



PRESS RELEASE

Advanced Accelerator Applications (AAA) Announces Pivotal Phase 3 NETTER-1 Study of Lutathera in Patients with Midgut Neuro Endocrine Tumors Meets Primary Endpoint and Data will be Presented in Presidential Session at the European Cancer Congress 2015

-- FDA Grants Priority Review to AAA's New Drug Application for Somakit-TATE, Lutathera's companion PET (Positron Emission Tomography) Diagnostic --

16 September 2015, Saint-Genis-Pouilly, France – Advanced Accelerator Applications (AAA), an international specialist in molecular nuclear medicine, today announced that the pivotal Phase 3 NETTER-1 clinical study investigating the treatment of Lutathera (177-Lu-Dotatate) in patients with inoperable, progressive, somatostatin receptor positive midgut Neuro Endocrine Tumors (midgut NETs) has met its primary endpoint, demonstrating a statistically significant and clinically meaningful increase in progression-free survival for Lutathera versus a double dose of Sandostatin LAR. The pivotal Phase 3 study results will be presented for the first time on Sunday, September 27, 2015, at the European Cancer Congress (ECC) 2015 in Vienna, Austria.

The late-breaking abstract was chosen to be presented in one of three Presidential sessions, and has also been selected to be featured as part of the official media program at ECC 2015.

The details of the presentation are as follows:

Abstract 6LBA: Late-Breaking Abstract: 177-Lu-Dotatate significantly improves progression-free survival in patients with mid gut neuroendocrine tumours: Results of the phase III NETTER-1 trial

Speaker: Prof. Philippe Ruszniewski, M.D

Presidential Session II (Hall D1)

Sunday, September 27, 2015

Session from 14:45-16:55 CEST (8:45-10:55 a.m. EDT); presentation expected to begin at 16:15 CEST (10:15 a.m. EDT)

Stefano Buono, CEO of AAA, clinical study investigator Prof. Philippe Ruszniewski, and Josh Mailman, an active member of the NET patient community, will be available onsite at the conference for interviews.

The press conference webcast will be available on September 27, from 7:00am CET onwards at <http://www.europeancancercongress.org/Webcasts-Photos>.

Other important news announced by AAA today is that the U.S. Food and Drug Administration (FDA) has granted Priority Review to AAA's New Drug Application (NDA) for SomaKit-TATE, a patented Kit for the preparation of ⁶⁸Ga-DOTATATE for injection, which is in development to help diagnose and

manage somatostatin receptor-positive NET patients using Positron Emission Tomography (PET). The Somakit NDA was submitted on July 1st, 2015 and it is the first NDA ever filed for a drug using Ga-68 as a positron emitter.

“Somakit-TATE has the potential to significantly improve the accuracy of diagnosis while reducing radiation exposure for patients. We believe that the use of Somakit-TATE should also offer, if approved, the opportunity to shorten a procedure that is performed over 24 hours or more to a couple of hours, with increased comfort for the patient,” said Stefano Buono, Chief Executive Officer of AAA. “We view Somakit as a companion diagnostic for Lutathera, our GEP-NET therapeutic candidate which is in its final stages of development, as the two compounds share exactly the same peptide. We believe that Somakit and Lutathera, if approved, have the potential to provide significant improvement in the treatment of GEP-NET patients.”

A Priority Review designation is granted by the FDA when a proposed drug exhibits the potential to offer a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition.

The FDA and the EMA granted Orphan Drug Designation for Ga-68 DOTATATE (Somakit) in March 2014.

About 177Lu-DOTATATE (Lutathera)

Lutathera (or 177Lu-DOTATATE) is a Lutetium-177, or 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). Lutathera was also granted Fast-Track designation by the FDA in April 2015 for the treatment of inoperable progressive midgut NETs. The FDA provides Fast-Track designation to product candidates that treat serious conditions and fill an unmet medical need in order to facilitate their development and expedite their review. Lutathera is also currently administered on a compassionate use and named patient basis for the treatment of NETs 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 an 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 NETs (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.

About Somakit-TATE

Somakit-TATE, a companion PET diagnostic product candidate for Lutathera, is a novel patented kit in development for radiolabeling somatostatin analogue peptides to help diagnose somatostatin-receptor-positive NET lesions. The kit has been designated as an orphan drug by the EMA and the FDA. Somakit-TATE has the potential to offer a standardized procedure for producing diagnostic compounds based on ⁶⁸Ga without the need of expensive pharmaceutical manufacturing equipment and extensive quality control testing.

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 currently has over 380 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 (+29.9% vs. 2013). For more information please visit: 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, EMA, US 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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