



**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

Name: Heinz Mäusli

Title: Chief Financial Officer

Date: January 9, 2017

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**ADVANCED ACCELERATOR APPLICATIONS S.A.**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release dated January 9, 2017 titled “Advanced Accelerator Applications CEO Provides Progress Report on Corporate Developments of 2016; Asserts Confidence in Ability to Address FDA Comments on Lutathera <sup>®</sup> NDA”

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## PRESS RELEASE

### **Advanced Accelerator Applications CEO Provides Progress Report on Corporate Developments of 2016; Asserts Confidence in Ability to Address FDA Comments on Lutathera<sup>®</sup> NDA**

**Saint-Genis-Pouilly, France – January 9, 2017 – Advanced Accelerator Applications S.A. (NASDAQ:AAAP)** (“AAA” or “the Company”), an international specialist in Molecular Nuclear Medicine (MNM), today issued a statement from Chief Executive Officer, Stefano Buono providing an update on corporate developments of 2016 and outlook for 2017. The statement is included in its entirety below.

“The past year has been characterized by rapid growth and advancement across almost every area of AAA. We expanded our branded product portfolio with the approval of four new Positron Emission Tomography (PET) diagnostics in a six-month period; successfully launched our first drug product in the U.S.; strengthened our supply chain and manufacturing capabilities through several key acquisitions; enlarged our theragnostic pipeline of oncology products by in-licensing two new compounds (NeoBomb1 and PSMA-R2); sponsored or supported 14 ongoing clinical trials with our lead investigational drug, Lutathera<sup>®</sup>, and other diagnostic candidates; and continued to deliver significant revenue growth, with a 23% increase for the first nine-months of 2016 with sales of €81.28 million, or US \$91.34 million.

In June 2016, after just 23 months from our pre-Investigational New Drug meeting with the U.S. Food and Drug Administration (FDA), our first U.S. product, NETSPOT<sup>®</sup>, a gallium Ga 68 dotatate PET diagnostic for neuroendocrine tumors (NETs), was approved. In addition, we also recently announced approval of SomaKit TOC<sup>™</sup> by the European Commission. The response of the U.S. NET patient and physician community to our NETSPOT<sup>®</sup> launch has been very positive. We are currently delivering more than 120 patient-ready doses of NETSPOT<sup>®</sup> per month, with the help of our national network of radiopharmacy partners. We have 13 radiopharmacies currently active and plan to expand to more than 40 sites over the first half of 2017. We are further encouraged by the granting of Transitional Pass-Through status by the Centers for Medicare & Medicaid Services (CMS) under an “A Code” for drug reimbursement. The same Healthcare Common Procedure Coding System “A Code” will be used on claims to private payers. This coding streamlines billing and reimbursement for all institutions using the product. We look forward to bringing the same enhanced patient management and convenience of a kit form to the European market with the launch of SomaKit TOC<sup>™</sup> in 2017.

We are working closely with both the FDA and the European Medicines Agency (EMA) to address requests related to the review of our New Drug Application (NDA) and Marketing Authorization Application (MAA) for Lutathera<sup>®</sup>. As we announced in September, the EMA had requested some additional clarifications and an inspection of one of our contract research organizations (CRO), which modified the anticipated review to a standard timeline. I am pleased to share that the majority of these clarifications have since been provided, and the inspection of the CRO has been completed. I am also quite pleased to inform you that our team is already deeply engaged in the issues identified by the FDA in its recent communications regarding format, traceability, uniformity, and completeness of the NETTER-1 and Erasmus clinical datasets. To remediate these issues, we have formed an internal task force to work closely with an additional CRO and consulting

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statistician we hired that specialize in the exact areas highlighted by the FDA. In September, we added a Head of Oncology in the U.S., who is already contributing enormously to this effort, and we are further strengthening our internal statistical capabilities, as well. It is our absolute focus and priority to deliver revised datasets meeting the FDA's requirements as soon as possible. The FDA also requested some additional subgroup analyses and safety updates, as well as other stratification factors. Our team is in the process of addressing these requests. I would like to reiterate that no additional clinical studies have been requested by the FDA, and aside from some open observations from facilities inspections, to date, the FDA has not made any comments on other sections of our NDA. We remain steadfast in our efforts to resolve all of these outstanding issues as soon as possible.

As the review process for Lutathera<sup>®</sup> moves forward, we are increasing our U.S. Expanded Access Program (EAP), in an effort to service the more urgent needs of NET patients. The EAP was opened in March 2016, and the first patient received the product in July. There are currently 14 sites across the U.S. participating in the EAP for Lutathera<sup>®</sup> in Arizona, California, Colorado, Iowa, Massachusetts, Missouri, New York, North Carolina, Pennsylvania, and South Carolina. Additional sites are expected to enroll in 2017. European compassionate use and named patient programs for Lutathera<sup>®</sup> already span 67 centers across 10 countries: Austria, Denmark, Estonia, Finland, France, Greece, Portugal, Spain, Switzerland, and the United Kingdom. More than 1,500 patients worldwide have been treated with Lutathera<sup>®</sup> through these programs.

Our enhanced supply chain and manufacturing capabilities will further support this activity and prepare us for Lutathera's<sup>®</sup> launch. Our acquisition of IDB Group in the Netherlands, in January 2016, provided AAA with a reliable supply of Lutetium 177 for the production of Lutathera<sup>®</sup>, as well as production capabilities for other future product candidates. Additionally, our first U.S. manufacturing and distribution facility in Millburn, NJ was completed this summer. This site currently distributes NETSPOT<sup>®</sup> kits for reconstitution and Oxygen-18 enriched water, and is undergoing validation for production of Lutathera<sup>®</sup>. The Millburn site is expected to supply Lutathera<sup>®</sup> to the entire North American market.

AAA's position as a leader in the European Molecular Nuclear Medicine market remains strong. We are increasing our penetration of PET and Single Photon Emission Computed Tomography (SPECT) products across multiple disease areas and continue to expand our portfolio of AAA branded products. In November, we announced Swiss marketing approval for DOPAVIEW<sup>®</sup> and AAACHoline, which are also marketed in France (as DOPAVIEW<sup>®</sup> and Fluorochol).

Our development pipeline also continues to advance. We augmented our pipeline of theragnostic pairings for oncology with the in-licensing of some PSMA ligand candidates from Johns Hopkins University for development in prostate cancer; and NeoBOMB1, a Gastrin Releasing Peptide Receptor (GRPR) antagonist for development in prostate, breast and gastrointestinal stromal tumors. We look forward to sharing our plans for these compounds in the coming months.

In July 2016, we signed a clinical trial agreement with the National Cancer Institute (NCI), whereby NCI will sponsor and conduct a study of Lutathera<sup>®</sup> in patients with inoperable pheochromocytoma and paraganglioma. In a Phase II trial conducted at the Erasmus Medical Center, that is part of our NDA and MAA, 45 patients with these indications were treated with a median Progression Free Survival of 24.8 months and a median Overall Survival that was not reached. We hope these results will be confirmed by the NCI trial. There are six additional investigator initiated studies currently ongoing with Lutathera<sup>®</sup> in indications such as primary refractory or relapsed high risk neuroblastoma; FDG-positive and negative gastroenteropancreatic, or GEP-NETs; and unresectable, progressive, well-differentiated neuroendocrine pancreatic carcinoma, with more planned in 2017.

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In August, we announced the start of two new AAA sponsored Phase II studies for our Annexin diagnostic candidate, in cardiovascular and cardio-oncology indications, which adds to our ongoing study of Annexin in rheumatoid arthritis and ankylosing spondylitis, and an investigator initiated study in the detection of infective heart disease. Other AAA sponsored or investigator initiated studies for our diagnostic products include a Phase I/IIa with SomaKit TOC™ in patients with proven GEP-NETs; a Phase I/IIa with Ga 68 labeled NeoBOMB1 in patients with advanced, TKI-treated gastrointestinal stromal tumors; and a Phase II with F-18 labeled fluoroestradiol, or FES to predict efficacy of endocrine therapy in breast cancer. These studies are a great way for us to increase our understanding of potential directions for our pipeline candidates, while gathering valuable clinical data.

As we enter 2017, we believe AAA is well positioned to achieve our goals. We have the infrastructure and capabilities to build on our success with NETSPOT®, and implement product launches for SomaKit TOC™ and then Lutathera®. We are increasing market penetration in both the U.S. and Europe. We continue to generate positive clinical data for Lutathera® and have a robust development pipeline. We are well capitalized to execute our strategy and secure our leadership as a key innovator in the Molecular Nuclear Medicine segment.

I thank our stakeholders for their continued support, and look forward to providing updates on our progress with the FDA's requests."

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#### **About Lutathera®**

Lutathera® (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® 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® 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® 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® arm and 68 in the Octreotide LAR 60 mg arm. 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% 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 500 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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**Contacts:**

**AAA Corporate Communications**

Rachel Levine  
Director of Communications  
[rachel.levine@adacap.com](mailto:rachel.levine@adacap.com)  
Tel: + 1-212-235-2395

**AAA Investor Relations**

Jordan Silverstein  
Director of Investor Relations  
[jordan.silverstein@adacap.com](mailto:jordan.silverstein@adacap.com)  
Tel: + 1-212-235-2394

**Media inquiries:**

**Makovsky & Company**

Lee Davies  
[ldavies@makovsky.com](mailto:ldavies@makovsky.com)  
Tel: +212-508-9651

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