



**SCOTTISH MEDICINES CONSORTIUM RECOMMENDS COMBINATION OF KISPLYX®
(LENVATINIB) PLUS KEYTRUDA® (PEMBROLIZUMAB) FOR FIRST-LINE TREATMENT OF
ADVANCED RENAL CELL CARCINOMA**

- *Scotland is the first country in the United Kingdom to recommend this combination therapy as a first-line treatment for advanced renal cell carcinoma (RCC)*
- *Over 1000 people are diagnosed with kidney cancer each year in Scotland¹*
- *Approximately 1 in 5 people in the UK with kidney cancer are diagnosed at an advanced stage (stage 4),² when prognosis is significantly worse³*

HATFIELD, HERTFORDSHIRE, UK, 13 June, 2022 – Eisai today announced that the Scottish Medicines Consortium (SMC) has recommended the use of a new combination of lenvatinib, the oral multiple receptor tyrosine kinase inhibitor discovered by Eisai, plus pembrolizumab, MSD’s anti-PD-1 therapy, within NHS Scotland for the treatment of advanced RCC.⁴ This follows the Medicines and Healthcare products Regulatory Agency (MHRA) approval of the treatment in the UK in November 2021.⁵

Lenvatinib is indicated for the treatment of adults with advanced renal cell carcinoma in combination with pembrolizumab, as a first-line treatment.⁶ RCC is the most common type of kidney cancer, accounting for around 80% of kidney cancer cases in the UK.⁷ Between 2013 and 2017 (follow-up 2018), over a third (36%) of people in the UK who were diagnosed with kidney cancer were diagnosed at an advanced or metastatic stage of the disease (stage 3 or 4).² It has the highest mortality rate of the genitourinary cancers, as more than a third of patients with RCC will die from the disease⁸, therefore, providing more treatment options for people with advanced RCC remains a priority.

“Rates of renal cell carcinoma are on the rise, and in the past decade cases have increased by 21% in Scotland,” said Dr Balaji Venugopal, Consultant in Medical Oncology at Beatson West of Scotland Cancer Centre and Honorary Clinical Senior Lecturer at University of Glasgow. “At The Beatson, we are committed to leading clinical research that helps bring new treatment options to patients with unmet needs. A team of dedicated patients and staff at The Beatson collaborated with Eisai on the early development of lenvatinib, including being one of the first hospitals in the world

to treat patients in clinical trials with this drug. We therefore welcome this combination therapy as a new option for the first line treatment of advanced renal cell carcinoma. The treatment will help to further expand the tools available to clinicians, allowing us to provide more individualised treatment plans to ultimately help extend the lives of our patients diagnosed with advanced renal cell carcinoma in Scotland.”

“We are delighted Scotland is the first country in the UK to recommend this important combination therapy. This SMC recommendation provides people living with advanced kidney cancer in Scotland a new and important, alternative first-line treatment option. The news will be widely welcomed by those kidney cancer patients, and their loved ones, who now have access to this treatment through NHS Scotland” said Kirsty Solman, Kidney Cancer Scotland, Health Care Professional Nurse.

The local reimbursement for the combination of lenvatinib and pembrolizumab in adults with advanced renal cell carcinoma is based on data from the Phase 3 trial: CLEAR (Study 307) / KEYNOTE-581, which demonstrated statistically significant improvements versus sunitinib in progression-free survival and overall survival among adults with advanced RCC.⁹ The trial’s primary endpoint was progression-free survival and secondary endpoints were overall survival and objective response as assessed by an independent review committee.⁹ Progression-free survival was longer with lenvatinib plus pembrolizumab than with sunitinib, with a median PFS of 23.9 months versus 9.2 months for sunitinib (HR=0.39 [95% CI, 0.32-0.49]; p<0.001). Overall survival was also longer with lenvatinib plus pembrolizumab than with sunitinib, with 79.2% of patients in the lenvatinib and pembrolizumab group versus 70.4% of patients in the sunitinib group alive at 24 months (HR=0.66 [95% CI, 0.49-0.88]; p=0.005).⁹ The most common adverse reactions (all grades \geq 25%) for lenvatinib plus pembrolizumab were diarrhoea (61%), hypertension (55%), hypothyroidism (47%), decreased appetite (40%), fatigue (40%), nausea (36%), stomatitis (35%), dysphonia (30%), weight loss (30%), proteinuria (30%), PPE syndrome (29%), arthralgia (28%), rash (27%), vomiting (26%) and constipation (25%).⁹

Additionally, *The Lancet Oncology* recently published a health-related quality of life (HRQoL) outcomes analysis of the phase 3 CLEAR study which demonstrated that patients treated with the combination of lenvatinib and pembrolizumab had similar or favourable HRQoL scores compared to those treated with sunitinib, further supporting the efficacy and safety profile of the combination as a first-line therapy for adults with advanced RCC.¹⁰



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Notes to editors

About renal cell carcinoma (RCC)

Worldwide, it is estimated there were more than 431,000 new cases diagnosed and more than 179,000 deaths from the disease in 2020.¹¹ Kidney cancer is of particular significance within Western Europe where it has one of the highest incidences in the world.^{12,3} In the UK, on average over 13,000 people are diagnosed with kidney cancer and over 4,700 die from the disease each year.¹³ RCC is by far the most common type of kidney cancer in the UK; about 80% of kidney cancers are RCCs.⁷ Most cases of RCC are discovered incidentally during imaging tests for other abdominal diseases.³ Over a third of patients with RCC will have advanced or metastatic disease at diagnosis, and as many as 40% of patients will develop metastases after primary surgical treatment for localised RCC.^{2,14} 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.³

About Kisplyx® (lenvatinib)

Lenvatinib is also indicated in Europe for the additional indications of:

- Monotherapy for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary / follicular / Hürthle cell) thyroid carcinoma, refractory to radioactive iodine.¹⁵
- Monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have received no prior systemic therapy.¹⁵
- In combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma, following one prior vascular endothelial growth factor (VEGF)-targeted therapy.⁶
- In combination with pembrolizumab for the treatment of adult patients with advanced or recurrent endometrial carcinoma who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and are not candidates for curative surgery or radiation.¹⁵



Further details on the treatment may be found here: [Lenvima®](#) and [Kisplyx®](#).

About Keytruda® (pembrolizumab)

Pembrolizumab is an anti-programmed cell death receptor-1 (PD-1) therapy that works by increasing the ability of the body's immune system to help detect and fight tumour cells. Pembrolizumab is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumour cells and healthy cells.¹⁶

About Eisai

At Eisai, everything we do is dedicated to giving our first thought to patients and their families through our *human health care (hhc)* philosophy.

Our collective passion and dedication to patient care is the driving force behind our efforts to discover, and develop, innovative medicines in areas where a high unmet medical need remains, including oncology. Eisai's oncology treatments strive to give patients with cancer as much meaningful time as possible. Together, we continue to drive the discovery, development and production of innovative oncology therapies that can make a difference and positively impact the lives of patients and their families.

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 please visit www.eisai.eu.

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