



PRESS RELEASE

Advanced Accelerator Applications Completes Resubmission of NDA for Lutetium Lu 177 Dotatate (Lutathera®) to FDA

Conference Call Today at 5:00 p.m. ET

July 27, 2017, Saint-Genis-Pouilly, France - Advanced Accelerator Applications S.A. (NASDAQ:AAAP) (AAA or the Company), an international specialist in Molecular Nuclear Medicine (MNM), today announced that the resubmission of the New Drug Application (NDA) for investigational drug lutetium Lu 177 dotatate* (Lutathera®) to the US Food and Drug Administration (FDA) was completed.

AAA resubmitted the NDA following receipt of a complete response letter (CRL) from the FDA in December 2016, in which the Agency cited issues with the format, traceability, uniformity, and completeness relating to the NETTER-1 and Erasmus clinical datasets, which precluded FDA reviewers from performing the required independent analysis of these clinical studies. The CRL also requested subgroup analyses for gender, age and racial subgroups, as well as other stratification factors and important disease characteristics, and a safety update on clinical and non-clinical studies. In addition, 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 that time on other sections of the NDA submission.

Stefano Buono, Chief Executive Officer of AAA, commented, *"We believe this submission addresses the issues identified in the CRL. Over the past few months our internal task force of statistical, clinical and regulatory experts has been working closely with additional contract research organizations and consulting statisticians specializing in management and conversion of clinical datasets and preparation of oncology dossiers to address the matters raised by the FDA in the CRL. As part of this process, we sent a test dataset to the FDA to confirm that the data and format are compatible and able to be analyzed. In addition, we engaged a team of consultants experienced in FDA reviews to perform a rigorous critique of both the datasets and the major clinical sections of the dossier prior to resubmitting. We look forward to receiving the Agency's feedback and continuing to support their review process."*

The company also announced that the FDA allowed an amendment to the protocol for the US Expanded Access Program (EAP) for lutetium Lu 177 dotatate (Lutathera®) to permit enrollment of patients with metastasized or locally advanced, inoperable neuroendocrine tumors (NETs) arising at all sites (including foregut, midgut and hindgut), and that have progressive disease during or after treatment with somatostatin analogues. In addition, the amendment includes the use of a 2.5% lysine/arginine amino acid solution as an additional option for renal protection.

"To date, more than 120 patients in the US have received treatment under the EAP, including several with non-midgut NETs under Named Patient Investigational New Drug applications filed by individual



investigators,” added Buono. “This amendment should facilitate access to treatment for additional patients in need.”

The company recently announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending the marketing authorization of lutetium (^{177}Lu) oxodotreotide (Lutathera[®])* for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults.

Conference Call Information

Advanced Accelerator Applications management will host a conference call today at 5:00 p.m. ET. Interested parties may participate by dialing 877-407-8133 (US) or +1-201-689-8040 (International), approximately five minutes before the call start time. A live webcast of the conference call will be available at: <http://www.investorcalendar.com/event/18565>. A replay of the call will be available through August 27, 2017, at 5:00 p.m. ET. Interested parties may access the replay by dialing 877-481-4010 (US) or +1-919-882-2331 (International) and entering ID number 18565. An archived webcast of the conference call will be available for 90 days on the Investor Relations page of the Advanced Accelerator Applications website: www.adacap.com.

* USAN: lutetium Lu 177 dotatate/INN: lutetium (^{177}Lu) oxodotreotide

About USAN: lutetium Lu 177 dotatate / INN: lutetium (^{177}Lu) oxodotreotide (Lutathera[®])

USAN: lutetium Lu 177 dotatate/INN: lutetium (^{177}Lu) oxodotreotide (Lutathera[®]) is an investigational ^{177}Lu -labeled somatostatin analog peptide. USAN: lutetium Lu 177 dotatate/INN: lutetium (^{177}Lu) oxodotreotide, (Lutathera[®]) belongs to an emerging form of treatments called Peptide Receptor Radionuclide Therapy (PRRT), which involves targeting tumors with radiolabeled molecules that bind to specific receptors expressed by the tumor. This novel compound has received orphan drug designation from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). Currently, USAN: lutetium Lu 177 dotatate/INN: lutetium (^{177}Lu) oxodotreotide (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). A New Drug Application submission to the FDA is currently under review.

About Advanced Accelerator Applications S.A.

Advanced Accelerator Applications is an innovative radiopharmaceutical company that develops, produces and commercializes Molecular Nuclear Medicine products. AAA's lead investigational therapeutic candidate, USAN: lutetium Lu 177 dotatate/INN: lutetium (^{177}Lu) oxodotreotide (Lutathera[®]), is a novel MNM compound in development 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 21 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and more than 500 employees in 13 countries (France, Italy, the UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, the US and Canada). AAA reported sales of €109.3 million in 2016 (+23% vs. 2015). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP". For more information, please visit: www.adacap.com.

About Molecular Nuclear Medicine ("MNM")

Molecular Nuclear Medicine is a medical specialty using trace amounts of active substances, called radiopharmaceuticals, to create images of organs and lesions, and to treat various diseases, like cancer. The technique works by injecting targeted radiopharmaceuticals into the patient's body that accumulate in the organs or lesions and reveal specific biochemical processes. MNM can be divided in two branches: Molecular Nuclear Diagnostics and Molecular Nuclear Therapy. Molecular nuclear diagnostics employs a variety of imaging devices and radiopharmaceuticals. PET (Positron Emission Tomography) and SPECT (Single Photon Emission Computed Tomography) are highly sensitive imaging technologies that enable physicians to diagnose different types of cancer, cardiovascular diseases, neurological disorders and other diseases in their early stages. Molecular nuclear therapy uses radioactive sources (radionuclides) to treat a range of tumor types. Using short-range particles, this therapy can target tumors with little effect on normal tissues.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains 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 that appear in a number of places in this press release include the Company's current expectation regarding future events and various matters, including expected timing of filings with the FDA and EMA, and approval dates. 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 USAN: lutetium Lu 177 dotatate/INN: lutetium (¹⁷⁷Lu) oxodotreotide (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 USAN: lutetium Lu 177 dotatate/INN: lutetium (¹⁷⁷Lu) oxodotreotide (Lutathera[®]) and our



other products or product candidates; our estimates regarding the market opportunity for USAN: lutetium Lu 177 dotatate/INN: lutetium (¹⁷⁷Lu) oxodotreotide (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 US; 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; regulatory actions or litigation; and general economic, political, demographic and business conditions in Europe, the US 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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