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EISAI ANNOUNCES PHASE II RESULTS FOR KISPLYX® (LENVATINIB) PLUS EVEROLIMUS IN ADVANCED RENAL CELL CARCINOMA AT INTERNATIONAL KIDNEY CANCER SYMPOSIUM 2020

HATFIELD, HERTFORDSHIRE, UK, 9 November, 2020 – Results from a phase II study (Study 218), demonstrated that noninferiority cannot be claimed for the starting dose of lenvatinib 14 mg (plus everolimus 5 mg) versus lenvatinib 18 mg (plus everolimus 5 mg) for patients with advanced renal cell carcinoma (RCC). Moreover, safety profiles were similar in both treatment arms. This data reinforces the use of the approved dose of 18mg lenvatinib plus 5mg everolimus.

“Several therapeutic options have been approved for the first-line treatment of advanced renal cell carcinoma however, many patients progress during first-line treatment and require subsequent lines of therapy. It is important that studies like this are conducted to ensure we are giving people the right treatment that they need at this stage without treating them excessively,” said Dr Hilary Glen, a lead EMEA Principal Investigator for the study and Consultant Medical Oncologist at the Beatson Institute for Cancer Research, Scotland. “The results from this study should come as a reassurance for healthcare professionals following guidelines and prescribing Kisplyx at its approved dose.”

These results were announced during an oral presentation by Dr Sumanta Pal from the Department of Medical Oncology &Therapeutics, City of Hope Comprehensive Cancer Center at the International Kidney Cancer Symposium (IKCS) 2020.[1] The primary endpoint of the study (NCT03173560) was to evaluate whether a lower starting dose of lenvatinib plus everolimus would provide similar efficacy to the licensed dose with an improved safety profile for patients. The primary efficacy endpoint of objective response rate (ORR) at Week 24 occurred in 32.1% (n=156) of patients treated with the lenvatinib 14 mg dose versus 34.8% (n=155) of patients treated with the lenvatinib 18 mg dose (odds ratio: 0.88 [90% CI: 0.59-1.32]; *P*-value: 0.2676), thereby not meeting the non-inferiority criteria for the 14 mg dose. The primary safety endpoint of patients with intolerable grade 2 or any ≥ grade 3 treatment-emergent adverse events (TEAEs) within 24 weeks occurred in a similar proportion of patients between the 14 mg and 18 mg treatment arms: 82.8% (n=157) vs 79.6% (n=152) (*P*-value: 0.4763), respectively.[1]

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Study 218 was conducted as a post-marketing commitment to the U.S. Food and Drug Administration and the European Medicines Agency (EMA) following priority review designation (in the U.S.) and approval of lenvatinib plus everolimus for the treatment of patients with advanced RCC who were previously treated with an anti-angiogenic therapy.

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Notes to editors

About Renal Cell Carcinoma (RCC)

Worldwide, it is estimated there were more than 403,000 new cases of kidney cancer diagnosed and more than 175,000 deaths from the disease in 2018.[2] Kidney cancer is of particular significance within Europe as it has one of the highest incidences in the world, particularly in Eastern Europe.[3] Renal cell carcinoma is by far the most common type of kidney cancer; about nine out of 10 kidney cancers are RCCs.[4] Most cases of RCC are discovered incidentally during imaging tests for other abdominal diseases.[2] Approximately 30% of patients with RCC will have metastatic disease at diagnosis, and as many as 40% will develop metastases after primary surgical treatment for localised RCC.[5,6] Survival is highly dependent on the stage at diagnosis, and with a 5-year survival rate of 12% for metastatic disease, the prognosis for these patients is poor.[2]

About Kisplyx® / Lenvima® (lenvatinib)

Lenvatinib is indicated in Europe:

- as monotherapy for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).[7]
- as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.[7]

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- in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy.[8]

About Eisai EMEA

At Eisai, everything we do is dedicated to giving our first thought to patients and their families through our human health care (*hhc*) philosophy. We are the European hub of Tokyo-based Eisai Co. Ltd., forming part of a multinational team working across a global network of R&D facilities, manufacturing sites and marketing subsidiaries.

Our collective passion and dedication to patient care is the driving force behind our efforts to discover and develop innovative medicines in a variety of therapeutic areas in which a high unmet medical need remains, including oncology and neurology.

Our mission is clear; we strive to make a significant long-lasting contribution to society in an ethical, compliant and sustainable way by embodying our *hhc* philosophy in everything we do.

For more information about Eisai in the EMEA region please visit www.eisai.eu.

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