YOUR BALVERSA® TREATMENT GUIDE

IT'S TIME TO SEE WHAT A TARGETED TREATMENT MAY DO FOR YOU

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.

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®.

Please see Important Safety Information on pages 14-16 and click here to see full BALVERSA® Prescribing Information.

What is bladder cancer (urothelial cancer)?

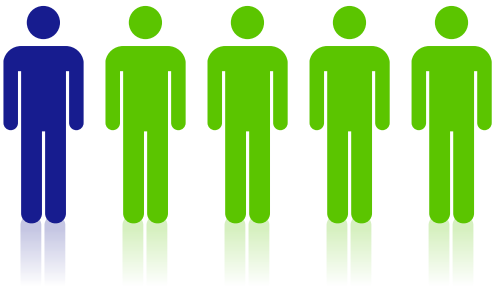
In bladder cancer (urothelial cancer), cells grow abnormally in the urinary bladder to form a tumor. Most bladder cancers start in the inner lining of the bladder, which is called the urothelium. If the tumor spreads outside the bladder, it's considered advanced bladder cancer.

I want to learn more about bladder cancer and the role of FGFR

What does it mean to have an abnormal *FGFR* gene?

FGFR stands for fibroblast growth factor receptor. FGFR helps cells grow, survive, and multiply. In certain types of cancer, including some cases of bladder cancer, the gene that controls FGFR can change or mutate (known as an *FGFR* alteration). The *FGFR* alteration may cause cancer cells to develop, leading to rapid growth and spread.

How many people with advanced bladder cancer have tumors with an abnormal *FGFR* gene?



APPROXIMATELY

20%*

of all people with advanced bladder cancer can have tumors with an abnormal *FGFR* gene

How do I find out if my tumor has an abnormal *FGFR* gene?

A doctor will send a sample of the tumor to a lab for analysis.

*Based on data derived from tumors of patients with muscle-invasive bladder cancer (MIBC).

NOTE: A glossary defining many medical terms used in this booklet appears on pages 18-19.

Learn about BALVERSA® (erdafitinib)

BALVERSA® is an oral prescription medicine used to treat adults who:

Have bladder cancer (urothelial cancer) that has spread or cannot be removed by surgery

Have a tumor that carries a certain type of abnormal *FGFR* gene

Have tried at least one other medicine by mouth or injection (systemic therapy) that did not work or is no longer working

Discuss all of your treatment options with your doctor.

Your doctor will perform a test to check for certain types of abnormal *FGFR* genes, and make sure that BALVERSA® is right for you.

IMPORTANT SAFETY INFORMATION (CONT'D)

Females who can become pregnant:

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

For more information, please visit www.balversa.com

Please see Important Safety Information on pages 14-16 and click here to see full BALVERSA® Prescribing Information.

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

IMPORTANT SAFETY INFORMATION (CONT'D)

Females who can become pregnant (cont'd):

- 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.

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

What is BALVERSA® (erdafitinib)?

How does BALVERSA® work?

BALVERSA® is a drug that is called a kinase inhibitor. A kinase inhibitor is a substance that blocks a type of enzyme (a protein) called a kinase. Human cells have many different kinases, and they help control important functions.

BALVERSA® works by stopping the activity of FGFR, which is present in the bladder cancer tumor cell as well as healthy cells throughout the body. Because BALVERSA® targets the FGFR protein and can affect all cells with this receptor, it may cause serious side effects.

BALVERSA® is the first medicine of its kind approved by the FDA to treat people with advanced bladder cancer where the tumor carries a certain abnormal *FGFR* gene.

FDA = U.S. Food and Drug Administration.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

What is BALVERSA® (erdafitinib)? (cont'd)

Is BALVERSA® right for you?

Talk to your doctor about whether BALVERSA® may be right for you.

In order for you to receive BALVERSA®, your doctor must first test your cancer for certain types of abnormal *FGFR* genes. To do this, your doctor will send a tissue sample from your tumor to a lab for analysis. This can be done with tissue from a new biopsy or with tissue that was already removed, so you may not need an additional procedure.

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

BALVERSA® (erdafitinib) Clinical Study Results

BALVERSA® was studied in 266 people with advanced bladder cancer who had tried immunotherapy

- A clinical study evaluated patients who had a tumor that tested positive for an *FGFR* mutation. About half of the people (n=136) received an 8 mg dose of BALVERSA® once daily, while the other half (n=130) received intravenous chemotherapy (docetaxel or vinflunine) once every 3 weeks

- After 2 weeks, if people taking BALVERSA® had phosphate levels below a certain target (determined by a blood test), their dose was increased to 9 mg once daily

- People stayed on BALVERSA® until their tumors started to grow or until they had side effects that were too severe

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of BALVERSA®? (cont'd)

BALVERSA® may cause serious side effects, including:

- **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.

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Please see Important Safety Information on pages 14-16 and click here to see full BALVERSA® Prescribing Information.

Balversa® (erdafitinib)
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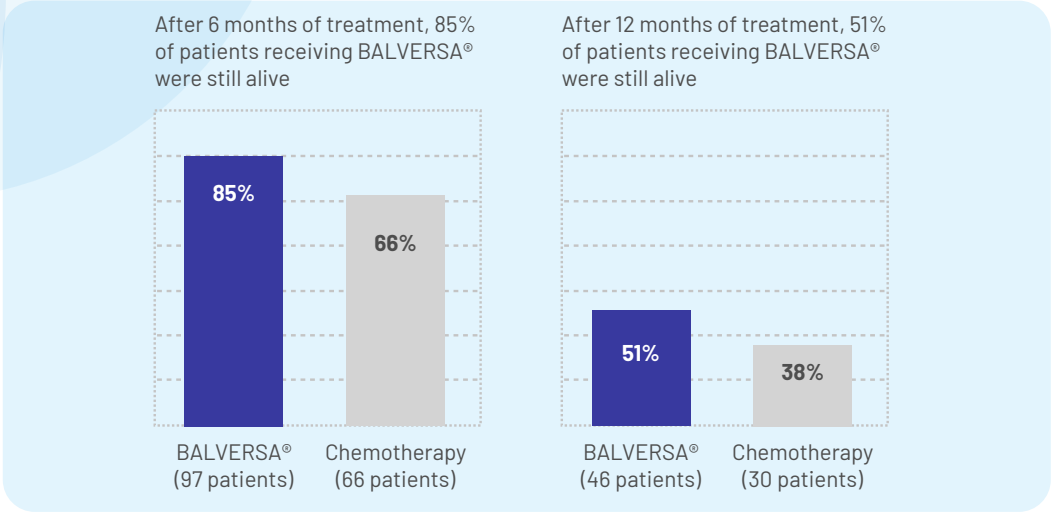
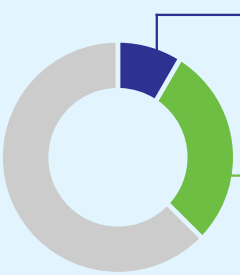
BALVERSA® may help you live longer and shrink tumors

Patients lived longer on BALVERSA® compared with chemotherapy



Median overall survival with BALVERSA® was 12.1 months vs 7.8 with chemotherapy

More people taking BALVERSA® saw their tumors shrink compared with chemotherapy



5.1% of people had their tumor disappear completely (known as a complete response), compared with 0.8% of people on chemotherapy

30.1% of people had their tumor partially shrink (known as a partial response), compared with 10.8% of people on chemotherapy

Remember, each person is different, so the results you see with BALVERSA® may not be the same as in the study.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of BALVERSA®? (cont'd)

- **High phosphate levels in the blood (hyperphosphatemia) (cont'd).**
  - 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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Balversa® (erdafitinib)
3, 4, 5 mg tablets

How will my doctor know if BALVERSA® (erdafitinib) is working?

Measuring tumor size is one way to see if there is a response

Your doctor may use several approaches to see how well BALVERSA® is working for you.

One way is to look at whether the tumor shrinks or disappears, and if it does, how long the response lasts.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of BALVERSA®? (cont'd)

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

How do I take BALVERSA®?

BALVERSA® is taken by mouth, once a day

BALVERSA® comes in tablet form. That means you don't have to travel to an infusion center for treatment with BALVERSA®. You can take it anywhere you happen to be when it's time to take your medicine.

- Take BALVERSA® exactly as your healthcare provider tells you
- Take BALVERSA® 1 time each day
- Swallow BALVERSA® tablets whole with or without food
- Your healthcare provider may change your dose of BALVERSA®, temporarily stop or completely stop treatment if you get certain side effects
- If you miss a dose of BALVERSA®, take the missed dose as soon as possible on the same day. Take your regular dose of BALVERSA® the next day. Do not take more BALVERSA® than prescribed to make up for the missed dose
- If you vomit after taking BALVERSA®, do not take another BALVERSA® tablet. Take your regular dose of BALVERSA® the next day

Your dose of BALVERSA® may change

Each person responds to medication differently. Finding the right dose of BALVERSA® is an important first step your doctor will take.

BALVERSA® has been associated with increased levels of phosphate (a common mineral found in your body and blood), known as hyperphosphatemia. Your doctor may adjust your dose based on blood phosphate levels or other side effects you may experience.

Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA® and then monthly, and may change your dose if needed.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of BALVERSA®? (cont'd)

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.

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Please see Important Safety Information on pages 14-16 and click here to see full BALVERSA® Prescribing Information.

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

Taking BALVERSA® (erdafitinib)

Take BALVERSA® as prescribed by your doctor to give the medication the best chance to work

Finding the right dose for you

Your doctor will start you on an 8 mg (two 4 mg tablets) dose of BALVERSA® once a day.

- After 14-21 days, your doctor will test your blood to check your phosphate levels

- Then, based on your phosphate levels and any side effects you may have, your doctor may change your dose. This is to help you get the best results from BALVERSA®

Don't be discouraged if your doctor changes your dose. Dosing of BALVERSA® is tailored to the individual.

Over the course of your therapy, your doctor will perform other tests and evaluations and adjust your dose if needed.

Your doctor may change your dose, temporarily stop, or completely stop treatment if you get certain side effects.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of BALVERSA®? (cont'd)

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.

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Taking BALVERSA® (erdafitinib)

Tips for taking BALVERSA®

Take BALVERSA® exactly as your doctor prescribes.

- Don't change your dose or stop taking BALVERSA® without consulting your doctor

Take BALVERSA® once a day, every day

Swallow the tablets whole

You can take BALVERSA® with or without food

What if I forget to take my pills?

If you forget a dose of BALVERSA®, take it as soon as possible on the same day. Then take your regular dose of BALVERSA® at your usual time the next day. Extra tablets should not be taken to make up for the missed dose.

If you vomit, don't take another dose until the next day. If you take too much BALVERSA®, call your doctor immediately.

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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.

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IMPORTANT SAFETY INFORMATION (CONT'D)

- **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® (erdafitinib) 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.

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IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of BALVERSA®? (cont'd)

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.

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 click here to see full BALVERSA® Prescribing Information.

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How can I get the most out of my treatment with BALVERSA® (erdafitinib)?

Record your experiences with BALVERSA® for your doctor

Keep notes about treatment effects and a list of questions for your doctor, and bring them to your next appointment.

Tell your doctor how you are feeling and what you are experiencing. This can help your treatment team meet your needs. Even if you think it's not serious, it's best to let your doctor know right away.

Glossary

Abnormal: Not normal; different from what is considered normal.

Alteration: A change resulting in something that is different from the original.

Biopsy: A tissue sample taken to diagnose disease.

Bladder: The organ that stores urine.

Bladder cancer: Cancer that forms in tissues of the bladder. Most bladder cancers are transitional cell carcinomas (cancer that begins in cells that make up the inner lining of the bladder).

Cell: In biology, the smallest unit that can live on its own. It makes up all living organisms and tissues in the body.

Chemotherapy: Treatment that uses drugs to stop the growth of cancer cells, either by killing them or by stopping them from dividing.

Complete response: The disappearance of all signs of cancer in response to treatment. This does not always mean the cancer has been cured. Also called complete remission.

FGFR (fibroblast growth factor receptor): FGFR helps cells to grow, survive, and multiply; genetic alterations in FGFR are thought to be important in the development of some bladder cancers.

Gene: Functional and physical unit of heredity passed from parents to offspring. Genes are large pieces or sequences of DNA.

Hyperphosphatemia: Having a high level of phosphate in your blood.

Immune system: A complex network of cells, tissues, organs, and the substances they make that helps the body fight infections and other diseases.

Immunotherapy: A type of therapy that uses the body's immune system to fight cancer.

Infusion: A method of putting fluids, including drugs, into the bloodstream. Also called intravenous infusion.

Glossary (cont'd)

Intravenous (IV): Usually refers to a way of giving a drug or other substance through a needle or tube inserted into a vein.

Kinase inhibitor: A substance that blocks a type of enzyme called a kinase. Human cells have many different kinases, and they help control important functions, such as cell signaling, metabolism, division, and survival. Certain kinases are more active in some types of cancer cells, and blocking them may help keep the cancer cells from growing.

Median: A statistics term; the middle value in a set of measurements.

Mutate: To change the genetic material of a cell. The changes (mutations) can be harmful, beneficial, or have no effect.

Objective response rate (ORR): The percentage of patients whose measurable tumors disappear (complete response) and decrease in size (partial response) after treatment.

Partial response: A decrease in the size of a tumor, or in the extent of cancer in the body, in response to treatment. Also called partial remission.

Phosphate: A naturally occurring mineral in the body, found in the bones and teeth.

Response: In medicine, an improvement related to treatment.

Tissue sample: A sample of tumor tissue.

Tumor: An abnormal mass of tissue that results when cells divide more than they should or do not die when they should. Tumors may be benign (not cancer), or malignant (cancer).

Urothelial cancer: Cancer that begins in cells called urothelial cells that line the urethra, bladder, ureters, and renal pelvis. Urothelial cells are also called transitional cells.

Urothelium: The inner lining of the bladder.

TALK TO YOUR DOCTOR ABOUT

BALVERSA®
(erdafitinib)

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

Once you and your doctor have decided that BALVERSA® is right for you

Patient Support for BALVERSA®

BALVERSA® is dispensed by a specialty pharmacy (CVS Specialty). To learn more about accessing BALVERSA®, please call 1-855-539-4712 or visit **CVSSpecialty.com**.

J&J withMe will identify options that may help make your treatment more affordable. Please visit **JNJwithMe.com/Balversa** for information on cost support programs that may be available for you. If you need help, please call 866-378-1910, Monday through Friday, 8:00 AM to 8:00 PM ET.

The support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

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Johnson&Johnson