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An International, Non-Interventional, Post-Authorization Long-Term Safety Study of LUTATHERA®, in Patients with Unresectable or Metastatic, Well-Differentiated, Somatostatin Receptor Positive Gastroenteropancreatic Neuroendocrine Tumours (SALUS Study)

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BACKGROUND: Following the results of the pivotal NETTER-1 study, LUTATHERA® (Advanced Accelerator Applications, a Novartis company) was approved in US (January 2018) and Europe (September 2017) to treat unresectable or metastatic, progressive, well differentiated, SSTR positive GEP-NETs.

SALUS is a multinational, multicentre, non-interventional, retrospective and prospective post-authorization long-term safety study of GEP-NET patients receiving Lutathera®.

METHODS: The main objective is to assess the long-term safety of LUTATHERA®, with focus on incidence and nature of potential second primary malignancies (SPM), including solid tumours and haematological neoplasia.
Secondary objectives include (i) incidence of other Potential risks (i.e. renal

dysfunction, myelosuppression/cytopenias, myelodysplastic syndrome, hypogonadism, sexual dysfunction, drug interaction with somatostatin/somatostatin analogues, tumour cell lysis-related hormone release-induced crises, hepatotoxicity, radiotoxicity); (ii) identification of potential new safety signals overall and in populations under-represented in NETTER-1; and (iii) drug utilization patterns in real world (RW) setting.

Circa 20 sites from US, France, UK, Portugal and Finland will participate in the study. To detect a 1-2% cumulative incidence of SPMs over 5 years, ~900 patients are required to achieve a precision of ±1%. To account for lost-to-follow-up patients (estimated at max rate of 10%), ~1000 patients will be recruited.

RESULTS: Patients will be recruited from the RW setting, including compassionate use or early access programs. Data collected as part of the standard clinical practice will be retrospectively and prospectively gathered from the patient's medical charts.

Data collection will start in Q3 2018 and continue until Q4 2024. Regular updates on the study progress will be provided to the Regulatory bodies. Collected data will include, but not limited to, adverse events, demographics, medical history, disease characteristics, SSTR tumour uptake, LUTATHERA® exposure, comorbidities and survival.

CONCLUSION: The gathered data is expected to provide long-term insight on safety and clinical utilization of LUTATHERA® in the RW setting.