PRESS RELEASE

Advanced Accelerator Applications Announces Health Canada Approval for Lutathera™, a treatment for gastroenteropancreatic neuroendocrine tumors (GEP-NETs)[1]

- *First ever approved Peptide Receptor Radionuclide Therapy in Canada*
- *Neuroendocrine tumors are rare malignancies that affect approximately 12,000-15,000 Canadians[2]*

Saint-Genis-Pouilly, France, February 7, 2019 - Advanced Accelerator Applications S.A. (AAA), a Novartis company and leader in nuclear medicine theragnostics, today announced that Health Canada has approved Lutathera™ (lutetium (177Lu) oxodotreotide) for the treatment of unresectable (not removable by surgery) or metastatic, well-differentiated, somatostatin receptor-positive (expressing the somatostatin receptor) gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adults with progressive disease[1].

Neuroendocrine tumors (NETs) are rare tumors originating in neuroendocrine cells (cross functional cells that receive signals from the nervous system triggering release of hormones) of numerous organs. They are most commonly found in the lungs, gastrointestinal tract and pancreas[2]. GEP-NETs are subdivided into two categories: tumors of the gastrointestinal (GI) tract and pancreatic NETs. Many people have symptoms that mimic other conditions; therefore, NETs are often misdiagnosed as something else[2]. Because NETs are poorly diagnosed, often by the time of diagnosis, the tumor has spread to other parts of the body (metastasis)[2].

Barak Palatchi, Chief Commercial Officer for Advanced Accelerator Applications, stated, “As the first ever approved Peptide Receptor Radionuclide Therapy (PRRT) in Canada, Lutathera represents an innovative new treatment option for GEP-NET patients. We believe nuclear medicine has the potential to offer many benefits to cancer patients and hope to bring further advances to Canada in the future as part of our commitment to reimagine medicine.”

Simron Singh, MD, MPH, FRCPC, medical oncologist at the Odette Cancer Centre at Sunnybrook Health Sciences Centre in Toronto, commented, “There are very few effective treatment choices for patients with advanced GEP-NETs who are not eligible for surgery, and whose disease has progressed on standard treatments. Having this therapy approved and available will offer physicians another alternative to help manage their patients’ disease.”

Jackie Herman, President of Carcinoid-Neuroendocrine Tumour Society Canada, noted, “Due to the orphan nature of GEP-NETs and difficulty in obtaining proper diagnosis, many patients are not diagnosed until their disease has become quite advanced and is more difficult to manage. The NET patient community welcomes the approval of new therapies that can offer hope to patients and their families.”

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].

Advanced Accelerator Applications is working to finalize the timing of product availability of Lutathera™ in Canada.

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. Please see Important Safety Information and Full Prescribing Information at: https://pdf.hres.ca/dpd_pm/00049099.PDF

About Advanced Accelerator Applications S.A.

Advanced Accelerator Applications, a Novartis company, is an innovative radiopharmaceutical company developing, producing and commercializing radioligand theragnostics (pairings of therapeutic and diagnostic drugs based on the same targeting molecule) for oncology. AAA is an established leader in radiopharmaceuticals for Positron Emission tomography (PET) and Single-Photon Emission Computed Tomography (SPECT) diagnostic imaging, mainly used in clinical oncology, cardiology and neurology. For more information, please visit: https://www.adacap.com/.

References

1. Advanced Accelerator Applications, LUTATHERA™ Product Monograph, January 9, 2019.
2. Carcinoid-Neuroendocrine Tumour Society Canada, NET One Page Facts, accessed January 16, 2019, at: https://cnetscanada.org/patients-caregivers/resources/489-2/.
3. Strosberg J, El-Haddad G, Wolin E, et al. Phase 3 Trial of 177Lu-Dotatate for Midgut Neuroendocrine Tumors. N Engl J Med 2017; 376:125-35.

Media Relations Contacts:

Advanced Accelerator Applications
Rachel Levine
+1 212 235 2395 (direct)
+1 917 375 2935 (mobile)
rachel.levine@adacap.com

Novartis Oncology
Julie Masow
+1 862 778 7220 (direct)
+1 862 579 8456 (mobile)
Julie.masow@novartis.com