PRESS RELEASE

Advanced Accelerator Applications Announces State of Israel Ministry of Health Approval for Lutathera®, in the Treatment of Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)[1]

- *First ever approved Peptide Receptor Radionuclide Therapy in Israel*
- *Offers new treatment option for patients with advanced disease*

Saint-Genis-Pouilly, France, July 29, 2019 – Advanced Accelerator Applications S.A. (AAA), a Novartis company and leader in precision targeted radioligand therapies and diagnostics, today announced that the Ministry of Health (MoH) in Israel has approved Lutathera® (lutetium (177Lu) oxodotreotide) for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP NETs) in adults.[1].

Neuroendocrine tumors (NETs) represent a rare group of tumors that can originate in the neuroendocrine (nerve and hormonal) cells of numerous organs and are sometimes referred to as carcinoid tumors. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) are subdivided into two categories: tumors of the gastrointestinal (GI) tract and pancreas. NETs are generally slow-growing, and in many cases do not secrete hormones. As a result, they can remain silent in the early years of disease progression, often delaying diagnosis in patients until they have advanced disease that has spread to other parts of the body[2].

“We are excited to offer Lutathera as a new treatment for Israeli patients with GEP-NETs,” said Barak Palatchi, Chief Operations Officer for Advanced Accelerator Applications. “AAA is committed to making innovative therapies accessible to as many patients as possible worldwide.”

“Treating patients with progressive GEP-NETs can be challenging as there are limited options,” stated Dr. Simona Glasberg, Head of, Neuroendocrine Tumor Unit, European Neuroendocrine Tumor Society Centers of Excellence (ENETS COE) in Hadassah Hebrew University Medical Center. “As a NET specialist, I view radioligand therapy as an important tool in my treatment paradigm. Having access to therapies with demonstrated clinical benefit is critical for improving the lives of people living with GEP-NETs.”

“The Israeli NET patient community has been eagerly awaiting the potential approval of this therapy,” noted Michael Rosenberg, Founder of the Middle East Neuroendocrine Tumor Society (MENETS). “Every new treatment option has the potential of extending the life of the patient and increase quality time spent with the entire family.”

The approval of Lutathera® is based on results of the pivotal Phase 3 NETTER-1 study which was published in January 2017 in The New England Journal of Medicine[3] and a single-arm, open-label study conducted by Erasmus Medical Center in Rotterdam, Netherlands[1]. Lutathera was previously approved for the treatment of GEP-NETs by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in 2017 and 2018, respectively.

About Lutathera®
Lutathera (lutetium (177Lu) oxodotreotide) is a lutetium Lu 177-labeled somatostatin analog peptide. Lutathera belongs to a class of treatments called Peptide Receptor Radionuclide Therapy (PRRT). Lutathera is comprised of a targeting molecule which carries a radioactive component. The Israeli Summary of Product Characteristics may be viewed at https://data.health.gov.il/drugs/index.html#/byDrug

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About Advanced Accelerator Applications S.A.

Advanced Accelerator Applications, S.A. (AAA), a Novartis company, is developing precision targeted radioligand therapies and diagnostics for oncology indications. We are committed to transforming patients' lives by leading innovation in nuclear medicine. AAA has a legacy as a leader in radiopharmaceutical drugs for Positron Emission tomography (PET) and Single-Photon Emission Computed Tomography (SPECT) diagnostic imaging. For more information, please visit: https://www.adacap.com/.

References

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2. Inbal U, Grozinsky-Glassberg S. Current treatment strategies for patients with advanced gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Clinical Diabetes and Endocrinology 20184:16.
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