FOR UK TRADE, MEDICAL AND CONSUMER HEALTH MEDIA ONLY

EISAI ANNOUNCES SCOTTISH MEDICINES CONSORTIUM RECOMMENDATION OF KISPLYX® (LENVATINIB) FOR THE TREATMENT OF ADULTS WITH ADVANCED RENAL CELL CARCINOMA

HATFIELD, HERTFORDSHIRE, ENGLAND, November 11, 2019 – Eisai announced today that the Scottish Medicines Consortium (SMC) recommended the use of Kisplyx® (lenvatinib) in combination with everolimus within NHS Scotland for the treatment of adults with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy.[1]

Kidney cancer is the seventh most common cancer in Scotland, with over 1,000 new cases diagnosed in 2017.[2] RCC is the most common type of kidney cancer in adults, representing over 80% of kidney cancer diagnoses in the UK.[3] At diagnosis, approximately a third of patients already have locally advanced or metastatic RCC.[4] It has the highest mortality rate of the genitourinary cancers, as more than a third of patients with RCC will die from the disease,[4] so advancing treatment options for people with RCC remains a public health priority.

“We are delighted that the SMC is recommending lenvatinib in combination with everolimus as a second line treatment for patients with advanced renal cell carcinoma”, said Maureen Johnson, Kidney Cancer Scotland’s Health Professional. “This news will be welcomed by patients and their families, who can be assured that NHS Scotland has access to this clinically effective combination to support their treatment.”

“This is great news for patients with advanced kidney cancer in Scotland,” commented Professor Robert Jones, Professor of Clinical Cancer Research, University of Glasgow. “It’s particularly pleasing that the lenvatinib and everolimus combination is now available, as patients in Glasgow have been involved in the clinical trials over several years. As a result of their contribution the benefits of lenvatinib can now be extended to other Scottish patients with advanced RCC.”

This recommendation is based on the results from Study 205, a randomised trial of 153 advanced RCC patients who had progressed after one previous VEGF therapy.[5] The results showed that there are significant differences in efficacy between the combination of lenvatinib and everolimus and everolimus monotherapy. When treated with lenvatinib in combination with everolimus (n=51), patients experienced a median progression-free survival (PFS) of 14.6 months compared with 5.5 months for those who received everolimus alone (n=50) (HR 0.40; 95% CI: 0.24–0.68; p=0.0005; investigator assessment).[5] In an updated post hoc analysis, median overall survival (OS) in the study population was 25.5 months in the lenvatinib plus everolimus group compared with 15.4 months in the everolimus group (HR 0.51; 95% CI: 0.30–0.88; p=0.024 and HR 0.59; 95% CI: 0.36–0.97).[5,6]

For lenvatinib in combination with everolimus, the most common any-grade treatment-emergent adverse events (TEAEs) were diarrhoea, decreased appetite and fatigue.[5] The most common TEAEs of Grade 3 or higher in the combination arm were diarrhoea (20%), fatigue (14%) and hypertension (14%).[5] Grade 3 and 4 events occurred in fewer patients treated with everolimus alone (50%) compared with those treated with the combination of lenvatinib plus everolimus (71%).[5]

Lenvatinib has been approved in combination with everolimus for the treatment of adult patients

with advanced RCC following one prior vascular endothelial growth factor (VEGF)-targeted therapy in Europe since 2016, [6] and has been available for use within NHS England since December 2017.[7]

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Notes to editors

About Kisplyx® (lenvatinib)
Lenvatinib, discovered and developed by Eisai, is an oral receptor tyrosine kinase (RTK) inhibitor that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors (VEGFR1 (FLT1), VEGFR2 (KDR) and VEGFR3 (FLT4)), and fibroblast growth factor (FGF) receptors FGFR1, 2, 3 and 4 in addition to other proangiogenic and oncogenic pathway-related RTKs (including the platelet-derived growth factor (PDGF) receptor PDGFRα; KIT; and RET) involved in tumour proliferation.[6] Lenvatinib possesses a distinct binding mode (Type V) to VEGFR2, as confirmed through X-ray crystal structural analysis, and exhibits rapid and potent inhibition of kinase activity, according to kinetic analysis in pre-clinical models.[8]

About everolimus
Everolimus is a selective mTOR (mechanistic target of rapamycin) inhibitor. mTOR is a key serine-threonine kinase, the activity of which is known to be upregulated in a number of human cancers.[9]

About Eisai Co., Ltd.
Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our human health care (*hhc*) philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realise our hhc philosophy by delivering innovative products in multiple therapeutic areas with high unmet medical needs, including oncology and neurology.

As a global pharmaceutical company, our mission extends to patients around the world through our investment and participation in partnership-based initiatives to improve access to medicines in developing and emerging countries.

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The development of lenvatinib underscores Eisai's *human health care* mission, the company's commitment to innovative solutions in disease prevention, cure and care for the health and well-being of people worldwide. Eisai is committed to the therapeutic area of oncology and to address the unmet medical needs of patients and their families.

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November 2019
UK-KIS-19-00071

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