
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR
15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of March, 2016

Commission File Number: 001-36826

ADVANCED ACCELERATOR APPLICATIONS S.A.
(Exact name of registrant as specified in its charter)

20 rue Diesel
01630 Saint Genis Pouilly, France
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes No

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ADVANCED ACCELERATOR APPLICATIONS S.A.

By: _____ /s/ Heinz Mäusli
Name: Heinz Mäusli
Title: Chief Financial Officer

Date: March 23, 2016

ADVANCED ACCELERATOR APPLICATIONS S.A.

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press Release dated March 23, 2016 titled "Advanced Accelerator Applications Provides Lutathera Update. Lutathera Expanded Access Program Now Open In U.S. to Eligible Patients NDA Filing to FDA and EMA Forthcoming"



PRESS RELEASE

Advanced Accelerator Applications Provides Lutathera Update

Lutathera Expanded Access Program Now Open In U.S. to Eligible Patients

NDA Filing to FDA and EMA Forthcoming

March 23, 2016, Saint-Genis-Pouilly, France – Advanced Accelerator Applications S.A. (NASDAQ:AAAP) (“AAA” or “the Company”), an international specialist in molecular nuclear medicine, today announced that the company has initiated an expanded access program (EAP) in the United States for the investigational product, Lutathera. Through the program, Lutathera is being made available for patients suffering from inoperable, somatostatin receptor positive, midgut carcinoid tumors, progressive under somatostatin analogue therapy. Healthcare professionals and patients can learn more about the Lutathera EAP by visiting www.clinicaltrials.gov (trial number: NCT02705313).

Under its expanded access programs, the U.S. Food and Drug Administration (FDA) works with companies to allow access to investigational therapies to patients with serious or life-threatening illnesses who do not otherwise qualify for participation in a clinical trial and for whom there are no comparable or satisfactory alternate therapies.

Today AAA also announced a New Drug Application (NDA) filing plan for Lutathera, following the pre-NDA meeting held on March 14, 2016. Given that rolling submissions are possible under the Fast-Track program granted for Lutathera, the Agency accepted a submission plan in which all parts of the NDA are to be sent by the end of the current month except for the ISS and ISE (Integrated Summaries of Safety and Efficacy Databases) which should be submitted within thirty days after the bulk of the submission.

The ISS and ISE databases required an additional amount of time because they merge Phase 3 Data from the NETTER-1 study with the Phase 2 data from an investigator sponsored single arm clinical study conducted at the Erasmus Clinical Center in Rotterdam, The Netherlands, between January 2000 and December 2012. This study enrolled a total of 1214 patients with various inoperable, somatostatin receptor positive NETs including bronchial carcinoid tumors, and the results of this study are to serve as a basis for assessing the efficacy and safety of Lutathera in all inoperable, metastatic NETs over-expressing somatostatin receptors.

The review clock for the NDA will not begin until AAA informs the FDA that a complete NDA has been submitted, including the ISS and ISE. The rolling submission will, however, allow the FDA to immediately start the review of the most relevant parts of the application, including the separate Clinical Reports of both NETTER-1 and the Phase 2 study.

Given the fact that rolling submissions are not permitted at the European Medicine Agency (EMA), a complete submission to the EMA will be completed by the end of April.

"We are excited that the bulk of the NDA application can proceed so soon after the pre-NDA meeting," said Stefano Buono, Chief Executive Officer of AAA. "The Expanded Access Program will help ensure that eligible patients who may benefit from treatment with Lutathera gain access to this investigational therapy in advance of the FDA's review of our submission. With the positive results of the pivotal Phase 3 NETTER-1 trial, it was important for us to find a way, in conjunction with the FDA, to offer U.S. patients access to the Lutathera treatment."

About the Lutathera EAP

The Lutathera EAP is a U.S.-only, single-arm study for patients suffering from inoperable, somatostatin receptor positive, midgut carcinoid tumors, progressive under somatostatin analogue therapy. Patients enrolled in the study will receive a treatment regimen of 4 administrations of Lutathera 7.4 GBq (200 mCi) at the date and time of infusion. The recommended interval between two infusions is 8 weeks, which could be extended up to 16 weeks in case of dose modifying toxicity. Additional enrollment criteria are available at www.clinicaltrials.gov (trial number: NCT02705313).

U.S.-based health care professionals seeking more information about the Lutathera EAP can e-mail AAAUSmedicalaffairs@adacap.com for further details.

Patients who are interested in enrolling to the Lutathera EAP should speak with their physician to understand if Lutathera is an appropriate treatment option.

Lutathera is an investigational therapy and is not approved for any indication in any market.

About Lutathera and NETTER-1

Lutathera (or ¹⁷⁷Lu-DOTATATE) is a Lu-177-labeled somatostatin analogue peptide currently under development for the treatment of gastro entero pancreatic neuroendocrine 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 III development in its pivotal NETTER-1 study, Lutathera is the most advanced candidate in development for PRRT.

Lutathera's NETTER-1 study is the first Phase 3 international, multi-center, randomized, controlled trial evaluating ¹⁷⁷Lu-DOTA0-Tyr3-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, safety, and health-related quality of life.

The Phase 3 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% in 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.

Within the current evaluable patient dataset for tumor responses (n=201), 18 patients (18%) reported complete and partial responses (CR+PR) in the Lutathera group versus 3 (3%) in the Octreotide LAR 60 mg group (p=0.0008). 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 objective radiographic response rate was 18% with Lutathera and 3% with control (p=0.0008). Interim OS analysis (13 deaths in Lutathera group and 22 in control group; p=0.019) strongly suggests an improvement in OS. Updated results are related to Lutathera safety profile. Only 5% of the patients (6 patients) experienced Lutathera dose modifying toxicity. Adverse events grade 3 or 4 neutropenia, thrombocytopenia and lymphopenia occurred in 1%, 2% and 9% of the patients in Lutathera arm vs. none in the control group.

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 for Lutathera in the NETTER-1 study were consistent with the results of Lutathera's previous Phase I-II study, with Lutathera demonstrating a favorable safety profile.

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 18 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and currently has over 430 employees in 13 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, U.S. and Canada). In 2014 AAA reported sales of €69.9 million (+29.9% vs. 2013). 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, 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.

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