

IMFINZI is approved for resectable Stage 2A-3B non-small cell lung cancer (NSCLC) with chemotherapy before surgery and alone after surgery.



What is IMFINZI?

IMFINZI is a prescription medicine used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC). IMFINZI may be used in combination with chemotherapy that contains platinum prior to surgery and alone after surgery when your NSCLC is able to be removed by surgery, and your tumor does not have an abnormal "EGFR" or "ALK" gene.

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

SELECT SAFETY INFORMATION

What is the most important information I should know about IMFINZI® (durvalumab)?

IMFINZI is a medicine that may treat certain cancers by working with your immune system. IMFINZI can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Please see additional Important Safety Information on <u>pages 27-30</u> and click the following for Full Prescribing Information including Medication Guide for <u>IMFINZI</u>.

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You're not alone

Around every 2 minutes, someone in the United States is diagnosed with lung cancer.
Over 80% of lung cancers are NSCLC, which means it's the most common type of lung cancer.

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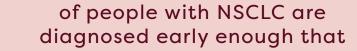
SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including: Lung problems: cough, shortness of breath, and chest pain





About
resectable
Stage 2A-3B
non-small cell
lung cancer
(NSCLC)



SURGERY IS AN OPTION



If your cancer isn't too large or hasn't spread too far, it may be resectable. **This means the cancer may be removed by surgery.**

Knowing the stage of your lung cancer

When treating cancer, doctors use a process called staging. This helps them figure out **how much cancer there is and if it has spread from where it started**.

NSCLC is divided into stages and substages, based on:

The size of the cancer

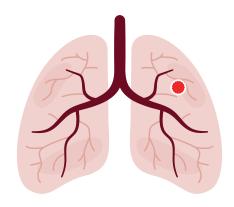
Where it is located

Whether it has spread to the lymph nodes or other parts of the body



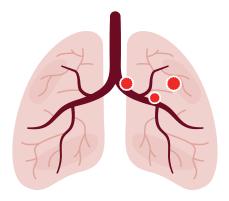
Understanding the stages of NSCLC (continued)

Knowing the stage of the cancer helps your care team come up with a treatment plan that works for you.



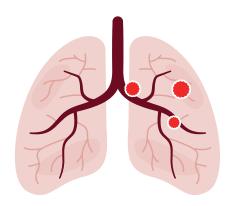
Stage 2A

The cancer has **not** spread to the nearby lymph nodes.



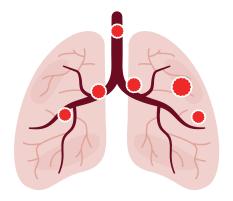
Stage 2B

The cancer has spread to the nearby lymph nodes **OR** the cancer is larger but has not spread to the lymph nodes.



Stage 3A

The cancer is larger and has spread to lymph nodes on the same side as the main lung tumor **OR** the cancer is even larger but may not have spread to the lymph nodes.



Stage 3B

The cancer is even larger and has spread to lymph nodes on the same side as the main lung tumor **OR** the cancer has spread to lymph nodes on either side of the body.



Talk to your doctor to learn more about your stage of NSCLC and what it may mean for your treatment plan.

IMFINZI helps treat resectable Stage 2A-3B NSCLC



SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Intestinal problems: diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; and severe stomach-area (abdomen) pain or tenderness

For additional Important Safety Information, please see pages 27-30.



IMFINZI IS APPROVED

for before & after surgery



IMFINZI is given in combination with chemotherapy **before surgery**. This is called neoadjuvant therapy. Then, IMFINZI is given alone **after surgery**. This is called adjuvant therapy.

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Liver problems: yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), and bleeding or bruising more easily than normal



How is IMFINZI given?

IMFINZI is given:



as an intravenous infusion



at your doctor's office



usually lasts about 60 minutes



or at an infusion center

Your doctor will test your blood to monitor you for any side effects.

Your doctor will decide how many treatments you need. They may stop treatment if your cancer gets worse or if you have any side effects that are too difficult to manage.

SELECT SAFETY INFORMATION (continued)

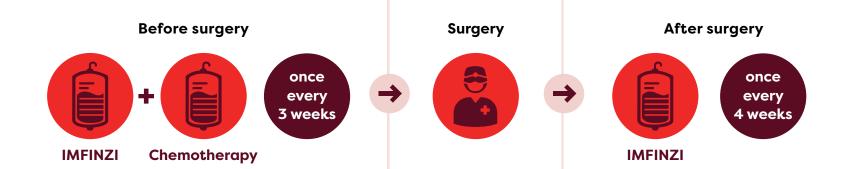
Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Hormone gland problems: headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems;

For additional Important Safety Information, please see pages 27-30.



IMFINZI may be an important part of your treatment plan



once every 3 weeks for up to 4 cycles (or up to 12 weeks).

IMFINZI is given alone once every 4 weeks for up to 12 cycles (or up to 48 weeks).

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Hormone gland problems (continued): rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness





How does IMFINZI work?

Meet the key players:



Healthy cell



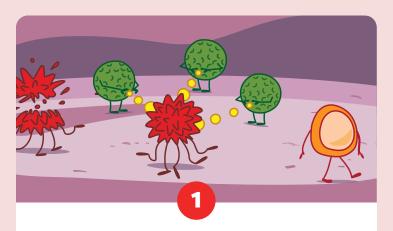
Immune system



Cancer cell



IMFINZI



The immune system serves as your body's natural defense against infections and diseases. It knows how to find and attack cancer cells when they appear in your body.

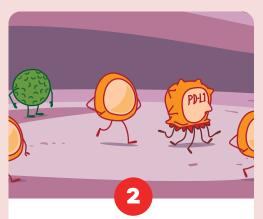
SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Kidney problems: decrease in your amount of urine, blood in your urine, swelling of your ankles, and loss of appetite

For additional Important Safety Information, please see pages 27-30.

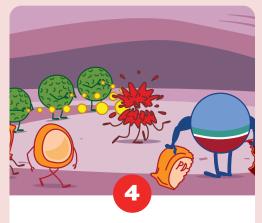




But cancer cells use a protein called PD-L1 to hide from your immune system.



IMFINZI works by binding to and blocking PD-L1 to remove the disguise and reveal the hidden cancer cells.



This means your immune system is better able to find and attack the cancer cells. IMFINZI may also affect healthy cells.

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including: Skin problems: rash, itching, skin blistering or peeling; painful sores or ulcers in mouth or nose, throat, or genital area;





How does chemotherapy work?

Meet the key players:



Healthy cell



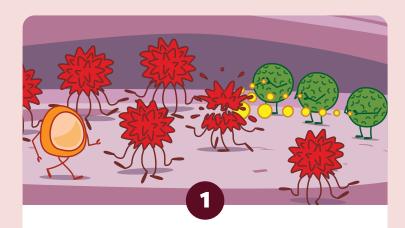
Immune system



Cancer cell



Chemotherapy



With the help of IMFINZI, your immune system works to fight cancer cells. But these cells multiply quickly.

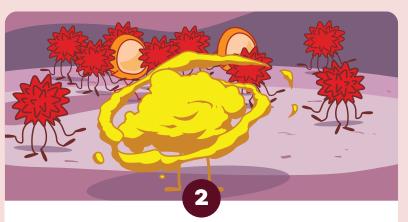
SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Skin problems (continued): fever or flu-like symptoms; and swollen lymph nodes

For additional Important Safety Information, please see pages 27-30.





This is where chemotherapy, a type of cancer treatment, can help.



Chemotherapy can destroy rapidly growing cells—such as cancer cells—throughout the body. Since chemotherapy can destroy fast-growing cells, healthy cells may also be affected.

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including: Pancreas problems: pain in your upper stomach area (abdomen), severe nausea or vomiting, and loss of appetite



A clinical trial compared two groups of adults with resectable Stage 2A-3B non-small cell lung cancer:

What were the clinical trial results with IMFINZI for resectable Stage 2A-3B NSCLC?

366

people planned to receive IMFINZI + chemotherapy before surgery, and then IMFINZI alone 374

people planned to receive placebo (no medicine) + chemo before surgery, and then placebo alone

- One goal was to measure the length of time after treatment started that people had without their cancer coming back (called event-free survival)
- Another goal was to measure if any cancer cells were left after surgery (called pathologic complete response)

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with IMFINZI.

For additional Important Safety Information, please see pages 27-30.



Event-free survival

IMFINZI + chemo, then IMFINZI glone Placebo + chemo, then placebo alone

73%

vs

63%

236 out of 374 people didn't see their cancer get worse or come back

268 out of 366 people didn't see their cancer get worse or come back

Median event-free survival was not reached with IMFINZI + chemo, then IMFINZI alone vs 25.9 months with placebo + chemo, then placebo alone.

Median EFS is the length of time that half the people are living without their cancer getting worse or coming back. When more than half the people don't see their cancer get worse or come back, median EFS has not been reached. Median is the middle number in a group of numbers arranged from lowest to highest.



IMFINZI + chemo, then IMFINZI alone reduced the chance of cancer getting worse or coming back

In a clinical trial, people who **received IMFINZI + chemo**, and then IMFINZI alone, **were nearly 32% less likely to have their cancer get worse or come back**.

SELECT SAFETY INFORMATION (continued)

Problems can also happen in other organs and tissues (continued). These are not all of the signs and symptoms of immune system problems that can happen with IMFINZI. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include: Chest pain, irregular heartbeats, shortness of breath or swelling of ankles;

For additional Important Safety Information, please see <u>pages 27-30</u>.





taking

More people

worse or come

+ chemo, then

placebo alone

back vs placebo



4x more people showed no signs of cancer cells after IMFINZI + chemo

Pathologic complete response (pCR) = no evidence of cancer cells in the lungs or lymph nodes after surgery

IMFINZI + chemo

63 out of 366 people, or 17%,

showed no signs of cancer cells after surgery

vs

Placebo + chemo

16 out of 374 people, or 4%,

showed no signs of cancer cells after surgery

SELECT SAFETY INFORMATION (continued)

Problems can also happen in other organs and tissues (continued). These are not all of the signs and symptoms of immune system problems that can happen with IMFINZI. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include: confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems; tingling, numbness or weakness of the arms or legs; double vision, blurry vision, sensitivity to light, eye pain, changes in eye sight; persistent or severe muscle pain or weakness, muscle cramps, joint pain, joint stiffness or swelling; and low red blood cells and bruising





Support for the treatment journey

Use the next section to familiarize yourself with tips for infusion days, the different specialists who can make up your care team, and educational resources.

>

How do I prepare for treatment?

A little planning can go a long way to help improve your treatment experience. Here are a few suggestions to help get you ready.

On infusion days, remember to:



Dress comfortably in loose-fitting clothes



Take any necessary identification and insurance cards



Eat a small meal before your infusion



Bring a list of medications you are currently taking



Write down any questions you may have for your care team



Drink plenty of water to stay hydrated



Show up early so you don't feel rushed



Keep yourself occupied with reading materials, puzzles, and/or mobile devices



Schedule your next infusion before you leave

Notes

Use the space below to write down any additional questions you may have, or to jot down notes during your appointment	

>

Who makes up my care team?

Studies have shown a multidisciplinary approach to cancer care can help improve results. This is when different specialists look at your care from various perspectives, working together to find a treatment plan that's right for you.

The specialists on your team may include:



Pulmonologist



Thoracic or chest surgeon



Medical oncologist



Radiation oncologist



Oncology nurse

Talk to a medical oncologist before surgery

A medical oncologist can partner with your surgeon to choose a treatment plan that will help you get the best results. **Ask your surgeon for a referral to a medical oncologist.**

SELECT SAFETY INFORMATION (continued)

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include: chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, and back or neck pain

For additional Important Safety Information, please see <u>pages 27-30</u>.



The most important member of your care team is you

Don't be afraid to talk openly with your care team members and ask questions when **needed**. Discussing all your options can help you make the right treatment decisions together.

These questions can help guide the conversation:



Making treatment decisions

- Which specialists will be part of my care team?
- How will my care team work together to create a treatment plan for me?



Understanding IMFINZI

- Could IMFINZI and chemotherapy help me fight my cancer?
- How does IMFINZI work?



Treating with IMFINZI and chemotherapy

- How long will I be on treatment before and after surgery?
- What are the possible side effects of IMFINZI and chemotherapy?

SELECT SAFETY INFORMATION (continued)

Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with IMFINZI. Your healthcare provider will monitor you for these complications





Finding support

Every person living with lung cancer has their own unique challenges and needs for different kinds of support. The resources listed on these pages are great places to find:

- Practical information about lung cancer
- Helpful tips for treatment
- Emotional support resources



American Lung Association is dedicated to improving lung health and preventing lung disease through education, advocacy, and research. Visit lung.org.



GO₂ for Lung Cancer provides life-changing patient information, support services, and resources to all those affected by lung cancer, free of charge. Visit **go2.org**.



Lung Cancer Research Foundation works to improve lung cancer outcomes by funding research for the prevention, diagnosis, treatment, and cure of lung cancer. Visit

 $\underline{lung can cerresear ch foundation.org}.$



LUNGevity Foundation offers a community of empowerment, support, and hope, with services and information on local events in your area. Visit **lungevity.org**.



LVNG With Lung Cancer is a community of more than 260,000 people around the globe who continue to inspire, support, educate, and connect with one another after being diagnosed with lung cancer. Visit **LVNG.com**.

AstraZeneca wants you to have support options available



The AstraZeneca Access 360TM program can help you get started with IMFINZI. For more information, call 1-844-ASK-A360 (1-844-275-2360), Monday-Friday from 8 AM-6 PM ET or visit MyAccess360.com.

The IMFINZI Patient Savings Program is available to assist with out-of-pocket costs for IMFINZI for eligible commercially insured patients. For more information, please visit www.azpatientsupport.com.

Key terms to know

You may come across some new or unfamiliar terms while learning more about your treatment plan. To help you feel more confident when talking about your condition, here are some common terms used by healthcare professionals:

therapy your cancer from coming back Chemotherapy A type of cancer treatment that attacks rapidly (chemo) growing cells, including cancer cells. Chemotherapy also affects healthy cells **Event-free** In a clinical trial, the amount of time after treatment started that people had without survival (EFS) their cancer coming back Immunotherapy A type of treatment that works with the immune system to find and attack hidden cancer cells. Immunotherapy may also affect healthy cells A type of medicine or treatment given through Infusion therapy a needle or a catheter, most likely into a vein A type of injection or infusion where medicine Intravenous

is delivered directly into a vein

(IV)

Treatment given after surgery to help prevent

Major pathologic In a clinical trial, the presence of 10% or fewer cancer cells in the lungs response (mPR) or lymph nodes after treatment Neoadjuvant **Treatment given before surgery** to help make it more effective therapy Oncologist A doctor who specializes in diagnosing and treating cancer In a clinical trial when there is **no evidence of cancer cells in the** Pathologic complete lungs or lymph nodes after surgery response (pCR) Treatment before and after surgery Perioperative therapy Placebo A treatment that doesn't contain any medicine. Scientists use it in clinical studies to compare results with another treatment **Programmed** A protein that disguises cancer cells from your immune system death-ligand 1 (PD-L1) Resectable Lung cancer that can be removed through surgery lung cancer The process of finding out how much cancer is in a person's body and where Staging it is located. Different types of cancer use different staging systems

Important Safety Information

What is the most important information I should know about IMFINZI® (durvalumab)?

IMFINZI is a medicine that may treat certain cancers by working with your immune system. IMFINZI can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:



Lung problems: cough, shortness of breath, and chest pain



Intestinal problems: diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; and severe stomach-area (abdomen) pain or tenderness



Liver problems: yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), and bleeding or bruising more easily than normal



Hormone gland problems: headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold;

IMPORTANT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Hormone gland problems (continued): constipation; your voice gets deeper; dizziness or fainting; and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness



Kidney problems: decrease in your amount of urine, blood in your urine, swelling of your ankles, and loss of appetite



Skin problems: rash; itching; skin blistering or peeling; painful sores or ulcers in mouth or nose, throat, or genital area; fever or flu-like symptoms; and swollen lymph nodes



Pancreas problems: pain in your upper stomach area (abdomen), severe nausea or vomiting, and loss of appetite



Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with IMFINZI. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include: Chest pain, irregular heartbeats, shortness of breath or swelling of ankles; confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems; tingling, numbness or weakness of the arms or legs; double vision, blurry vision, sensitivity to light, eye pain, changes in eye sight; persistent or severe muscle pain or weakness, muscle cramps, joint pain, joint stiffness or swelling; and low red blood cells and bruising



Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include: chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, and back or neck pain



IMPORTANT SAFETY INFORMATION (continued)



Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with IMFINZI. Your healthcare provider will monitor you for these complications

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with IMFINZI. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with IMFINZI if you have severe side effects

Before you receive IMFINZI, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. IMFINZI can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with IMFINZI.
- You should use an effective method of birth control during your treatment and for 3 months after the last dose of IMFINZI. Talk to your healthcare provider about birth control methods that you can use during this time.

IMPORTANT SAFETY INFORMATION (continued)

- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with IMFINZI.
- are breastfeeding or plan to breastfeed. It is not known if IMFINZI passes into your breast milk. Do not breastfeed during treatment and for 3 months after the last dose of IMFINZI.

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 IMFINZI?

IMFINZI can cause serious side effects (see pages 27-28):

The most common side effects of IMFINZI when used with platinum-containing chemotherapy in adults with NSCLC that can be removed by surgery include low red blood cells (anemia), nausea, constipation, feeling tired, muscle or bone pain, and rash.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of IMFINZI. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may <u>report side effects related to AstraZeneca products</u>. If you prefer to report these to the FDA, either visit <u>www.FDA.gov/medwatch</u> or call 1-800-FDA-1088.

What is IMFINZI?

IMFINZI is a prescription medicine used to treat adults with **a type of lung cancer called non-small cell lung cancer (NSCLC).** IMFINZI may be used in combination with chemotherapy that contains platinum prior to surgery and alone after surgery when your NSCLC is able to be removed by surgery, **and** your tumor does not have an abnormal "EGFR" or "ALK" gene.

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







