

FDA Approval of CABOMETYX® for Previously Untreated Advanced Renal Cell Carcinoma



Ipsen's partner Exelixis announces FDA Approval of CABOMETYX®(cabozantinib) Tablets for Previously Untreated Advanced Renal Cell Carcinoma

Exelixis announced that Cabozantinib was approved by the United States Food and Drug Administration (FDA) for the expanded indication of patients with previously untreated advanced renal cell carcinoma (aRCC) after a priority review process. This is an extension of the previously approved indication, second-line treatment of metastatic renal cancer. The approval is based on data from the CABOSUN study, where cabozantinib demonstrated statistically significant and clinically meaningful improvement in progression-free survival compared to a treatment that is recommended as first-line treatment today. On September 8, 2017, Ipsen announced that the European regulatory authorities - the EMA - validated the application for Cabometyx® for the treatment in first line aRCC, leading to potential approval as first-line treatment also in Europe and the Nordic countries.

Please follow [the link](#) to access the press release.

Contact Nordic countries: Peter Myrenfors, Nordic Medical Director, Ipsen. +46 8 451 60 00, peter.myrenfors@ipsen.com