

ASTRAZENECA'S IMFINZI™ (DURVALUMAB) RECEIVES US FDA ACCELERATED APPROVAL FOR PREVIOUSLY TREATED PATIENTS WITH ADVANCED BLADDER CANCER

Approval granted regardless of PD-L1 status, based on tumor response rate and duration of response

IMFINZI is the cornerstone in an extensive Immuno-Oncology program across multiple cancer types and stages of disease

(WILMINGTON, Del., May 1, 2017) – AstraZeneca and its global biologics research and development arm, MedImmune, today announced that the US Food and Drug Administration (FDA) has granted accelerated approval to IMFINZI™ (durvalumab). IMFINZI is indicated for the treatment of patients with a type of bladder cancer called urothelial carcinoma. IMFINZI may be used when urothelial carcinoma has spread or cannot be removed by surgery and chemotherapy that contains platinum did not work or is no longer working. IMFINZI is approved under the FDA's accelerated approval pathway, based on the response of your cancer as measured by tumor size and how long the response lasts. This means that AstraZeneca is required to complete further studies in bladder cancer patients. It is not known if IMFINZI is safe and effective in children.

Pascal Soriot, Chief Executive Officer of AstraZeneca, said: "We are excited to offer IMFINZI as a breakthrough therapy for patients with locally-advanced or metastatic bladder cancer. IMFINZI is the cornerstone of our extensive Immuno-Oncology program, in development across many tumor types, as monotherapy and in combination. This first approval for IMFINZI brings us another step closer to our goal of redefining the way cancer is treated."

IMFINZI is also being studied as a first-line treatment for urothelial carcinoma, both by itself and in combination with another cancer medicine that works along with your immune system.

Nicholas J. Vogelzang, MD, FACP, FASCO, Clinical Professor at the University of Nevada School of Medicine; SWOG GU Vice Chair; US Oncology Research GU Chair; Comprehensive Cancer Centers of Nevada, said: "The usual course of treatment for patients with advanced bladder cancer begins with a standard platinum-containing chemotherapy. Patients who have disease progression during or following chemotherapy are left with few other treatment options. The approval of IMFINZI to treat this population of select patients signifies hope for those who are currently suffering, or may find themselves with limited options in the future."

The recommended dose of IMFINZI is 10 mg/kg body weight administered through an intravenous (IV) line over a 60-minute period, every two weeks until the cancer progresses or the patient experiences intolerable side effects. IMFINZI is associated with a number of serious, sometimes fatal, risks. Please see the **IMPORTANT SAFETY INFORMATION** below.

News Release

With the help of IMFINZI, your body is given the power to take on bladder cancer. IMFINZI is not chemotherapy—it's an immunotherapy that works with your body's natural defenses to help fight cancer.

When cancer cells appear in your body, your immune system works to recognize and attack them. PD-L1 is a protein that disguises cancer cells from the immune system. For people with bladder cancer, IMFINZI works by blocking PD-L1 to remove the disguise so your immune system is better able to find and attack these cancer cells. There is a chance that IMFINZI may affect healthy cells, too.

The accelerated FDA approval of IMFINZI, a type of cancer treatment that works with your immune system to fight cancer, is based on data from Study 1108. This Phase I/II trial looked at the safety and efficacy of IMFINZI in patients with urothelial carcinoma (bladder cancer). In a clinical study of 182 patients with locally advanced or metastatic bladder cancer, whose cancer progressed on or after platinum-containing chemotherapy, more than one out of six patients (31/182) saw their tumors get smaller with IMFINZI. Five patients saw a complete response, while 26 patients had a partial response. Although the primary objective of the clinical study was not focused on average time to response, the 31 patients who responded did so with an average time of approximately six weeks with 45% (14 patients) still responding after six months of treatment. Final results may be different because this study is still ongoing.

IMPORTANT SAFETY INFORMATION

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

IMFINZI is a medicine that may treat a type of cancer in the bladder and urinary tract by working with your immune system.

In some patients, IMFINZI can cause the immune system to attack normal organs and tissues and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death.

Call or see your healthcare provider right away if you develop any symptoms of the following problems or if these symptoms get worse:

Lung problems (pneumonitis). Signs and symptoms may include new or worsening cough, shortness of breath, and chest pain.

Liver problems (hepatitis). Signs and symptoms include yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), drowsiness, dark urine (tea colored), bleeding or bruising more easily than normal, and feeling less hungry than usual.

News Release

Intestinal problems (colitis). Signs and symptoms may include diarrhea; more bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; and severe stomach-area (abdomen) pain or tenderness.

Hormone gland problems (especially the thyroid, adrenals, pituitary, and pancreas). Signs and symptoms that your hormone glands are not working properly may include headaches that will not go away or unusual headaches; extreme tiredness; weight gain or weight loss; dizziness or fainting; feeling more hungry or thirsty than usual; hair loss; feeling cold; constipation; your voice gets deeper; urinating more often than usual; nausea or vomiting; stomach area (abdomen) pain; and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.

Kidney problems, including nephritis and kidney failure. Signs of kidney problems may include producing less urine than normal, blood in your urine, swelling in your ankles, and loss of appetite.

Skin problems. Signs may include rash, itching, and skin blistering.

Problems in other organs. Signs and symptoms may include neck stiffness; headache; confusion; fever; changes in mood or behavior; blurry vision, double vision, or other vision problems; and eye pain or redness.

Severe infections. Signs and symptoms may include fever, cough, frequent urination, pain when urinating, and flu-like symptoms.

Severe infusion reactions. Signs and symptoms may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling like passing out, back or neck pain, and facial swelling.

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 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 had an organ transplant
- Have lung or breathing problems
- Have liver problems
- Are being treated for an infection
- Are pregnant or plan to become pregnant
 - IMFINZI can harm your unborn baby
 - If you are able to become pregnant, you should use an effective method of birth control during your treatment and for at least 3 months after the last

News Release

dose of IMFINZI. Talk to your healthcare provider about which birth control methods to use

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

Tell your healthcare provider about all the medicines you take. This includes 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 above).

The most common side effects include:

- Feeling tired
- Muscle and/or bone pain
- Constipation
- Decreased appetite
- Nausea
- Swelling
- Urinary tract infection

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 healthcare provider for medical advice about side effects. You may report side effects to FDA at www.fda.gov/medwatch or 1-800-FDA-1088.

Please see full [Prescribing Information](#) and [Medication Guide](#).

– ENDS –

NOTES TO EDITORS

About Immuno-Oncology patient resources

AstraZeneca strives to ensure that appropriate patients and their oncologists have access to IMFINZI and relevant support resources. These include educational resources, an Oncology Nurse Educator program and financial assistance programs. Additionally, AstraZeneca has launched Lighthouse, a program that provides support to patients during any immune-mediated adverse events they may encounter during treatment, through medically trained

News Release

Lighthouse Advocates. The program aims to make patients' treatment experience as comfortable as possible. Find out more about Lighthouse at LighthouseProgram.com or call 1-855-LHOUSE1 (1-855-546-8731).

About IMFINZI™ (durvalumab)

IMFINZI™ is a prescription medicine used to treat a type of cancer called urothelial carcinoma. It may be used when your cancer has spread or cannot be removed by surgery, and chemotherapy that contains platinum did not work or is no longer working. When cancer cells appear in your body, your immune system works to recognize and attack them. PD-L1 is a protein that disguises cancer cells from the immune system. IMFINZI works by blocking PD-L1 to remove the disguise so your immune system is better able to find and attack these cancer cells. There is a chance that IMFINZI may affect healthy cells, too.

Durvalumab is also being tested in the first-line treatment of patients with unresectable (cannot be surgically removed) and metastatic bladder cancer as a single therapy and in combination with tremelimumab, a checkpoint inhibitor that targets CTLA-4, as part of the DANUBE Phase III trial, which had the last patient commenced dosing during the first quarter of 2017 (global trial, excluding China). Additional clinical trials are ongoing to investigate durvalumab as a single therapy or in combination with tremelimumab in multiple solid tumors and blood cancers.

About bladder cancer

Urothelial bladder cancers arise from the innermost layer of the bladder and are the sixth most common form of cancer in the US. It is estimated that in 2017, approximately 79,000 Americans will be diagnosed with bladder cancer, and almost 17,000 will die from this disease. Metastatic bladder cancer remains an area of unmet medical need with five-year overall survival rates of approximately 5%.

About MedImmune

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology; Respiratory, Cardiovascular & Metabolic Diseases; and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centers, with additional sites in Cambridge, UK, and Mountain View, Ca. For more information, please visit www.medimmune.com.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three main therapy areas – Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca-us.com and follow us on Twitter @AstraZenecaUS.