## Doctor Discussion Guide: For CTEPH Patients Who Cannot Be Treated With Surgery

If you have been diagnosed with chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) that cannot be treated with surgery (inoperable), you may have questions about this condition and your treatment options. It's important to be able to talk to your doctor to learn about CTEPH and how you can help manage your condition.

This guide provides questions that you can ask your doctor to help guide your discussion and get the most out of your next visit.

### Questions to ask your doctor

	Living with CTEPH					
		What are the typical symptoms of CTEPH and how		How will having CTEPH impact me?		
大		can I better manage them?		What types of daily activities can I participate in?		
		How common is CTEPH?		Are there any activities I should avoid?		
		What caused my CTEPH?				
	Trec	ating CTEPH				
		_				
		Is CTEPH curable?		What do I do if I am not reacting well to my medication and how can I manage side effects?		
		What is pulmonary endarterectomy (or PEA)?		How do I know my treatment is working?		
		What treatment options are available for CTEPH?		How do I set and maintain a schedule for my		
		Why was surgery not an option for me?		medication?		
		Will I be on treatment long term?		What happens if I miss a dose of my medication?		
		Will my medications and/or doses ever change?		Are there any vitamins or over-the-counter		
		What should I expect when beginning my treatment?		medications that would be helpful?		
		Are there side effects that I should expect with treatment?				
	Doc	ctor Visits				
		How often should I come in for checkups?		What kind of goals should I set when it comes to		
60		Is there anything I can do to prepare for my appointments with you?		improving my CTEPH symptoms?  Are there any other types of doctors or healthcare		
		How do I track my progress with CTEPH?		providers that I should be seeing?		
	Res	ources and Support				
		Is there a support program that can help patients like me?		Are there organized events that I can attend to learn more about my CTEPH?		
		How do I connect with others who can share their CTEPH experience with me?		Do you have any brochures or information that can help me learn more about CTEPH?		

Please see Indication and Important Safety Information on the following pages. For important risk and use information, click here for the full Prescribing Information, including Boxed Warning and Medication Guide.

# Notes from your visit with your doctor

Date:	

#### **IMPORTANT SAFETY INFORMATION**

Adempas® (riociguat) can cause serious birth defects if taken during pregnancy.

- Females must not be pregnant when they start taking Adempas (riociguat) tablets or become pregnant during treatment with Adempas.
- Females who are able to get pregnant must have a negative pregnancy test before beginning treatment with Adempas, each month during treatment, and 1 month after you stop treatment with Adempas. Talk to your doctor about your menstrual cycle. Your doctor will decide when to do the test.
- Females who <u>are able</u> to get pregnant are females who:
  - Have entered puberty, even if they have not started their period, have a uterus, and have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had their ovaries removed).
- Females who <u>are not able</u> to get pregnant are females who:
  - Have not yet entered puberty, do not have a uterus, or have gone through menopause.

#### **INDICATION**

## Adempas is a prescription medicine used to treat adults with:

- chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) treated with surgery but who continue to have high pulmonary blood pressure (persistent) or it comes back after surgery (recurrent), or that cannot be treated with surgery.
  - CTEPH is a type of high blood pressure in the arteries of your lungs caused by blood clots that narrow or block blood flow. Adempas can improve your ability to exercise (measured by 6-minute walk distance) and can help to improve some of your symptoms.

The Adempas clinical studies included mostly patients with WHO functional class II-III symptoms. It is unknown if Adempas is safe and effective in children.

## Aim Patient Support Program



#### **Aim Nursing Support**

- 24/7 hotline provided by the specialty pharmacy
- At-home visits in consultation with your healthcare professional

Call 1-855-4ADEMPAS (1-855-423-3672) to learn more.



#### **Aim Access and Financial Support**

#### Co-pay Assistance Program\*

- Reduce out-of-pocket costs: up to 100% of co-pays or coinsurance paid directly to the insurer Patient Assistance Program (PAP)<sup>†</sup>
- Eligible individuals can apply to receive medication free of cost for up to one year. Eligibility and criteria may vary

\*Patients must have private commercial insurance with a percentage coinsurance or co-pay requirement. Medicare or Medicaid patients are ineligible. Assistance is for one year, after which, patients must re-apply. Patients must notify the program of any change in their insurance status. Patients in certain states may be ineligible. The co-pay assistance program has an annual cap per patient year.

<sup>†</sup>Medicare Part D patients will be enrolled based on calendar year.



#### myAim Education & Encouragement

#### Helpful tools and personalized communications

- Educational support and personalized treatment resources through some of the key stages of treatment
- Tips on what to discuss with your doctor and information about other online resources and support



Talk to others on a similar path, or become a mentor yourself.

Learn more at <u>mymentorprogram.com</u>



Real-life stories of patients like you living with PAH and CTEPH.

Learn more at www.adempas-us.com/myjourney

<u>Click here</u> to sign up for Aim Patient Support or learn more at Adempas-US.com.

## IMPORTANT SAFETY INFORMATION (continued)

Females who are able to get pregnant must use two acceptable forms of birth control, during Adempas® (riociguat) treatment and for one month after stopping Adempas.

- If you have had a tubal sterilization, have a progesterone implant, or have an IUD (intrauterine device), these methods can be used alone and no other form of birth control is needed.
- Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out how to prevent pregnancy during treatment with Adempas.
  - Do not have unprotected sex. Talk to your doctor or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your doctor may tell you to use emergency birth control.
  - Tell your doctor right away if you miss a menstrual period or think you may be pregnant for any reason.

If you are the parent or caregiver of a female child who started taking Adempas before reaching puberty, you should check your child regularly to see if she is developing signs of puberty. Tell your doctor right away if you notice that she is developing breast buds or any pubic hair. Your doctor should decide if your child has reached puberty. Your child may reach puberty before having her first menstrual period.

Females can only receive Adempas through a restricted program called the Adempas Risk Evaluation and Mitigation Strategies (REMS) program. If you are a female who can become pregnant, you must talk to your doctor, understand the benefits and risks of Adempas, and agree to all of the instructions in the Adempas REMS program. Males can receive Adempas without taking part in the Adempas REMS program.



Please see additional Important Safety Information on the following pages. For important risk and use information, <u>click here</u> for the full Prescribing Information, including Boxed Warning and Medication Guide.

#### **IMPORTANT SAFETY INFORMATION (continued)**

#### Do not take Adempas if:

- you are pregnant, plan to become pregnant, or become pregnant during treatment with Adempas.
   Adempas can cause serious birth defects.
- you take:
  - a nitrate medicine to treat high blood pressure or heart disease, such as nitroglycerin, or a medicine called a nitric oxide donor, such as amyl nitrite
  - certain other medicines that contain sildenafil (Revatio or Viagra), tadalafil (Adcirca or Cialis), vardenafil (Levitra or Staxyn), dipyridamole, or theophylline. Revatio and Adcirca are also used to treat PAH
- you have pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).

Ask your doctor or pharmacist if you are not sure if you take any of the medicines listed above.

#### Before you take Adempas, tell your doctor if you:

 smoke; have recently had serious bleeding from your lungs, or if you have had a medical procedure called bronchial arterial embolization to stop you from coughing up blood; have problems with your heart or blood circulation; have low blood pressure; have liver problems; have kidney problems or are on dialysis; have narrowing of the pulmonary veins, a condition called pulmonary veno-occlusive disease or PVOD; have any other medical conditions.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Adempas and other medicines may affect each other causing side effects. Do not start any new medicine until you check with your doctor.

#### What should I avoid while taking Adempas?

- Do not get pregnant while taking Adempas. If you miss a menstrual period, or think you might be pregnant, call your doctor right away.
- It is not known if Adempas passes into your breast milk.
   You should not breastfeed if you take Adempas. Talk to your doctor about the best way to feed your baby if you take Adempas.

- Adempas may make you feel dizzy. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how Adempas affects you. Talk with your doctor if you are concerned about when it is safe for you to do these activities.
- **Smoking.** Adempas may not work as well if you smoke during treatment. Tell your doctor if you stop smoking or start smoking during treatment with Adempas, because your dose of Adempas may need to be changed.

#### Adempas can cause serious side effects including:

- Serious birth defects.
- Reduced blood pressure. This may cause symptoms of low blood pressure, such as lightheadedness, chest pain, and dizziness especially in people who are dehydrated, have a severe blockage of blood flow out of the heart, or have certain other medical problems. Your doctor will check you for any of these problems.
- Increased risk of bleeding, including bleeding from the respiratory tract. Tell your doctor right away if you cough up blood during treatment with Adempas.
- Worsening of symptoms in people with Pulmonary Veno-Occlusive Disease (PVOD). If you have PVOD, treatment with Adempas may cause a build-up of fluid in your lungs (pulmonary edema) which may result in shortness of breath. Your doctor may tell you to stop taking Adempas and switch you to a different medicine.

#### The most common side effects of Adempas are:

 Headache; dizziness; indigestion; swelling of your hands, legs, feet, and ankles (peripheral edema); nausea; diarrhea; and vomiting

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Adempas.

For important risk and use information please see the full Prescribing Information, including Boxed Warning and Medication Guide, here.

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

BAYER, the Bayer Cross, Aim, and Adempas are registered trademarks of Bayer.



