



**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ADVANCED ACCELERATOR APPLICATIONS S.A.**

By: /s/ Heinz Mäusli

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Name: Heinz Mäusli

Title: Chief Financial Officer

Date: December 21, 2016

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**ADVANCED ACCELERATOR APPLICATIONS S.A.**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release dated December 21, 2016 titled “Advanced Accelerator Applications Receives Complete Response Letter from FDA for Lutathera <sup>®</sup> , an Investigational Treatment for Neuroendocrine Tumors”

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## PRESS RELEASE

### **Advanced Accelerator Applications Receives Complete Response Letter from FDA for Lutathera<sup>®</sup>, an Investigational Treatment for Neuroendocrine Tumors**

#### ***No Additional Clinical Studies Requested***

**Saint-Genis-Pouilly, France – December 21, 2016 – Advanced Accelerator Applications S.A. (NASDAQ:AAAP)** (“AAA” or the “Company”), an international specialist in Molecular Nuclear Medicine (MNM), today announced that following the issuance of a previously disclosed Discipline Review Letter (DRL) in November, the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for Lutathera<sup>®</sup> for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adults.

Similar to the DRL, the CRL refers to issues with the format, traceability, uniformity, and completeness relating to the NETTER-1 and Erasmus clinical datasets, which are precluding FDA reviewers from performing the required independent analysis of these clinical studies. In addition, the CRL requests subgroup analyses for gender, age and racial subgroups, as well as other stratification factors and important disease characteristics. A safety update on clinical and non-clinical studies, which is already in process, was also requested in the CRL. Finally, the CRL noted that any observations made during inspections of manufacturing facilities supporting the NDA need to be resolved prior to approval of the NDA.

No additional clinical studies were requested in the CRL and there were no comments at this time on other sections of the NDA submission.

*“We are pleased that the CRL reiterates the issues previously raised by the DRL, and does not contain any other significant requirements,”* stated Stefano Buono, Chief Executive Officer of AAA. *“Receiving the DRL in advance of the CRL was helpful, as we are already working on revising the datasets, and will incorporate the requested supplemental information into our resubmission.”*

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#### **About Lutathera<sup>®</sup>**

Lutathera<sup>®</sup> (or lutetium Lu 177 dotatate) is a Lu-177-labeled somatostatin analogue peptide currently in development for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. Lutathera<sup>®</sup> belongs to an emerging form of treatments called Peptide Receptor Radionuclide Therapy (PRRT), which involves targeting neuroendocrine 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). Currently, Lutathera<sup>®</sup> is 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 the analysis of the Lutathera<sup>®</sup> Phase III NETTER-1 trial's primary endpoint of Progression Free Survival (PFS), the number of patients having disease progression or death was 23 in the Lutathera<sup>®</sup> arm and 68 in the Octreotide LAR 60 mg arm. The NETTER-1 study met its primary endpoint by demonstrating that treatment with Lutathera<sup>®</sup> was associated with a statistically significant and clinically meaningful risk reduction of 79% of disease progression or death versus Octreotide LAR 60 mg (hazard ratio 0.21, 95% CI: 0.13-0.33; p<0.0001). New Drug Application and Marketing Authorization Application submissions to the FDA and EMA are currently under review.

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## **About Advanced Accelerator Applications**

Advanced Accelerator Applications is an innovative radiopharmaceutical company that develops, produces and commercializes Molecular Nuclear Medicine products. AAA's lead therapeutic product candidate, Lutathera<sup>®</sup>, is a novel MNM compound that AAA is currently developing for the treatment of Neuroendocrine Tumors, a significant unmet medical need. Founded in 2002, AAA has its headquarters in Saint-Genis-Pouilly, France. AAA currently has 22 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and has over 490 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 (+27% vs. 2014) and sales of €81.3 million for the first 9 months of 2016 (+23% vs. 9 months 2015). 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<sup>®</sup> 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<sup>®</sup> and our other products or product candidates; our estimates regarding the market opportunity for Lutathera<sup>®</sup>, 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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