



## PRESS RELEASE

### Advanced Accelerator Applications Announces FDA Priority Review for Lutathera

**Saint-Genis-Pouilly, France - June 27, 2016 – Advanced Accelerator Applications S.A. (NASDAQ:AAAP)** (“AAA” or “the Company”), an international specialist in Molecular Nuclear Medicine (MNM), today announced that the U.S. Food and Drug Administration (FDA) has accepted the company’s New Drug Application (NDA) and granted Priority Review for Lutathera, a Lu-177-labeled somatostatin analogue peptide currently under development for the treatment of gastro entero pancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. The Prescription Drug User Fee Act (PDUFA) target action date is December 28, 2016.

Priority review is assigned to applications for drugs that treat serious conditions and would, if approved, provide significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions.

The Lutathera NDA is based on the results of a randomized pivotal Phase 3 study, NETTER-1 that compared treatment using Lutathera with a double dose of Octreotide LAR in patients with inoperable midgut NETs progressive under Octreotide LAR treatment and overexpressing somatostatin receptors. The NETTER-1 study met its primary endpoint by demonstrating that treatment with Lutathera was associated with a statistically significant and clinically meaningful risk reduction of 79% in disease progression or death versus a treatment with a double dose of Octreotide LAR. Efficacy and safety data from a large Phase I-II trial conducted in more than 1,200 patients in NET indications is also part of the NDA.

*“We are encouraged that the FDA has granted Priority Review for Lutathera as a potential treatment for GEP-NETs,” said Stefano Buono, Chief Executive Officer of AAA. “We believe this action emphasizes the need to improve the lives of these patients.”*

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#### **About Neuro Endocrine Tumors (NETs)**

Neuro Endocrine Tumors, also known as NETs, are a group of tumors originating in the neuroendocrine cells of many different organs. NETs can remain clinically silent for years delaying the diagnosis in a large number of patients. These cancers are rare but they are the second most common type of gastrointestinal malignancy and their incidence is increasing. The estimated incidence of NETs for the combined populations of the United States and the European Union is approximately 47,300.

NETs are classified as orphan diseases by U.S. and European regulatory authorities, meaning that they affect a relatively small population of individuals in the relevant jurisdiction. In the United States, orphan



drugs are defined as drugs that treat diseases or conditions that affect 200,000 or fewer individuals in the country. In the European Union, orphan drugs are defined as drugs that treat diseases or conditions that affect fewer than five out of 10,000 individuals in the European Union.

### **About Lutathera**

Lutathera (or lutetium Lu 177 dotatate) is a Lu-177-labeled somatostatin analogue peptide currently in development for the treatment of gastro entero pancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. Lutathera belongs to an emerging form of treatments called Peptide Receptor Radionuclide Therapy ("PRRT"), which involves targeting carcinoid tumors with radiolabeled somatostatin analogue peptides. This novel compound has received orphan drug designation from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). Lutathera was also granted fast-track designation by the FDA in April 2015 for the treatment of inoperable progressive midgut NETs. Lutathera is also currently administered on a compassionate use and named patient basis for the treatment of NETs and other tumors over-expressing somatostatin receptors in ten European countries and in the US under an Expanded Access Program (EAP) for midgut NETs. In an analysis of the Phase 3 trial's primary endpoint of PFS assessment, completed by the Company in September 2015, the Lutathera arm of the trial demonstrated a significant improvement in PFS compared to the PFS for Octreotide LAR 60 mg arm, suggesting a significant therapeutic effect for patients with midgut NETs. NDA and MAA submissions to the FDA and EMA are currently under review.

### **About Advanced Accelerator Applications**

Advanced Accelerator Applications (AAA) is an innovative radiopharmaceutical company that develops, produces and commercializes Molecular Nuclear Medicine (MNM) products. AAA's lead therapeutic product candidate, Lutathera, is a novel MNM compound that AAA is currently developing for the treatment of Neuro Endocrine Tumors, a significant unmet medical need. Founded in 2002, AAA has its headquarters in Saint-Genis-Pouilly, France. AAA currently has 20 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and has over 440 employees in 13 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, U.S. and Canada). AAA reported sales of €88.6 million in 2015 (+26.8% vs. 2014) and sales of €26.9 million for 1Q 2016 (+29.6% vs. 1Q15). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP". For more information please visit: [www.adacap.com](http://www.adacap.com).

### **Cautionary Statement Regarding Forward-Looking Statements**

This press release may contain forward-looking statements. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company's strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking



statements contain these identifying words. Forward-looking statements reflect the Company's current expectation regarding future events. These forward-looking statements involve risks and uncertainties that may cause actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, but are not limited to, changing market conditions, the successful and timely completion of clinical studies, the timing of our submission of applications for regulatory approvals, EMA, FDA and other regulatory approvals for our product candidates, the occurrence of side effects or serious adverse events caused by or associated with our products and product candidates; our ability to procure adequate quantities of necessary supplies and raw materials for Lutathera and other chemical compounds acceptable for use in our manufacturing processes from our suppliers; our ability to organize timely and safe delivery of our products or product candidates by third parties; any problems with the manufacture, quality or performance of our products or product candidates; the rate and degree of market acceptance and the clinical utility of Lutathera and our other products or product candidates; our estimates regarding the market opportunity for Lutathera, our other product candidates and our existing products; our anticipation that we will generate higher sales as we diversify our products; our ability to implement our growth strategy including expansion in the U.S.; our ability to sustain and create additional sales, marketing and distribution capabilities; our intellectual property and licensing position; legislation or regulation in countries where we sell our products that affect product pricing, taxation, reimbursement, access or distribution channels; and general economic, political, demographic and business conditions in Europe, the U.S. and elsewhere. Except as required by applicable securities laws, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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