to 12 additional refills may be provided if needed. Offer is not health insurance, and may be modified or discontinued at any time without notice. Other limitations may apply. In the Initiation Rx section of this form, please indicate if you are prescribing the Starter Kit or have provided or will provide the patient with a Sample Kit.

Prescriber signature: _____

Date (MM/DD/YY) ____/____/____

TO HEALTHCARE PROVIDER:
Fax the completed Start Form, a copy of insurance card, AND pharmacy benefit card (both sides of each) to **833-XXX-XXXX** or enroll online at **www.ZELTASIAportal.com**. For assistance or more information, please visit ZELTASIA.com or call 1-833-ZELTASIA (833-XXX-XXXX).

Patient Authorization and Agreement to Share Health Information

The Company X ZELTASIA Support Program is a support program by Company X that helps patients understand their insurance coverage and financial support options for ZELTASIA (litifimod), provides co-pay and free medication support to qualified patients, and provides educational, nurse, and lab and diagnostic support services. To participate in the Program, Company X will need to receive, use, and disclose your personal information. Please read this authorization carefully, and contact ZELTASIA Support Program at 1-833-ZELTASIA (833-XXX-XXXX) if you have any questions. Once you have read and agreed to this form, fax your signed copy to 833-XXX-XXXX.

1. What information will be used and disclosed?
My personal information will be disclosed, including:

- Information on the Program enrollment form
- My contact information and phone carrier/device information (for calls and texts)
- Date of birth and Social Security Number (SSN is voluntary)
- Professional and employment information
- Financial and income information
- Insurance information
- Health records and information, including diagnoses, medications, and lab tests
- Biometric and genetic information, including tests that identify the kind of illness that I have and/or medication indicated for my treatment

2. Who will disclose, receive, and use the information? This authorization permits my Health Caretakers, which include my healthcare providers, pharmacies, lab service providers, diagnostic service providers, health plans, and health insurers who provide services to me, as well as other people who I say can help me apply, to disclose my personal information to Company X, the third parties it works with, and other authorized agents, subsidiaries, and assignees (collectively "Company X"). Company X may also share my information with my Health Caretakers and with other healthcare providers, pharmacists, health insurers, and charitable organizations to determine if I am eligible for, or enrolled in, another plan or program.

3. What is the purpose for the use and disclosure?
My personal information will be used by and shared with the persons and organizations described in this authorization in order to:

- Process my application for the ZELTASIA Support Program services and provide the Program services to me, including verifying my insurance benefits, assistance with prior authorizations from my insurance, researching alternative insurance coverage options, providing information and education about the services through a case manager, and referring me and my Health Caretakers to other plans, support, or assistance programs that may be able to help me with access to my medication
- Provide me with healthcare services, including lab and diagnostic tests and related healthcare procedures related to ZELTASIA. I understand these healthcare services are not provided, or employed, by my healthcare professional. I understand that my insurance may be billed for these services and that I may have a separate co-pay or cost-sharing obligation for using these services
- Provide co-pay assistance and/or free medication to me, if I am eligible
- Contact my Health Caretakers and me about the programs and the services that are available
- Contact other healthcare providers and charitable organizations to determine if I am eligible for, or enrolled in, another plan or program
- Contact me for marketing purposes, including providing me with information about my medication, refill reminders, surveys, and other information and alerts that Company X believes may be of interest to me (and some of which may be sent directly to my phone if I choose)
- Improve or develop the Program's services and other internal business purposes including analytics

Authorization for Sale and Marketing Purposes:
I authorize my pharmacies, lab service providers, and diagnostic service providers to receive payment from Company X in exchange for providing my information to Company X, as well as using it for the purposes described in this authorization.

TO HEALTHCARE PROVIDER:
Fax the completed Start Form, a copy of insurance card, AND pharmacy benefit card (both sides of each) to **833-XXX-XXXX** or enroll online at **www.ZELTASIAportal.com**. For assistance or more information, please visit ZELTASIA.com or call 1-833-ZELTASIA (833-XXX-XXXX).

Patient Authorization and Agreement to Share Health Information (cont'd)

4. **When will this authorization expire?** This authorization will be effective for 5 years unless it expires earlier by law or I cancel it in writing. I may cancel this authorization by writing to: ZELTASIA Support Program, PO Box XXXXXX, Charlotte, NC XXXXX. If I cancel this authorization, I will no longer be able to participate in the Program. The Program will stop using or disclosing my information for the purposes listed in this authorization, except as necessary to end my participation or as required or allowed by law. I understand that if I receive free medication, I must reapply at least every year, sign this authorization again, and be accepted.

5. **Notices:** I understand that once my health information has been disclosed, privacy laws may no longer restrict its use or disclosure. Company X may use and disclose my information for the purposes described in this authorization or as allowed or required by law. I understand that Company X does not sell or rent personal information collected about me from this Program. I have a right to receive a copy of this authorization after I have signed it. I further understand that I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits and treatment by my healthcare providers will not change, but I will not have access to the Program services. I understand that certain state laws may allow for the right to request access to, or deletion of, my information. I understand that these state rights are not absolute and only apply in certain circumstances. Therefore, I acknowledge that I may not receive a response to my request to the extent required or permitted under relevant laws. I agree that I may need to provide additional information in order to verify my identity, such as a government-issued ID, before my request to receive access to, or deletion of, my information will be honored. I will not be discriminated against for exercising my rights, but I understand that I may not be able to receive Program services if I do not allow use of my information. To submit an access or deletion request, I may call 1-855-XXX-XXXX or complete the online form at www.companyx.com/dpo/us/request.

6. **Patient certifications:** I certify that the personal information that I provide to Company X is true and complete. I agree that, at any time during my participation, Company X may request additional documentation to verify my personal information. If there is missing information or I do not respond to requests for additional documents, my participation may be delayed or I may no longer be able to participate. If I qualify for, and receive, co-pay assistance or free medication assistance from Company X, I agree to comply with the Program rules on your enrollment form and I will not get reimbursed for the assistance I receive from anyone else, including from an insurance program, another charity, or a health savings, flexible spending, or other health reimbursement account. I understand that assistance may be temporary and that I may be required to apply every year. I will contact the Program at 1-833-XXX-XXXX if my insurance or treatment changes in any way. If I have Medicare Part D, I will also not count any free medication I receive toward my true out-of-pocket (TrOOP) costs. I understand that the Program may be discontinued or the rules for participation may change at any time without notice.

7. **Consent for autodialed calls & texts (optional):** I authorize the receipt of autodialed calls and text messages from the Program. I understand that my authorization is not a condition of purchase, or use, of ZELTASIA (litifimod) or any other Company X product and that the Program is valid with most major US carriers. I understand that my carrier's message and data rates may apply. I understand that information Company X obtains from me in connection with use of autodialed calls and text messages is used by the Program under the terms of this authorization. I can stop autodialed calls and text messages at any time by calling ZELTASIA Support Program at 1-833-ZELTASIA (833-XXX-XXXX). I can also stop text messages by texting "STOP" to 763-XXX-XXXX or the phone number from which I received a text message. For help, I can text "HELP" to 763-XXX-XXXX or the phone number from which I received a text message.

The patient or his/her personal representative must be provided with a copy of both pages of this form after it has been signed.

ZELTASIA CO-PAY PROGRAM TERMS AND CONDITIONS

1. The ZELTASIA Co-pay Program is valid only for patients with commercial (private) insurance prescribed ZELTASIA (litifimod) for an FDA-approved indication. The Program includes a prescription benefit offer for out-of-pocket drug costs and a medical assessment benefit offer for out-of-pocket costs for the initial blood tests, ECG screening and first dose observation, where the full cost is not covered by the patient's insurance.
2. Patients are not eligible for the prescription benefit offer if they have prescription insurance coverage through a state or federal healthcare program, including but not limited to Medicare, Medicaid, MediGap, CHAMPUS, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD) programs. Patients are not eligible for the medical assessment benefit offer if they have insurance coverage for their prescription or medical assessment through a state or federal healthcare program, or reside in Massachusetts, Michigan, Minnesota, or Rhode Island. Patients who move from commercial plans to state or federal healthcare programs will no longer be eligible.
3. Patient must be 18 years of age or older.
4. Patients pay as little as $0 in out-of-pocket costs per prescription, subject to a maximum benefit of $18,000 during a calendar year. Patients pay as little as $0 in out-of-pocket costs for the medical assessment, subject to a maximum benefit of $2000. Patients are responsible for any costs that exceed the maximum amounts.
5. To receive the medical assessment benefit, an Explanation of Benefits (EOB) form must be submitted, along with copies of receipts for any payments made. This benefit is available without obligation to continue with ZELTASIA therapy.
6. The Program expires on December 31, 2021.
7. All Program payments are for the benefit of the patient only.
8. Patients, pharmacists, and prescribers may not seek reimbursement from health insurance, health savings or flexible spending accounts, or any third party for any part of the prescription or medical assessment benefit received by the patient through this Program.
9. Patient's acceptance of any Program benefit confirms that it is consistent with the patient's insurance and that the patient will report the value received as may be required by his/her insurance provider.
10. Program valid only in the United States and Puerto Rico. Void where prohibited by law, taxed, or restricted.
11. The Program cannot be combined with any other offer, rebate, coupon, or free trial.
12. The Program is not conditioned on any past, present, or future purchase, including refills.
13. The Program is not insurance.
14. Company X reserves the right to rescind, revoke, or amend this Program at any time without notice.

IMPORTANT SAFETY INFORMATION

Indication
ZELTASIA is indicated for the treatment of adults with relapsing forms of multiple sclerosis (MS).

Important Safety Information
Do not start ZELTASIA if you:

- Have had a heart attack, chest pain (also known as unstable angina), stroke or mini-stroke (also known as transient ischemic attack or TIA) or certain types of heart failure in the last 6 months
- Have a history or presence of certain types of irregular or abnormal heartbeat (also known as arrhythmia) that is not corrected by a pacemaker
- Have severe breathing problems during your sleep (also known as sleep apnea)
- Are allergic to litifimod or any of the ingredients in ZELTASIA

ZELTASIA may cause serious side effects, including:

- **Slow heart rate (also known as bradycardia) when you start taking ZELTASIA.** ZELTASIA can cause your heart rate to temporarily slow down, especially after you take your initial dose. Slow heart rate may occur if you restart ZELTASIA after missing more than 14 consecutive days of treatment. Prior to restarting ZELTASIA, please consult with your physician as you will need a new 7-day starter pack to minimize the risk of heart rate reductions.

Call your healthcare provider if you experience the following symptoms of slow heart rate such as:

- Dizziness
- Lightheadedness
- Feeling like your heart is beating slowly or skipping beats
- Shortness of breath
- Confusion
- Chest pain

- **Infections.** ZELTASIA can increase the risk of infections. You should not receive live vaccines during treatment with ZELTASIA and for 3 months after you stop taking ZELTASIA. Vaccines may not work as well when given during treatment with ZELTASIA. ZELTASIA lowers the number of lymphocytes (a type of white blood cell) and this may lower the ability of your immune system to fight infections. This will usually go back to normal within 3 months of stopping treatment. Your health care provider should review a recent blood test of your white blood cells before you start taking ZELTASIA.

Call your health care provider right away if you have any of these symptoms of an infection during treatment with ZELTASIA and for 3 months after your last dose of ZELTASIA:

- Fever
- Feeling very tired
- Flu-like symptoms
- Cough
- Urinary discomfort
- Rash

- **Progressive multifocal leukoencephalopathy (PML).** Although no cases have been seen in patients in clinical trials with ZELTASIA, PML may occur. PML is a rare brain infection that may lead to death or severe disability. If PML happens, it usually happens in people with weakened immune systems but has happened in people who do not have weakened immune systems. Call your healthcare provider right away if you experience any new or worsening symptoms of PML such as:
  - Weakness on one side of the body
  - Changes in thinking or memory
  - Personality changes
  - Changes in vision
  - Confusion
- **A problem with your vision called macular edema.** Macular edema can cause some of the same vision symptoms as a multiple sclerosis (MS) attack (also known as “optic neuritis”). Tell your healthcare provider any time you notice vision changes during treatment with ZELTASIA. Your risk of macular edema is higher if you have diabetes or have had an inflammation of your eye called uveitis. Call your healthcare provider right away if you have any of the following:
  - Blurriness or shadows in the center of your vision
  - A blind spot in the center of your vision
  - Sensitivity to light
  - Unusually colored vision

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

- Have liver problems
- Have a slow heart rate
- Have a fever or infection
- Are unable to fight infections due to a disease, or you take or have taken medicines that lower your immune system
- Have received a vaccine in the past 30 days or are scheduled to receive a vaccine. ZELTASIA may cause vaccines to be less effective
- Have macular edema or have risk factors for macular edema such as uveitis which is a type of (an inflammation of the eye) or diabetes
- Are pregnant or plan to become pregnant.
  - If you are a female who can become pregnant, you should use effective birth control during your treatment with ZELTASIA and for at least 3 months after you stop taking ZELTASIA
- Are breastfeeding or plan to breastfeed.
  - It is not known if ZELTASIA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ZELTASIA, are breastfeeding, or plan to breastfeed

Tell your healthcare provider about all the medicines you take or have recently taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take or have taken medicines that affect your immune system, including corticosteroids, or other treatments for multiple sclerosis. Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist when you get a new medicine.

ZELTASIA cause possible side effects, including:

- **Swelling and narrowing of the blood vessels in your brain.** A condition called PRES (Posterior Reversible Encephalopathy Syndrome) has happened rarely in adults taking ZELTASIA. It is not known if ZELTASIA caused this. ZELTASIA should be stopped if this condition occurs. PRES will usually get better. However, if left untreated, it may lead to a stroke. Call your healthcare provider right away if you have any of the following symptoms:
  - Sudden severe headache
  - Sudden confusion
  - Sudden loss of vision or other changes in your vision
- **Increased blood pressure.** Your healthcare provider should check your blood pressure during treatment with ZELTASIA
- **Fetal risk.** It is not known if ZELTASIA can cause abnormalities of the fetus. You should use effective birth control during your treatment with ZELTASIA and for at least 3 months after you stop taking ZELTASIA. Call your healthcare provider if you think you may be pregnant [See “What should I tell my healthcare provider before taking ZELTASIA?”]
- **Allergic reactions.** Call your healthcare provider if you have symptoms of an allergic reaction, including a rash, itchy hives, or swelling of the lips, tongue or face

The most common side effects of ZELTASIA can include:

- Colds and sore throat
- Abnormal liver tests
- Urinary tract infections
- High blood pressure (hypertension)
- Upper respiratory tract infections

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

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

Please see full Prescribing Information and Medication Guide in the accompanying folder or at ZELTASIA.com