



## PRESS RELEASE

### **Advanced Accelerator Applications Announces FDA Approval of NETSPOT™ (Somakit-TATE), a Kit for the Preparation of Gallium Ga 68 Dotatate for Neuroendocrine Tumor Detection**

***NETSPOT™ will be the new name for Somakit-TATE, a PET (Positron Emission Tomography) Diagnostic***

**Saint-Genis-Pouilly, France – June 2, 2016 – Advanced Accelerator Applications S.A. (NASDAQ:AAAP)** (“AAA” or “the Company”), an international specialist in molecular nuclear medicine, today announced that the US Food and Drug Administration (FDA) has approved NETSPOT™ (Somakit-TATE) for the localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients. NETSPOT™ received approval following a Priority Review from the FDA.

NETSPOT™ is the new market name for Somakit-TATE (a kit for the preparation of gallium Ga 68 dotatate injection) in the US. NETSPOT™ is the first approved drug using Ga 68 as a positron emitter. Gallium Ga 68 dotatate received Orphan Drug Designation from both the FDA and European Medicines Agency (EMA) in March 2014.

Following today’s approval, NETSPOT™ will be made available to the US market as soon as possible. AAA intends to commercialize the product in the US in two forms: As a kit for reconstitution using a Ga 68 generator, and as NETSPOT™ Injection, a ready-to-use dose delivered from a local radiopharmacy in selected metropolitan areas.

NETSPOT™ is currently approved for use with the GalliaPharm Ga 68 generator from Eckert & Ziegler.

*“The FDA approval of NETSPOT™ is a key milestone in our mission of improving the lives of NET patients,” said Stefano Buono, Chief Executive Officer of AAA. “NETSPOT™ has the potential to significantly improve the accuracy of NET diagnosis, while reducing radiation exposure for patients. We believe that the use of NETSPOT™ should also offer increased comfort for patients by potentially shortening a procedure that is currently performed over 24 hours or more to just a few hours.”*

The estimated incidence of NETs for the combined populations of the United States and the European Union is approximately 47,300 patients/year.<sup>1</sup> Even though NETs have historically been considered as rare tumors (orphan disease) their incidence has grown over 500% over the last 3 decades.<sup>2,3,4</sup>

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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.

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NETs are classified as orphan diseases by European and U.S. 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 NETSPOT™**

NETSPOT™ is a novel patented kit developed by AAA for the preparation of gallium Ga 68 dotatate for injection, for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients using Positron Emission Tomography ("PET"). The kit has been designated as an orphan drug by the EMA and the FDA.

## **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).

## **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, such as 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. Molecular Nuclear Diagnostics employs a variety of imaging devices and radiopharmaceuticals. PET (Positron Emission Tomography) and SPECT (Single Photon Emission 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.

### **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.

### **References**

1. Lawrence B, et al. 2011 (table 3 page 8)
  2. JC Yao et al. 2008 - see abstract on 1st page
  3. Frilling et al. Endoc Related Cancer 2012, 19: R163-815
  4. Lawrence et al. Endocrinol Metab Clin N Am. 2011, 40:1–18
  5. Kuiper et al. 2011
  6. Pavel et al. 2016
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