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Eisai gets marketing approval from EC for LENVIMA

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As First-Line Treatment in Adults with Advanced or Unresectable Hepatocellular Carcinoma

Eisai Co., Ltd. and Merck & Co., Inc., Kenilworth N.J., U.S.A., known as MSD outside of the United States and Canada, announced that the European Commission (EC) has granted a marketing authorization for the oral receptor tyrosine kinase (RTK) inhibitor LENVIMA (lenvatinib mesylate) as a single agent for the first-line treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.

This is the first new first-line treatment option for advanced or unresectable HCC to be approved in Europe in approximately 10 years.

This approval was based on results from REFLECT (Study 304), where LENVIMA demonstrated a treatment effect on overall survival (OS) by statistical confirmation of non-inferiority, as well as statistically significant superiority and clinically meaningful improvements in progression-free survival (PFS) and objective response rate (ORR) when compared with sorafenib in patients with previously untreated unresectable HCC.

REFLECT showed that LENVIMA achieved the primary endpoint, demonstrating a treatment effect on OS by statistical confirmation of non-inferiority to sorafenib.