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# NEW DATA FOR KISPLYX® (LENVATINIB) PLUS KEYTRUDA® (PEMBROLIZUMAB) PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE DEMONSTRATE SIGNIFICANT IMPROVEMENT IN PROGRESSION FREE SURVIVAL AND OVERALL SURVIVAL VERSUS STANDARD OF CARE IN ADVANCED RENAL CELL CARCINOMA

**HATFIELD, HERTFORDSHIRE, UK, 13 February, 2021** – Eisai today announced that new data from the Phase 3 CLEAR trial (KEYNOTE-581/Study 307) has been published in The New England Journal of Medicine.[1] The results will also be simultaneously presented (Abstract #269)[2] at the virtual 2021 Genitourinary Cancers Symposium in an oral presentation, on 13 February 2021. The study showed that Kisplyx® (lenvatinib) plus Keytruda® (pembrolizumab), the anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside the United States and Canada), as well as lenvatinib plus everolimus significantly improved progression-free survival versus sunitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC).[1,2]

“The combination of lenvatinib plus pembrolizumab was shown to produce a statistically significantly improvement in outcomes compared to the current standard of care, in first line use for advanced renal cell carcinoma, particularly with regards to progression free survival, overall survival and objective response rates. Lenvatinib plus everolimus also showed a significant improvement in progression free survival compared to current standard of care”, said Professor Dr Thomas Powles, The Royal Free and Barts Health NHS Trust, London, United Kingdom. “These data show the potential of these combinations to provide patients with much-needed new treatments, in an area where effective options are limited.”

After a median follow-up of 27 months, lenvatinib plus pembrolizumab demonstrated statistically significant improvements across all efficacy endpoints, including progression-free survival (PFS), overall survival (OS) and objective response rate (ORR). Lenvatinib plus pembrolizumab reduced the risk of disease progression or death by 61% (HR=0.39 [95% CI: 0.32-0.49]; p<0.001), with a median PFS of 23.9 months (95% CI: 20.8-27.7) versus 9.2 months (95% CI: 6.0-11.0) for patients treated with sunitinib. Lenvatinib plus everolimus also showed statistically significant improvement in PFS and ORR endpoints versus sunitinib; the improvement for OS was not statistically significant. Lenvatinib plus everolimus reduced the risk of disease progression or death by 35%

(HR=0.65 [95% CI: 0.53-0.80]; p<0.001), with a median PFS of 14.7 months (95% CI: 11.1-16.7) versus 9.2 months (95% CI: 6.0-11.0) for patients treated with sunitinib.[1]

The safety profiles of both lenvatinib plus pembrolizumab and lenvatinib plus everolimus were consistent with previously reported studies. Grade ≥3 treatment-related adverse events occurred in 71.6% of patients in the lenvatinib plus pembrolizumab arm and 73.0% of patients in the lenvatinib plus everolimus arm compared with 58.8% of patients in the sunitinib arm.[2]

In March 2018, Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A., through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of lenvatinib, both as monotherapy and in combination with pembrolizumab, the anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, N.J., U.S.A.

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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.[3] Kidney cancer is of particular significance within Europe as it has one of the highest incidences in the world, particularly in Eastern Europe.[4] Renal cell carcinoma is by far the most common type of kidney cancer; about nine out of 10 kidney cancers are RCCs.[5] Most cases of RCC are discovered incidentally during imaging tests for other abdominal diseases.[5] 25-57% of patients with RCC will have metastatic disease at diagnosis, and as many as 50% will develop metastases after primary surgical treatment for localised RCC.[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.[7]

### 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).[8]
- as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.[8]
- 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.[9]

**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.

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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**References**

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