PATIENT BROCHURE

On Eye Problems Including Central Serous Retinopathy/ Retinal Pigment Epithelial Detachment (CSR/RPED)

WHAT IS BALVERSA® (erdafitinib)?

BALVERSA® is a prescription medicine used to treat adults with bladder cancer (urothelial cancer) that has spread or cannot be removed by surgery:

- which has a certain type of abnormal *FGFR* gene, **and**
- who have tried at least one other medicine by mouth or injection (systemic therapy) that did not work or is no longer working.

Your healthcare provider will test your cancer for certain types of abnormal *FGFR* genes and make sure that BALVERSA® is right for you.

BALVERSA® is not recommended for the treatment of people who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.

It is not known if BALVERSA® is safe and effective in children.

IMPORTANT SAFETY INFORMATION

BALVERSA® may cause serious side effects, including eye problems and high phosphate levels in the blood (hyperphosphatemia). BALVERSA® can harm your unborn baby. You should not become pregnant during treatment with BALVERSA®.

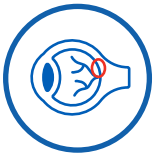
Please see additional Important Safety Information throughout this brochure and the accompanying full BALVERSA® Prescribing Information.

Balversa® (erdafitinib)
3, 4, 5 mg tablets

Eye Problems in Patients Receiving BALVERSA® Treatment[1]

- Eye problems are common when taking BALVERSA® and can also be serious.
- Eye problems can include dry or inflamed eyes, inflamed cornea (front part of the eye), and disorders of the retina, an internal part of the eye.
- This can include a condition called Central Serous Retinopathy/ Retinal Pigment Epithelial Detachment (CSR/RPED).

What is Central Serous Retinopathy/ Retinal Pigment Epithelial Detachment (CSR/RPED)?



CSR/RPED affects the retina, the light sensitive part of the eye.[2,3]

- Fluid builds up behind the retina, causing a bubble-like swelling in the eye which may lead to changes in vision.[2,3]
- In RPED, fluid is in the layer of cells beneath the retina (retinal pigment epithelium).[4]

IMPORTANT SAFETY INFORMATION

What are the possible side effects of BALVERSA®?

BALVERSA® may cause serious side effects, including:

- **Eye problems.** Eye problems are common with BALVERSA® but can also be serious. Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye) and disorders of the retina, an internal part of the eye. Tell your healthcare provider right away if you develop blurred vision, loss of vision or other visual changes. You should use artificial tear substitutes, hydrating or lubricating eye gels or ointments at least every 2 hours during waking hours to help prevent dry eyes. During treatment with BALVERSA®, your healthcare provider will send you to see an eye specialist.

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Balversa® (erdafitinib) 3, 4, 5 mg tablets

CSR/RPED has been seen during BALVERSA® treatment in clinical studies[1]

- The safety of BALVERSA® was studied in 479 patients with advanced bladder cancer and who tested positive for an *FGFR* mutation. CSR/RPED was reported in approximately 22% of patients (105 out of 479 people) treated with BALVERSA®.
- For patients who experienced CSR/RPED with BALVERSA®, symptoms generally occurred 46 days after starting treatment.
- In 104 patients with CSR, 40% of patients (approximately 42 people) required a temporary stop of BALVERSA® and 56% of patients (approximately 58 people) required a reduction in the dose of BALVERSA®. 2.9% of patients (approximately 3 people) permanently stopped taking BALVERSA®.
- Of the 24 of patients who restarted treatment with BALVERSA®, 67% of patients (approximately 16 people) had recurrence or worsening of CSR.
- CSR continued in 41% of the 104 patients (approximately 43 people) with CSR at the study cutoff.
- If you have additional questions about CSR/RPED, please speak to your healthcare provider or eye care specialist.

IMPORTANT SAFETY INFORMATION

- **High phosphate levels in the blood (hyperphosphatemia).** Hyperphosphatemia is common with BALVERSA® but can also be serious. High levels of phosphate in your blood may lead to build-up of minerals such as calcium in different tissues in your body. Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA®, and then monthly.
  - Your healthcare provider may prescribe changes in your diet or phosphate-lowering therapy, or change or stop treatment with BALVERSA® if needed.
  - Tell your healthcare provider right away if you develop painful skin lesions, any muscle cramps, or numbness or tingling around your mouth.

The most common side effects of BALVERSA® include:

- nails separate from the bed or poor formation of the nail
- mouth sores
- diarrhea
- increased level of creatinine in the blood
- increased level of the enzyme alkaline phosphatase in the blood
- change in liver function
- decreased red blood cells (anemia)
- decreased salt (sodium) levels in the blood
- tiredness
- dry mouth
- dry skin
- decreased phosphate in the blood
- decreased appetite
- change in sense of taste
- constipation
- increased level of calcium in the blood
- dry eye
- redness, swelling, peeling or tenderness, mainly on the hands or feet (hand-foot syndrome)
- increased level of potassium in the blood
- hair loss
- fluid buildup behind the retina in your eye

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Balversa® (erdafitinib) 3, 4, 5 mg tablets

Tell your healthcare provider immediately if you experience any of these eye problems during your BALVERSA® treatment[1]:

Blurred vision | **Vision loss** | **Any other visual changes**

Why should you have regular eye examinations during BALVERSA® treatment?

- Throughout your BALVERSA® treatment, you will be asked by your healthcare provider to have regular eye examinations[1]:
  - monthly for the first 4 months
  - then once every 3 months
  - and urgently anytime you may have eye symptoms
- You should use artificial tear substitutes, hydrating or lubricating eye gels or ointments at least every 2 hours during waking hours to help prevent dry eyes.[1]
- Regular eye examinations are still important even if you do not have any CSR/RPED symptoms.
  - Some patients with CSR/RPED may not experience any changes in vision, and CSR/RPED may only be detected upon eye examination.[2,3]

What eye tests may be performed?[1]

Visual acuity[5]

You will be asked to read from an eye chart to measure your vision over distances.

Optical coherence tomography[6]

Your eyes may be dilated, then a camera-like device will take images of the back of your eye.

Slit lamp examination[7]

The front of your eye will be examined using a microscope.

Fundoscopy[8]

The back of your eye will be examined using a special lens.

IMPORTANT SAFETY INFORMATION

Tell your healthcare provider right away if you develop any nail or skin problems including nails separating from the nail bed, nail pain, nail bleeding, breaking of the nails, color or texture changes in your nails, infected skin around the nail, an itchy skin rash, dry skin, or cracks in the skin.

BALVERSA® may affect fertility in females who are able to become pregnant. Talk to your healthcare provider if this is a concern for you.

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

Please see additional Important Safety Information throughout this brochure and the accompanying full BALVERSA® Prescribing Information.

Balversa® (erdafitinib) 3, 4, 5 mg tablets

What happens if you develop CSR/RPED while taking BALVERSA®?[1]

- If CSR/RPED is detected, your healthcare provider will stop your BALVERSA® treatment for a period of time.
- If BALVERSA® treatment is restarted, it may be at a lower dose to help prevent CSR/RPED from returning.
- If CSR/RPED is severe or not improving, your BALVERSA® treatment will be permanently stopped.

Patient Information Card

Your healthcare provider will give you an information card explaining that you are currently taking BALVERSA® and may be at risk of developing CSR/RPED.

- This information card is to alert your eye care specialist or other healthcare provider of the necessary eye exams you require before or while being treated with BALVERSA®, and actions to take if eye problems, such as CSR/RPED, are detected.
- Please carry this card with you. You will need to show this card to your eye care specialist or other healthcare provider at every appointment.

If you have additional questions about CSR/RPED, please speak to your healthcare provider or eye care specialist.

Please speak with your healthcare provider **immediately** if you are experiencing any side effects while treated with BALVERSA®.

IMPORTANT SAFETY INFORMATION

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

Keep BALVERSA® out of the reach of children.

General information about the safe and effective use of BALVERSA®.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use BALVERSA® for a condition for which it was not prescribed. Do not give BALVERSA® to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about BALVERSA® that is written for healthcare professionals.

Please see additional Important Safety Information throughout this brochure and the accompanying full BALVERSA® Prescribing Information.

Balversa® (erdafitinib) 3, 4, 5 mg tablets

IMPORTANT SAFETY INFORMATION

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

- have vision or eye problems.
- are pregnant or plan to become pregnant. BALVERSA® can harm your unborn baby. You should not become pregnant during treatment with BALVERSA®.

Females who can become pregnant:

— Your healthcare provider may do a pregnancy test before you start treatment with BALVERSA®.

— You should use effective birth control during treatment and for 1 month after the last dose of BALVERSA®. Talk to your healthcare provider about birth control methods that may be right for you.

— Tell your healthcare provider right away if you become pregnant or think you may be pregnant.

Males with female partners who can become pregnant:

— You should use effective birth control when sexually active during treatment with BALVERSA® and for 1 month after the last dose.

- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 1 month after the last dose of BALVERSA®.

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 BALVERSA®?

BALVERSA® may cause serious side effects, including:

- **Eye problems.** Eye problems are common with BALVERSA® but can also be serious. Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye) and disorders of the retina, an internal part of the eye. Tell your healthcare provider right away if you develop blurred vision, loss of vision or other visual changes. You should use artificial tear substitutes, hydrating or lubricating eye gels or ointments at least every 2 hours during waking hours to help prevent dry eyes. During treatment with BALVERSA®, your healthcare provider will send you to see an eye specialist.
- **High phosphate levels in the blood (hyperphosphatemia).** Hyperphosphatemia is common with BALVERSA® but can also be serious. High levels of phosphate in your blood may lead to build-up of minerals such as calcium in different tissues in your body. Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA®, and then monthly.
  — Your healthcare provider may prescribe changes in your diet or phosphate-lowering therapy, or change or stop treatment with BALVERSA® if needed.
  — Tell your healthcare provider right away if you develop painful skin lesions, any muscle cramps, or numbness or tingling around your mouth.

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IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of BALVERSA®? (continued)

The most common side effects of BALVERSA® include:

- nails separate from the bed or poor formation of the nail
- mouth sores
- diarrhea
- increased level of creatinine in the blood
- increased level of the enzyme alkaline phosphatase in the blood
- change in liver function
- decreased red blood cells (anemia)
- decreased salt (sodium) levels in the blood
- tiredness
- dry mouth
- dry skin
- decreased phosphate in the blood
- decreased appetite
- change in sense of taste
- constipation
- increased level of calcium in the blood
- dry eye
- redness, swelling, peeling or tenderness, mainly on the hands or feet (hand-foot syndrome)
- increased level of potassium in the blood
- hair loss
- fluid buildup behind the retina in your eye

Tell your healthcare provider right away if you develop any nail or skin problems including nails separating from the nail bed, nail pain, nail bleeding, breaking of the nails, color or texture changes in your nails, infected skin around the nail, an itchy skin rash, dry skin, or cracks in the skin.

BALVERSA® may affect fertility in females who are able to become pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all possible side effects of BALVERSA®. 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.

Keep BALVERSA® out of the reach of children.

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Please see accompanying full Prescribing Information for BALVERSA®.

References: 1. BALVERSA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Semeraro F, Morescalchi F, Russo A, et al. Central serous chorioretinopathy: Pathogenesis and management. *Clin Ophthalmol*. 2019;13:2341-2352. **3.** The American Society of Retina Specialists. Central Serous Chorioretinopathy. Asrs.org. Accessed January 8, 2024. https://www.asrs.org/patients/retinal-diseases/21/central-serous-chorioretinopathy **4.** American Academy of Ophthalmology. Pigment Epithelial Detachment. AAO.org. Published November 21, 2012. Accessed January 8, 2024. https://www.aao.org/eye-health/ask-ophthalmologist-q/information-on-pigment-epithelial-detachment **5.** American Academy of Ophthalmology. Eye Exams 101. AAO.org. Published January 1, 2021. Accessed January 8, 2024. https://www.aao.org/eye-health/tips-prevention/eye-exams-101 **6.** American Academy of Ophthalmology. What is Optical Coherence Tomography? AAO.org. Published June 28, 2021. Accessed January 8, 2024. https://www.aao.org/eye-health/treatments/what-is-optical-coherence-tomography **7.** American Academy of Ophthalmology. What is Slit Lamp? AAO.org. Published April 23, 2018. Accessed January 8, 2024. www.aao.org/eye-health/treatments/what-is-slit-lamp **8.** NCI Dictionary of Cancer Terms. Cancer.gov. Published February 2, 2011. Accessed January 8, 2024. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/fundoscopy

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If you have additional questions about CSR/RPED, please speak to your healthcare provider or eye care specialist.

Please speak with your healthcare provider **immediately** if you are experiencing any side effects while treated with BALVERSA®.

For more information, visit **www.balversa.com**

Please see additional Important Safety Information throughout this brochure and the accompanying full BALVERSA® Prescribing Information.

Johnson&Johnson

Balversa® (erdafitinib)
3, 4, 5 mg tablets

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Information Card For Patients Receiving BALVERSA® (erdafitinib)

Balversa® (erdafitinib) 3, 4, 5 mg tablets

BALVERSA® patients: Please carry this card, along with this brochure, and provide it to your eye care specialist or healthcare provider at every appointment. The intent of this card is to alert your eye care specialist or healthcare provider that you are receiving BALVERSA® treatment, and of the necessary eye exams you require. Ask your eye specialist to follow up with your oncology specialist for any additional follow-up or questions about your condition.

Indication: BALVERSA® is a prescription medicine used to treat adults with bladder cancer (urothelial cancer) that has spread or cannot be removed by surgery:

- which has a certain type of abnormal *FGFR* gene, **and**
- who have tried at least one other medicine by mouth or injection (systemic therapy) that did not work or is no longer working.

Your healthcare provider will test your cancer for certain types of abnormal *FGFR* genes and make sure that BALVERSA® is right for you.

BALVERSA® is not recommended for the treatment of people who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.

It is not known if BALVERSA® is safe and effective in children.

Patient's name:

.....

I am taking the following medication: BALVERSA®

Dear Eye Care Specialist or Other Healthcare Provider,

Eye problems are common when taking BALVERSA® and can include dry or inflamed eyes, inflamed cornea (front part of the eye), and disorders of the retina including Central Serous Retinopathy/Retinal Pigment Epithelial Detachment (CSR/RPED).[1]

Information for Healthcare Professionals

BALVERSA®-treated patients should receive monthly eye exams during the first 4 months of treatment and every 3 months afterwards, plus urgently at any time if experiencing vision problems.

These examinations should include: Optical coherence tomography, assessment of visual acuity, slit lamp examination, and fundoscopy.

If CSR/RPED is detected, please contact the prescriber of BALVERSA® mentioned in this document.

HCP's name:	Staff/Nurse's name:
.....	.....
HCP's telephone number:	**Staff/Nurse's telephone number:**
.....	.....

IMPORTANT SAFETY INFORMATION

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

- have vision or eye problems.
- are pregnant or plan to become pregnant. BALVERSA® can harm your unborn baby. You should not become pregnant during treatment with BALVERSA®.

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— Your healthcare provider may do a pregnancy test before you start treatment with BALVERSA®.
— You should use effective birth control during treatment and for 1 month after the last dose of BALVERSA®. Talk to your healthcare provider about birth control methods that may be right for you.
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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of BALVERSA® (erdafitinib)?

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- decreased salt (sodium) levels in the blood
- tiredness
- dry mouth
- dry skin
- decreased phosphate in the blood
- decreased appetite
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- constipation
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- hair loss
- fluid buildup behind the retina in your eye

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Reference: 1. BALVERSA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.