PRESS RELEASE

AAA Announces Positive Results From Phase 3 Study NETTER-1 Evaluating Lutathera in Patients with Advanced Midgut Neuroendocrine Tumors

Detailed study results presented at the European Cancer Congress 2015 reported Lutathera significantly improves progression-free survival

Key Highlights

- Lutathera 7.4 GBq every 8 weeks (x4 administrations) statistically significantly prolonged progression-free survival in patients with advanced midgut neuroendocrine tumors ($p<0.0001$, hazard ratio 0.21; 95% CI 0.13-0.34).
- The median PFS in the Lutathera arm has not yet been reached whilst the median PFS in the Octreotide LAR 60mg arm was 8.4 months.
- Safety data generated from this study are consistent with the known safety profile of Lutathera.

27 September 2015, Saint-Genis-Pouilly, France – Advanced Accelerator Applications S.A. ("AAA" or "the Company"), an international specialist in Molecular Nuclear Medicine (MNM), announced today that the pivotal Phase 3 NETTER-1 study for Lutathera (^{177}Lu-DOTATATE) met its primary endpoint of assessing progression-free survival (PFS), demonstrating that Lutathera significantly improved PFS when compared with Sandostatin LAR 60mg (Octreotide LAR) in patients with advanced midgut neuroendocrine tumors (NETs).

The results were presented in late-breaking abstract 6LBA "177-Lu-Dotatate significantly improves progression-free survival in patients with mid gut neuroendocrine tumors: Results of the phase III NETTER-1 trial." This abstract was presented today at the European Cancer Congress in Vienna during Presidential Session II.

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 a treatment with a double dose of Octreotide LAR (hazard ratio 0.21, 95% CI: 0.13-0.34; $p<0.0001$). The median PFS in the Lutathera arm is not yet reached, whilst the median PFS in the Octreotide LAR 60 mg arm was 8.4 months. The adverse events observed on Lutathera in NETTER-1 are consistent with the results of Lutathera's previous Phase I-II study, with Lutathera demonstrating a favorable safety profile.

"*NETTER-1 is the first large scale, multinational Phase 3 trial to demonstrate the efficacy of Lutathera in patients with advanced midgut NETs,*" said Stefano Buono, Chief Executive Officer of AAA. "*We are very pleased with the favorable results demonstrated in the study. We believe that Lutathera has the potential to provide a clinically significant benefit for patients and improve the standard of care for this disease.*"

Prof. Philippe Ruszniewski, Gastroenterology-Pancreatology Dept, Beaujon Hospital, Clichy, and Dean of the School of Medicine at Paris Diderot University (France), a study investigator commented: "*The NETTER-1 results demonstrate a clinically important and statistically significant increase in progression-free survival for patients with advanced midgut NETs treated with Lutathera. This is the first time a Phase 3 clinical trial has demonstrated an increased PFS with PRRT in the treatment of GEP-NETs.*"

Results

Enrollment was completed in February 2015, with a target of 230 patients randomized (1:1) in 36 sites in Europe and 15 sites in the United States. At the time of statistical analysis, the number of centrally confirmed disease progressions or deaths was 23 in the Lutathera group and 67 in the Octreotide LAR 60 mg group. The median PFS was not yet reached for Lutathera and was 8.4 months with 60 mg Octreotide LAR [95% CI: 5.8-11.0 months], $p<0.0001$, with a hazard ratio of 0.21 [95% CI: 0.13-0.34]. Within the current evaluable patient dataset for tumor responses (n=201), 19 patients (19%) reported complete and partial responses (CR+PR) in the Lutathera group versus 3 (3%) in the Octreotide LAR 60 mg group ($p<0.0004$). Although the overall survival (OS) data is not mature enough for a definitive analysis, the number of deaths was 13 in the Lutathera group and 22 in the Octreotide LAR 60 mg group ($p<0.0186$ at interim analysis), which initially suggests an improvement in OS.

The Phase 3 NETTER-1 study provides evidence of a clinically meaningful and statistically significant increase in PFS and objective response rate (ORR), and also suggests a survival benefit in patients with advanced midgut neuroendocrine tumors treated with Lutathera.

The adverse events observed on Lutathera in the NETTER-1 study were generally consistent with their respective known adverse event profile.

All main secondary endpoints are currently being analyzed.

About Lutathera

Lutathera (or ^{177}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). 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. Currently at the end of its Phase 3 development with the NETTER-1 pivotal study, Lutathera is the most advanced candidate in development for PRRT.

About NETTER-1

NETTER-1 is the first Phase III multi-center, randomized, controlled trial evaluating ^{177}Lu-DOTA^{0}-Tyr^{3}-Octreotate (Lutathera) in patients with inoperable, progressive, somatostatin receptor positive midgut NETs. 230 patients with Grade 1-2 metastatic midgut NETs (both functioning and not

functioning) were randomized to receive Lutathera 7.4 GBq every 8 weeks (x4 administrations) versus Octreotide LAR 60 mg every 4-weeks. The primary endpoint was PFS per RECIST 1.1 criteria, with objective tumor assessment performed by an independent reading center every 12 weeks. Secondary objectives included objective response rate, overall survival, toxicity, and health-related quality of life.

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.

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 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 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). In the first 6 months of 2015 revenues reached €43 million (+29.5% vs. H1 2014). 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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