Helsinn Therapeutics (U.S.) Inc., Signs Co-Promotion Agreement for Cancer Therapeutic Zykadia® in the US

- *Zykadia® (ceritinib) is an approved treatment for patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive*
- *Helsinn Therapeutic (U.S.), Inc.'s highly specialized cancer sales team will provide detailing services for Zykadia® in the US*

Lugano, Switzerland, September 5, 2017 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, today announces that its US subsidiary Helsinn Therapeutics (US), Inc. ("HTU"), has signed a co-promotion agreement with Novartis for Zykadia®, an approved treatment for patients with ALK-positive metastatic non-small cell lung cancer (NSCLC) as detected with an FDA approved test.

As part of the agreement, Novartis has granted a non-exclusive, non-sublicensable right to HTU to provide detailing services for Zykadia® in the US. Novartis will retain all other activities in the US, including marketing and development. HTU cancer sales team will begin their services for Zykadia® on September 5, 2017.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented: "*We are delighted to have signed this agreement for the co-promotion of Zykadia with Novartis, which enjoys a world-leading reputation in cancer therapeutics. For Helsinn, the agreement validates the quality and expertise of the HTU sales team in the US and we plan to initiate promotional activities in September through our specialty cancer sales force. By working with Novartis on such an important newly approved first-line therapy, HTU expects to expand its critical experience marketing therapeutic cancer drugs and working alongside healthcare professionals as we increase the scope of our therapeutic pipeline*."

About Zykadia

Zykadia is an oral, selective inhibitor of anaplastic lymphoma kinase (ALK), a gene that can fuse with others to form an abnormal "fusion protein" that promotes the development and growth of certain tumors in cancers including non-small cell lung cancer. Zykadia is currently approved in

over 69 countries worldwide. Please visit https://www.hcp.novartis.com/products/zykadia/(link is external) for additional information.

Indication

ZYKADIA® is indicated for the treatment of patients with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

Zykadia Important Safety Information

Zykadia may cause serious side effects.

Zykadia may cause stomach upset and intestinal problems in most patients, including diarrhea, nausea, vomiting and stomach-area pain. These problems can be severe. Patients should follow their doctor's instructions about taking medicines to help these symptoms, and should call their doctor for advice if symptoms are severe or do not go away.

Zykadia may cause severe liver injury. Patients should have blood tests prior to the start of treatment with Zykadia, every two weeks for the first month of treatment and monthly thereafter, and should talk to their doctor right away if they experience any of the following symptoms: tiredness (fatigue), itchy skin, yellowing of the skin or the whites of the eyes, nausea or vomiting, decreased appetite, pain on the right side of the abdomen, urine turns dark or brown, or bleeding or bruising more easily than normal.

Zykadia may cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Symptoms may be similar to those symptoms from lung cancer. Patients should tell their doctor right away about any new or worsening symptoms, including trouble breathing or shortness of breath, fever, cough, with or without mucous, or chest pain.

Zykadia may cause very slow, very fast, or abnormal heartbeats. Doctors should check their patient's heart during treatment with Zykadia. Patients should tell their doctor right away if they feel new chest pain or discomfort, dizziness or lightheadedness, faint, or have abnormal

heartbeats, blue discoloration of lips, shortness of breath, swelling of lower limbs or skin, or if they start to take or have any changes in heart or blood pressure medicines.

Zykadia may cause high levels of glucose in the blood. People who have diabetes or glucose intolerance, or who take a corticosteroid medicine have an increased risk of high blood sugar with Zykadia. Patients should have glucose blood tests prior to the start of treatment with Zykadia and during treatment. Patients should follow their doctor's instructions about blood sugar monitoring and call their doctor right away with any symptoms of high blood sugar, including increased thirst and/or urinating often.

Zykadia may cause high levels of pancreatic enzymes in the blood and may cause pancreatitis. Patients should have blood tests prior to the start of treatment with Zykadia and as needed during their treatment with Zykadia. Patients should talk to their doctor if they experience signs and symptoms of pancreatitis which including upper abdominal pain that may spread to the back and get worse with eating.

Before patients take Zykadia, they should tell their doctor about all medical conditions, including liver problems; diabetes or high blood sugar; heart problems, including a condition called long QT syndrome; if they are pregnant, if they think they may be pregnant, or if they plan to become pregnant; are breastfeeding or plan to breastfeed.

Zykadia may harm unborn babies. Women who are able to become pregnant must use a highly effective method of birth control (contraception) during treatment with Zykadia and up to 3 months after stopping Zykadia. Patients and their doctor should decide whether to take Zykadia or breastfeed, but should not do both.

Patients should tell their doctor about medicines they take, including prescription medicines, over-the-counter medicines, vitamins and herbal supplements.

The most common adverse reactions with an incidence of >=10% diarrhea, nausea, vomiting, liver laboratory test abnormalities, fatigue, abdominal pain, decreased appetite, weight decreased constipation, blood creatinine increased, rash, anemia, and esophageal disorder. Grade 3-4 adverse reactions with an incidence of >=5% were fatigue, vomiting, diarrhea, abdominal pain, weight loss, nausea, and prolonged QT Interval.

Patients should stop taking Zykadia and seek medical help immediately if they experience any of the following, which may be signs of an allergic reaction:

- Difficulty in breathing or swallowing
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with a red rash or raised bumps

Patients should tell their doctor of any side effect that bothers them or does not go away. These are not all of the possible side effects of Zykadia. For more information, patients should ask their doctor or pharmacist.

Patients should take Zykadia exactly as their health care provider tells them. Patients should not change their dose or stop taking Zykadia unless their health care provider advises them to. Zykadia should be taken once a day on an empty stomach. Patients should not eat for at least 2 hours before and 1 hour after taking Zykadia. If a dose of Zykadia is missed, they should take it as soon as they remember. If their next dose is due within the next 12 hours, they should skip the missed dose and take the next dose at their regular time. They should not take a double dose to make up for a forgotten dose. Patients should not drink grapefruit juice or eat grapefruit during treatment with Zykadia, as it may make the amount of Zykadia in their blood increase to a harmful level. If patients have to vomit after swallowing Zykadia capsules, they should not take more capsules until their next scheduled dose.

Please see full Prescribing Information for Zykadia.

References

[1] Zykadia® (ceritinib) Full Prescribing Information.

About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the

commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland and the U.S., a representative office in China as well as a product presence in approximately 190 countries globally.

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