



## PRESS RELEASE

### **AAA Signs Distribution Agreement for Lutathera in Japan with FUJIFILM RI Pharma, Co., LTD**

30 June 2015, Saint-Genis-Pouilly, France – Advanced Accelerator Applications S.A. (“AAA” or “the Company”), an international specialist in Molecular Nuclear Medicine (MNM), announces that it has entered into a distribution agreement for Lutathera in Japan with FUJIFILM RI Pharma, Co., LTD (“FRI”), a leading in-country distributor of nuclear medicine and diagnostic imaging products. Lutathera is currently in a pivotal Phase III trial, both in the US and EU, with results expected in Q3.

As part of the agreement, AAA will receive launch and development milestone payments, in addition to royalties on product sales. Lutathera will be manufactured by AAA in Europe and sold to FRI by its subsidiary AAA International.

AAA and FRI will work together to meet all Japanese regulatory requirements and prepare for national approval.

*“We are pleased to have signed our first distribution agreement for Lutathera in Asia with FRI” said Stefano Buono, Chief Executive Officer of AAA. “FRI provides important sales, marketing and distribution capabilities for Lutathera in the Japanese market as well as providing the support needed to gain regulatory clearance in Japan. We believe Asia is a significant market for Lutathera, and Japan represents an important first presence as we introduce the product into the region. Our plans are to continue implementing selected distributorships such as our agreement with FRI, in countries where we have not planned a direct presence.”*

*“In Europe’s five key markets and the US, AAA’s plan is to build complete and dedicated commercial structures in each country to support the launch and promotion of Lutathera and Somakit, Lutathera’s companion diagnostic, for which a New Drug Application (NDA) will soon be submitted to the FDA,” added Stefano Buono.*

Gérard Ber, Chief Operating Officer of AAA, commented: *“Meeting an unmet medical need with Lutathera for gastroenteropancreatic neuroendocrine tumor (GEP-NET) patients around the world is a key strategic objective of AAA. As we start developing the Lutathera franchise, we look forward to additional commercialization agreements for other countries and the ability to provide cancer patients with better care on an increasingly global scale.”*

Lutathera is currently in a pivotal Phase III trial for the treatment of midgut NETs in 51 clinical centers in the United States and EU (the NETTER-1 clinical study). Enrollment was completed in February 2015 and the number of events necessary to meet the primary endpoint has been reached. The results of the NETTER-1 trial for Lutathera will be presented during the ESMO meeting in September 2015.

Based on current evidence of efficacy and safety, Lutathera is already available in 9 European countries (Austria, Denmark, Estonia, Finland, Greece, Portugal, Spain, Switzerland and the UK) under compassionate use or named patients programs and in France under a Cohort Temporary Authorization of Use (ATU de Cohorte).



## **About 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, for example, 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 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 Lutathera and ongoing clinical trials**

Lutathera (or <sup>177</sup>Lu-DOTATATE) is a Lu-177-labeled somatostatin analogue peptide currently under development for the treatment of Gastro-Entero-Pancreatic Neuro Endocrine Tumors (GEP-NETs). This novel compound has received orphan drug designation from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), which provides post market authorization exclusivity in the US (7 years), and Europe (10 years). It has been approved for treatment of all NETs on a compassionate use and named patient basis in ten European countries.

Lutathera belongs to an emerging form of treatments called Peptide Receptor Radionuclide Therapy (PRRT) which involves targeting carcinoid tumors with radiolabeled somatostatin analogue peptides.

There is a real unmet medical need for an effective treatment of inoperable, advanced NETs and there are currently no therapeutic options available for patients with NETs other than pancreatic (about 10% of NETs are pancreatic) who are progressive under somatostatin analogues. Currently at the end of its Phase III development with the NETTER-1 pivotal study, Lutathera is the most advanced candidate in development for PRRT.

NETTER-1 is an international, multi-center, randomized, Phase III study comparing treatment with Lutathera to a double dose of Octreotide LAR in patients with inoperable, progressive under Octreotide LAR treatment, midgut carcinoids (midgut NETs) overexpressing somatostatin receptors. The primary endpoint of the trial is the assessment of progression-free survival. Secondary endpoints include safety, objective response rate, time to tumor progression, overall survival and quality of life. The study is conducted in 51 clinical centers in the United States and Europe. Enrollment was completed in February 2015 and 74 events are expected to meet the primary endpoint. Lutathera is aiming at covering an unmet medical need, as after progression from “cold” analogues of somatostatin such as Octreotide LAR (Novartis) or Somatuline (Ipsen), there are no alternative therapies approved in this indication.

## **About Advanced Accelerator Applications**

Advanced Accelerator Applications (AAA) is a radiopharmaceutical company founded in 2002 to develop innovative diagnostic and therapeutic products. AAA's main focus is in the field of Molecular Imaging and targeted, individualized therapy for the management of patients with serious conditions



(“Personalized Medicine”). AAA currently has 17 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and has over 350 employees in 11 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, Israel, U.S. and Canada). In 2014 AAA reported sales of €69.9 million (+29.8% vs. 2013). 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, like cancer. The technique works by injecting targeted radiopharmaceuticals into the patient’s body that accumulate in the organs or lesions that 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. Theragnostics is today used to define “companion drugs”. This means that a therapeutic drug is developed and is approved to be used together with a diagnostic test. The test can tell you if the drug is suitable for a specific disease in a specific patient and checks if the treatment could be effective, thus increasing the cost-effectiveness of the whole treatment. MNM can integrate diagnostics and therapeutics properties into a single theragnostic drug and is a key discipline in the transition from population-based medicine to Personalized Medicine.

### **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, EMA, U.S. FDA and other regulatory approvals for our product candidates, the establishment of corporate alliances, the impact of competitive products and pricing, new product development, and uncertainties related to the regulatory approval process or the ability to obtain drug product in sufficient quantity or at standards acceptable to health regulatory authorities to complete clinical trials or to meet commercial demand. 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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