



PADCEV® Discussion Guide and Symptom Tracker

Bring this guide to your next appointment to:

- Help you have more detailed conversations with your healthcare team
- Help you keep your healthcare team aware of how you are feeling while taking PADCEV

Office contacts:

Doctor:

Nurse:

Location:

Phone:

Appointment reminders:

| | | | |
|-------|----------------------|-------|----------------------|
| Date: | <input type="text"/> | Time: | <input type="text"/> |
| | <input type="text"/> | | <input type="text"/> |
| | <input type="text"/> | | <input type="text"/> |

WHAT IS PADCEV?

PADCEV is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery. PADCEV may be used alone if you:

- have received an immunotherapy medicine **and** chemotherapy that contains platinum, **or**
- are not able to receive a chemotherapy that contains the medicine cisplatin and you have received one or more prior therapy.

PADCEV may be used with pembrolizumab (also known as Keytruda®) if you:

- are not able to receive a chemotherapy that contains the medicine cisplatin.

It is not known if PADCEV is safe and effective in children.

PADCEV with pembrolizumab was FDA-approved based on a clinical study that measured how many people had a tumor response. There is another study of PADCEV with pembrolizumab ongoing to confirm the clinical benefit

SELECT SAFETY INFORMATION

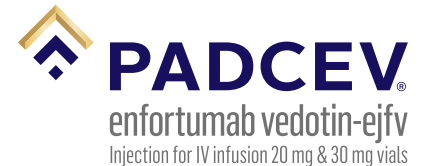
What is the most important information I should know about PADCEV?

PADCEV may cause serious side effects, including:

Skin reactions. Skin reactions including severe skin reactions have happened in people treated with PADCEV and may be more common when PADCEV is given with pembrolizumab. In some cases, these severe skin reactions have caused death. Most severe skin reactions occurred during the first cycle of treatment but may happen later. Your healthcare provider will monitor you, may stop your treatment with PADCEV completely or for a period of time (temporarily), may change your dose, and may prescribe medicines if you get skin reactions. Tell your healthcare provider right away if you develop any of these signs of a new or worsening skin reaction:

- | | | |
|--|---|------------------------------|
| • target lesions (skin reactions that look like rings) | • blistering or peeling of the skin | • fever or flu-like symptoms |
| • rash or itching that continues to get worse | • painful sores or ulcers in mouth or nose, throat, or genital area | • swollen lymph nodes |

Please see Important Safety Information throughout, and read the Patient Information for more information, including risk of Serious Side Effects.



IMPORTANT SAFETY INFORMATION



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

- are currently experiencing numbness or tingling in your hands or feet.
- have a history of high blood sugar or diabetes.
- have liver problems.
- are pregnant or plan to become pregnant. PADCEV can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with PADCEV.
- are breastfeeding or plan to breastfeed. It is not known if PADCEV passes into your breast milk. Do not breastfeed during treatment and for at least 3 weeks after the last dose of PADCEV.



Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with PADCEV.
- You should use an effective method of birth control during your treatment and for at least 2 months after the last dose of PADCEV.



Males with a female sexual partner who is able to become pregnant:

- If your female partner is pregnant, PADCEV can harm the unborn baby.
- You should use an effective method of birth control during your treatment and for at least 4 months after the last dose of PADCEV.



Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking PADCEV with certain other medicines may cause side effects.

What are the possible side effects of PADCEV?

PADCEV may cause serious side effects, including:

- **Skin Reactions.** See “What is the most important information I should know about PADCEV?”
- **High blood sugar (hyperglycemia).** An increase in blood sugar is common during treatment with PADCEV. Severe high blood sugar, a serious condition called diabetic ketoacidosis (DKA), and death have happened in people with and without diabetes



treated with PADCEV. Tell your healthcare provider right away if you have any symptoms of high blood sugar, including: frequent urination, increased thirst, blurred vision, confusion, it becomes harder to control your blood sugar, drowsiness, loss of appetite, fruity smell on your breath, nausea, vomiting, or stomach pain.



- **Lung problems.** PADCEV may cause severe or life-threatening inflammation of the lungs that can lead to death. These severe problems may happen more often when PADCEV is given in combination with pembrolizumab. Tell your healthcare provider right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough.



- **Nerve problems.** Nerve problems called peripheral neuropathy are common during treatment with PADCEV and can sometimes be severe. Nerve problems may happen more often when PADCEV is given in combination with pembrolizumab. Tell your healthcare provider right away if you get new or worsening numbness or tingling in your hands or feet or muscle weakness.




- **Eye problems.** Certain eye problems are common during treatment with PADCEV. Tell your healthcare provider right away if you have dry eyes, increased tearing, blurred vision, or any vision changes. You may use artificial tear substitutes to help prevent or treat dry eyes.



- **Leakage of PADCEV out of your vein into the tissues around your infusion site (extravasation).** If PADCEV leaks from the injection site or the vein into the nearby skin and tissues, it could cause an infusion site reaction. These reactions can happen right after you receive an infusion, but sometimes may happen days after your infusion. Tell your healthcare provider or get medical help right away if you notice any redness, swelling, itching, blister, peeling skin or discomfort at the infusion site.

Please see Important Safety Information throughout, and read the Patient Information for more information, including risk of Serious Side Effects.

 **PADCEV**
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

IMPORTANT SAFETY INFORMATION (CONT'D)

Your healthcare provider may decrease your dose of PADCEV®, or temporarily or completely stop your treatment with PADCEV if you have severe side effects.

The most common side effects of PADCEV when used alone include:

- rash. **See “What is the most important information I should know about PADCEV?”**
- changes in liver and kidney function tests
- increased sugar (glucose) in the blood. **See “High blood sugar (hyperglycemia)”**
- tiredness
- hair loss
- decreased appetite
- diarrhea
- decreased sodium, phosphate and protein (albumin) in the blood
- nausea
- itching
- change in sense of taste
- increased uric acid in the blood
- increased lipase (a blood test done to check your pancreas)
- decreased white blood cell, red blood cell, and platelet counts
- decreased weight
- dry skin

If your healthcare provider prescribes PADCEV in combination with pembrolizumab for you, also read the Medication Guide that comes with pembrolizumab for important information about pembrolizumab.

The most common side effects of PADCEV when used in combination with pembrolizumab include:

- increased sugar (glucose) in the blood. **See “High blood sugar (hyperglycemia)”**
- changes in liver function and kidney function tests
- rash. **See “What is the most important information I should know about PADCEV?”**
- decreased red blood cell and white blood cell counts
- tiredness
- decreased sodium, phosphate and protein (albumin) in the blood
- increased lipase (a test done to check your pancreas)
- hair loss
- decreased weight
- diarrhea
- itching
- decreased appetite
- nausea
- change in sense of taste
- urinary tract infection
- constipation
- increased or decreased potassium
- increased calcium in the blood
- swelling of the arms, hands, legs and feet
- dry eye. **See “Eye problems”**
- dizziness
- joint aches
- dry skin


PADCEV may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of PADCEV.



Call your doctor for medical advice about side effects.
You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Important Safety Information throughout, and [read the Patient Information for more information, including risk of Serious Side Effects.](#)

 **PADCEV**
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

Discussing PADCEV® with your healthcare team

Starting a new treatment can come with questions. Use these sample questions to start the conversation with your healthcare team and help you get the information you need.

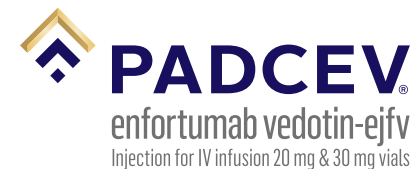
How is PADCEV different from other treatments I have tried?

How many times a month will I need to go to the clinic, infusion center, or doctor's office for my treatment?

How will I know if this treatment is working for me?

How will this treatment affect my daily life?

Please see Important Safety Information throughout, and [read the Patient Information for more information, including risk of Serious Side Effects.](#)



PADCEV® questions for caregivers

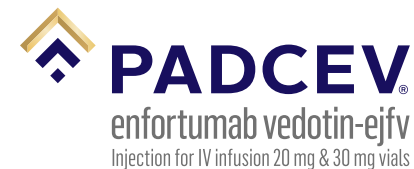
Caregivers play an important part in helping patients on their treatment journeys. Caregivers should discuss subjects such as these with the patient's healthcare professional or nurse navigator to see how they can best support their loved one and themselves.

Is there someone I can talk to for emotional support, or are there support groups I can join?

Is there a website or other materials where I can learn more about PADCEV, advanced bladder cancer, and supporting my loved one through treatment?

Is there financial support that you can connect us with?

Please see Important Safety Information throughout, and [read the Patient Information for more information, including risk of Serious Side Effects.](#)



Discussing possible side effects with your healthcare team

Use the below sample questions to discuss the possible side effects of treatment with PADCEV® alone or in combination with pembrolizumab.

What are the possible side effects I may experience during treatment?

When should I call the doctor if I experience a side effect?

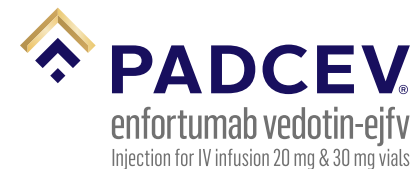
When do side effects usually occur? Do some side effects occur earlier than others?

How will side effects impact my treatment?



Visit [PADCEV.com/resources](https://www.padcev.com/resources) for more information about your treatment and for additional resources to download or print.

Please see Important Safety Information throughout, and [read the Patient Information for more information, including risk of Serious Side Effects.](#)




Tracking your symptoms

It's important to keep your healthcare team aware of how you're feeling. The earlier you let your healthcare team know, the more they'll be able to help you. Use the tables on pages 7 and 8 to track any symptoms you might be experiencing while taking PADCEV® alone or in combination with pembrolizumab.

For each day you experience a symptom, write the number that represents the degree of the symptom:

-  **1**
 Hardly noticeable
-  **2**
 Noticeable, but can still do usual activities
-  **3**
 Uncomfortable, unable to do some activities
-  **4**
 Very uncomfortable, hard to do any activities
-  **5**
 Unbearable, unable to do any activities

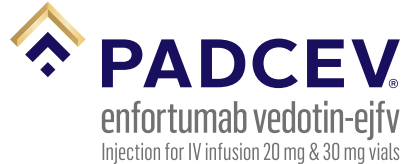
| | Week of: | | | | | | | Week of: | | | | | | | Week of: | | | | | | | Week of: | | | | | | |
|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|
| List the symptoms that you are experiencing below | S | M | T | W | T | F | S | S | M | T | W | T | F | S | S | M | T | W | T | F | S | S | M | T | W | T | F | S |
| Example: <i>Feeling tired</i> | 1 | | 2 | 2 | 3 | | 1 | 1 | 1 | 2 | 1 | | 2 | 1 | 2 | 2 | 1 | | | 1 | 1 | | 1 | 1 | 2 | | 1 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

 **REMINDER:** When used alone, PADCEV is given on days 1, 8, and 15 of a 28-day treatment cycle. Each PADCEV with pembrolizumab cycle is 21 days. PADCEV is given on days 1 and 8. Pembrolizumab is then given about 30 minutes after PADCEV on day 1.

 **NOTE:** Print or download additional copies of pages 7 and 8 to track symptoms beyond week 12.

 If you experience certain side effects, your healthcare team may decrease your dose or stop your treatment with PADCEV for a period of time (temporarily) or completely. Call your healthcare team right away if you experience side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



Please see Important Safety Information throughout, and read the Patient Information for more information, including risk of Serious Side Effects.




Tracking your symptoms (cont'd)

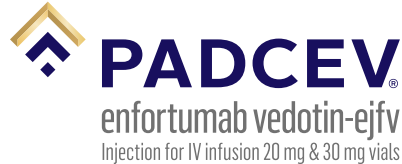
| | Week of: | | | | | | | Week of: | | | | | | | Week of: | | | | | | | Week of: | | | | | | |
|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|
| List the symptoms that you are experiencing below | S | M | T | W | T | F | S | S | M | T | W | T | F | S | S | M | T | W | T | F | S | S | M | T | W | T | F | S |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| | Week of: | | | | | | | Week of: | | | | | | | Week of: | | | | | | | Week of: | | | | | | |
|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|----------|---|---|---|---|---|---|
| List the symptoms that you are experiencing below | S | M | T | W | T | F | S | S | M | T | W | T | F | S | S | M | T | W | T | F | S | S | M | T | W | T | F | S |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

-  **REMINDER:** PADCEV® is given on days 1, 8, and 15 of a 28-day treatment cycle. Each PADCEV with pembrolizumab cycle is 21 days. PADCEV is given on days 1 and 8. Pembrolizumab is then given about 30 minutes after PADCEV on day 1.
-  **NOTE:** Print or download additional copies of pages 7 and 8 to track symptoms beyond week 12.

 Call your healthcare team right away if you experience side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Important Safety Information throughout, and read the Patient Information for more information, including risk of **Serious Side Effects**.



PADCEV Support SolutionsSM is here to help

The Patient Connect Program, part of PADCEV Support Solutions, may be able to help connect you and your loved ones to educational resources and support based on your particular needs.*



For more information, call PADCEV Support Solutions at
1-888-402-0627 Monday-Friday, 8:30 AM to 8:00 PM ET

For more information about PADCEV[®] and to download additional copies of this Discussion Guide and Symptom Tracker, please visit [PADCEV.com](https://www.padcev.com).

*Support is provided through third-party organizations that operate independently and are not controlled or endorsed by Astellas or Seagen. Availability of support and eligibility requirements are determined by these organizations.

Please see Important Safety Information throughout, and [read the Patient Information for more information, including risk of Serious Side Effects.](#)



© 2023 Astellas Pharma US, Inc. and Seagen Inc. All rights reserved. 081-1033-PM 03/23
PADCEV[®] and the PADCEV device are trademarks jointly owned by Agensys, Inc., and Seagen Inc.
Astellas and the flying star logo are registered trademarks of Astellas Pharma Inc.
Seagen and the Seagen logo are registered trademarks of Seagen Inc.
PADCEV Support SolutionsSM, a component of Astellas Pharma Support SolutionsSM, is a service mark jointly owned by Agensys, Inc., and Seagen Inc.
Keytruda[®] is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.
All other marks referenced herein are the property of their respective owners.



PATIENT INFORMATION

PADCEV® (PAD-sev)
(enfortumab vedotin-ejfv)
for injection

If your healthcare provider prescribes PADCEV in combination with pembrolizumab for you, also read the Medication Guide that comes with pembrolizumab for important information about pembrolizumab.

What is the most important information I should know about PADCEV?

PADCEV may cause serious side effects, including:

Skin reactions. Skin reactions including severe skin reactions have happened in people treated with PADCEV and may be more common when PADCEV is given with pembrolizumab. In some cases, these severe skin reactions have caused death. Most severe skin reactions occurred during the first cycle of treatment but may happen later. Your healthcare provider will monitor you, may stop your treatment with PADCEV completely or for a period of time (temporarily), may change your dose, and may prescribe medicines if you get skin reactions. Tell your healthcare provider right away if you develop any of these signs of a new or worsening skin reaction:

- target lesions (skin reactions that look like rings)
- rash or itching that continues to get worse
- blistering or peeling of the skin
- painful sores or ulcers in mouth or nose, throat, or genital area
- fever or flu-like symptoms
- swollen lymph nodes

See “**What are the possible side effects of PADCEV?**” for more information about side effects.

What is PADCEV?

PADCEV is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery.

- PADCEV may be used alone if you:
 - have received an immunotherapy medicine **and** chemotherapy that contains platinum, **or**
 - are not able to receive a chemotherapy that contains the medicine cisplatin and you have received 1 or more prior therapy.
- PADCEV may be used with pembrolizumab if you:
 - are not able to receive a chemotherapy that contains the medicine cisplatin.

It is not known if PADCEV is safe and effective in children.

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

- are currently experiencing numbness or tingling in your hands or feet
- have a history of high blood sugar or diabetes
- have liver problems
- are pregnant or plan to become pregnant. PADCEV can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with PADCEV.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with PADCEV.
- You should use an effective method of birth control during your treatment and for at least 2 months after the last dose of PADCEV.

Males with a female sexual partner who is able to become pregnant:

- If your female partner is pregnant, PADCEV can harm the unborn baby.
- You should use an effective method of birth control during your treatment and for at least 4 months after the last dose of PADCEV.
- are breastfeeding or plan to breastfeed. It is not known if PADCEV passes into your breast milk. Do not breastfeed during treatment and for at least 3 weeks after the last dose of PADCEV.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking PADCEV with certain other medicines may cause side effects.

How will I receive PADCEV?

- PADCEV will be given to you by intravenous (IV) infusion into your vein over 30 minutes.
- PADCEV is given over periods of time called “cycles”.
- If you receive PADCEV alone.
 - Each PADCEV cycle is 28 days.
 - You will receive PADCEV on days 1, 8 and 15 of every cycle.
- If you receive PADCEV with pembrolizumab,
 - Each cycle is 21 days.
 - You will receive PADCEV on days 1 and 8 of every cycle.
- Your healthcare provider will decide how many treatment cycles you need.
- Your healthcare provider may do blood tests regularly during treatment with PADCEV.

What are the possible side effects of PADCEV?

PADCEV may cause serious side effects, including:

- See “What is the most important information I should know about PADCEV?”
- **High blood sugar (hyperglycemia).** An increase in blood sugar is common during treatment with PADCEV. Severe high blood sugar, a serious condition called diabetic ketoacidosis (DKA), and death have happened in people with and without diabetes, treated with PADCEV. Tell your healthcare provider right away if you have any symptoms of high blood sugar, including:
 - frequent urination
 - increased thirst
 - blurred vision
 - confusion
 - it becomes harder to control your blood sugar
 - drowsiness
 - loss of appetite
 - fruity smell on your breath
 - nausea, vomiting, or stomach pain
- **Lung problems.** PADCEV may cause severe or life-threatening inflammation of the lungs that can lead to death. These severe problems may happen more often when PADCEV is given in combination with pembrolizumab. Tell your healthcare provider right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough.
- **Nerve problems.** Nerve problems called peripheral neuropathy are common during treatment with PADCEV and can also sometimes be severe. Nerve problems may happen more often when PADCEV is given in combination with pembrolizumab. Tell your healthcare provider right away if you get new or worsening numbness or tingling in your hands or feet or muscle weakness.
- **Eye problems.** Certain eye problems are common during treatment with PADCEV. Tell your healthcare provider right away if you have dry eyes, increased tearing, blurred vision, or any vision changes. You may use artificial tear substitutes to help prevent or treat dry eyes.
- **Leakage of PADCEV out of your vein into the tissues around your infusion site (extravasation).** If PADCEV leaks from the injection site or the vein into the nearby skin and tissues, it could cause an infusion site reaction. These reactions can happen right after you receive an infusion, but sometimes may happen days after your infusion. Tell your healthcare provider or get medical help right away if you notice any redness, swelling, itching, blister, peeling skin, or discomfort at the infusion site.

Your healthcare provider may decrease your dose of PADCEV, or temporarily or completely stop your treatment with PADCEV if you have severe side effects.

The most common side effects of PADCEV when used alone include:

- rash. See “What is the most important information I should know about PADCEV?”
- changes in liver and kidney function tests
- increased sugar (glucose) in the blood. See “High blood sugar (hyperglycemia)” above.
- tiredness
- decreased white blood cell, red blood cell, and platelet counts
- hair loss
- decreased appetite
- diarrhea
- decreased sodium, phosphate and protein (albumin) in the blood
- nausea
- itching
- change in sense of taste
- increased uric acid in the blood
- increased lipase (a blood test done to check your pancreas)
- decreased weight
- dry skin

The most common side effects of PADCEV when used in combination with pembrolizumab include:

- increased sugar (glucose) in the blood. See “High blood sugar (hyperglycemia)” above.
- changes in liver function and kidney function tests
- rash. See “What is the most important information I should know about PADCEV?”
- decreased red blood cell and white blood cell counts
- tiredness
- decreased sodium, phosphate and protein (albumin) in the blood
- increased lipase (a test done to check your pancreas)
- hair loss
- decreased weight
- diarrhea
- itching
- decreased appetite
- nausea
- change in sense of taste
- urinary tract infection
- constipation
- increased or decreased potassium
- increased calcium in the blood
- swelling of the arms, hands, legs and feet
- dry eye. See “Eye problems” above.
- dizziness
- joint aches
- dry skin

PADCEV may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of PADCEV.

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

General information about the safe and effective use of PADCEV.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about PADCEV that is written for healthcare professionals.

What are the ingredients in PADCEV?

Active ingredient: enfortumab vedotin-ejfv

Inactive ingredients: histidine, histidine hydrochloride monohydrate, polysorbate 20, and trehalose dihydrate.

Manufactured and Marketed by: Astellas Pharma US, Inc., Northbrook, Illinois 60062

Distributed and Marketed by: Seagen Inc., Bothell, WA 98021

U.S. License 2124

PADCEV is a registered trademark jointly owned by Agensys, Inc. and Seagen Inc.

©2023 Agensys, Inc. and Seagen Inc.

For more information, go to www.padcev.com or call 1-888-4-PADCEV

357259-EV-USA

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 4/2023