# PRESS RELEASE

# Advanced Accelerator Applications reports 26.8% sales growth in 2015 and continues to show significant clinical progress across both therapeutic and diagnostic platforms

## *Company announces completed submission of Lutathera NDA and MAA to FDA and EMA respectively*

**2015 Highlights**

- Reported a year-on-year increase in sales of 26.8% for the full-year and 14% for the fourth quarter of 2015.
- Completed an IPO and listed on the Nasdaq Global Select Market under the ticker "AAAP"
- Presented favorable results of pivotal Phase III trial, NETTER-1, for Lutathera for the treatment of neuroendocrine tumors
- Received Fast Track designation from the FDA for Lutathera for the treatment of patients with inoperable, progressive, well-differentiated, Octreoscan-positive carcinoid tumors of the midgut
- Submitted a New Drug Application (NDA) with the US Food and Drug Administration (FDA) for Ga-68 DOTATATE (Somakit-TATE) and was granted priority designation and submitted a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for Ga-68 DOTATOC (Somakit-TOC)
- Enrolled the first patient in a Phase I/II clinical trial for its key diagnostic candidate Annexin V-128 in rheumatoid arthritis and ankylosing spondylitis.

April 29, 2016, Saint-Genis-Pouilly, France - Advanced Accelerator Applications S.A. (NASDAQ:AAAP) ("AAA" or "the Company"), an international specialist in Molecular Nuclear Medicine (MNM), today announced its fourth quarter and full year 2015 financial results.

Mr. Stefano Buono, AAA's CEO, commented, "*2015 was a pivotal year for AAA. We continued our trend of significant sales growth, and the year was marked by the completion of two key milestones, namely: the completion of our IPO and simultaneous listing on the Nasdaq under the ticker "AAAP" and the announcement of favorable results from the pivotal Phase 3 NETTER-1 trial evaluating our lead therapeutic candidate, Lutathera. We also submitted an NDA and MAA in the U.S. and Europe, respectively, for Somakit, which could be the ideal in-vivo companion diagnostic for Lutathera.*"

Mr. Buono concluded, "*In 2016, we have already achieved several key milestones to advance the company forward and support our future success. With our Lutathera filing now complete and submitted to the FDA and the EMA and the anticipated Somakit approval in both the US and Europe, we look forward to reporting our commercial developments gearing up towards the launch of both products.*"

**Q4 and Full-Year 2015 Financial Results**

Total sales for the Q4 2015 were €22.48 million (USD[(1)] 24.41 million), a 14% year-on-year increase compared to €19.7 million (USD[(1)] 21.4 million) in Q4 2014. For the year ended 31 December 2015

total sales were €88.6 million (USD[(1)] 96.2 million), a 26.8% year-on-year increase compared to €69.9 million (USD[(1)] 75.9 million) for the full year 2014.

Operating loss for the full year ended 31 December 2015 was €9.5 million (USD[(1)] 10.4 million), compared to a loss of €8.6 million (USD[(1)] 9.3 million) for the full year 2014.

For the year ended 31 December 2015, the Company reported a net loss of €17.0 million (USD[(1)] 18.5 million), compared to €10.8 million (USD[(1)] 11.7 million) for the full year 2014.

For the full year ended 31 December 2015, adjusted EBITDA (see corresponding reconciliation exhibit below) was €1.8 million (USD[(1)] 1.9 million), a 47% year-on-year decrease compared to €3.4 million (USD[(1)] 3.7 million) for the full year 2014.

*(1) Translated solely for convenience into USD at the noon buying rate of €1.00=US$1.0859 at December 31, 2015.*

**Lutathera Update**

The Lutathera Phase 3 study NETTER-1 trial showed 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 in patients with progressive midgut carcinoid tumors. The study demonstrated a favorable safety profile of the treatment, consistent with the experience that has been cumulated so far in academic institutions.

The NETTER-1 data was first presented in September 2015 at ESMO and further results were presented in more recent congresses such as ASCO GI, NANETS and ENETS.

Today AAA announced that the company had completed its rolling NDA submission to the FDA and that it had also recently submitted a Lutathera MAA to the EMA. In these filings AAA has asked for Priority Review from the FDA and Accelerated Assessment from the EMA. Accelerated Assessment from the EMA has recently been granted.

**Conference Call**

At 11:00 a.m. Eastern Time today, AAA's management will host a conference call and a simultaneous webcast to discuss results from its full year 2015 as well as provide 2016 guidance and a general business update. To access the webcast live via the internet, please connect to the company's website at www.adacap.com 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to hear the webcast. Alternatively, please call 1-877-751-5015 (U.S.) or 1-615-247-0178 (international) and dial the audience passcode 96896214 to access the call.

A replay of the webcast will be archived on the company's website for one year.

---

**About Lutathera and NETTER-1**

Lutathera (or $^{177}$Lu-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 and in the US under an Expanded Access Program (EAP).

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: 0.13-0.33; $p<0.0001$). 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.

Complete and partial responses (CR+PR) were reported in 18 patients (18%) 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 14 in the Lutathera group and 26 in the Octreotide LAR 60 mg group ($p=0.0043$ at interim analysis), which suggests an improvement in OS. 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 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 18 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 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, like 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.

**Reconciliation of adjusted EBITDA to net income (loss) for the year from continuing operations**

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2015 | | 2014 | 2013 | 2012 |
| | US$[(1)] | Euro | Euro | Euro | |
| | (US Dollars and Euros in thousands) | | | | |
| Net profit/(loss) for the period | (18,461) | (17,001) | (10,803) | (12,781) | (20,504) |
| **Adjustments:** | | | | | |
| Finance income (including changes in fair value of contingent consideration) | (1,255) | (1,156) | (396) | (387) | (232) |
| Finance costs (including changes in fair value of contingent consideration) | 8,526 | 7,852 | 2,196 | 10,155 | 16,512 |
| Income taxes | 837 | 771 | 404 | 1,157 | 536 |
| Depreciation and amortization | 12,294 | 11,321 | 11,993 | 9,545 | 6,495 |
| **Adjusted EBITDA** | **1,941** | **1,787** | **3,394** | **7,689** | **2,807** |
| Sales | 96,227 | 88,615 | 69,865 | 53,806 | 40,834 |
| **Adjusted EBITDA margin** | **2.0%** | **2.0%** | **4.9%** | **14.3%** | **6.9%** |

*(1) Translated solely for convenience into dollars at the noon buying rate of €1.00=US$1.0859 at December 31, 2015.*

**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.

***Contacts***


***AAA Media Relations***

Laetitia Defaye
Head of Corporate Communications
laetitia.defaye@adacap.com
Tel: +33 (0)6 86 65 73 52

Véronique Mermet
Communications Officer
veronique.mermet@adacap.com
Tel: +33 (0)4 50 99 30 70

***AAA Investor Relations***

Jordan Silverstein
Director of Investor Relations
jordan.silverstein@adacap.com
Tel: + 1-212-235-2394

**Media enquiries**

**FTI Consulting**
Shauna Elkin
shauna.elkin@fticonsulting.com
Tel: +1-212-850-5613

**Axess Public Relations (Italy)**
Dario Francolino
dario.francolino@axesspr.com
Tel: +39 3488818029

## CONSOLIDATED STATEMENTS OF INCOME

### FOR THE YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013

| In € thousands | 12.31.2015 | 12.31.2014 | 12.31.2013 |
|---|---|---|---|
| Sales | 88,615 | 69,865 | 53,806 |
| Raw materials and consumables used | (18,335) | (14,597) | (9,185) |
| Personnel costs | (29,520) | (21,089) | (16,265) |
| Other operating expenses | (44,447) | (35,015) | (24,644) |
| Other operating income | 5,474 | 4,230 | 3,977 |
| Depreciation and amortization | (11,321) | (11,993) | (9,545) |
| **Operating loss** | **(9,534)** | **(8,599)** | **(1,856)** |
| Finance income (including changes in fair value of contingent consideration) | 1,156 | 396 | 387 |
| Finance costs (including changes in fair value of contingent consideration) | (7,852) | (2,196) | (10,155) |
| **Net finance loss** | **(6,696)** | **(1,800)** | **(9,768)** |
| **Loss before income taxes** | **(16,230)** | **(10,399)** | **(11,624)** |
| **Income taxes** | **(771)** | **(404)** | **(1,157)** |
| **Loss for the year** | **(17,001)** | **(10,803)** | **(12,781)** |
| **Attributable to:** | | | |
| Owners of the Company | (17,001) | (9,499) | (12,152) |
| Non-controlling interests | - | (1,304) | (629) |
| **Loss per share** | | | |
| Basic (€ per share) | (0.25) | (0.15) | (0.22) |
| Diluted (€ per share) | (0.25) | (0.15) | (0.22) |

# CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

## YEAR ENDED DECEMBER 31, 2015, 2014 AND 2013

| In € thousands | 12.31.2015 | 12.31.2014 | 12.31.2013 |
|---|---|---|---|
| **Loss for the year** | **(17,001)** | **(10,803)** | **(12,781)** |
| **Other comprehensive income / (expense):** | | | |
| **Items that may be reclassified subsequently to profit or loss** | | | |
| Exchange differences on translating foreign operations | 3,239 | 2,053 | (125) |
| **Items that will never be reclassified subsequently to profit or loss** | | | |
| Remeasurement of defined benefit liability | (559) | (61) | 17 |
| **Other comprehensive income / (expense) net of tax (1)** | 2,680 | 1,992 | (108) |
| **Total comprehensive loss for the year** | **(14,321)** | **(8,811)** | **(12,889)** |
| **Total comprehensive loss attributable to:** | | | |
| Owners of the Company | (14,321) | (7,776) | (12,061) |
| Non-controlling interests | - | (1,035) | (828) |

(1) Tax effect of € 176 thousand at December 31, 2015, € 31 thousand at December 31, 2014 and € (5) thousand at December 31, 2013.

## CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

### AT DECEMBER 31, 2015, 2014 AND 2013

| ASSETS (In € thousands) | 12.31.2015 | 12.31.2014 | 12.31.2013 |
|---|---|---|---|
| **Non-current assets** | **112,687** | **107,842** | **103,449** |
| Goodwill | 22,662 | 21,377 | 21,252 |
| Other intangible assets | 31,884 | 32,410 | 30,581 |
| Property, plant and equipment | 56,332 | 51,779 | 49,280 |
| Financial assets | 1,512 | 1,959 | 2,336 |
| Deferred tax assets | 297 | 317 | - |
| **Current assets** | **161,416** | **78,672** | **40,028** |
| Inventories | 4,105 | 3,363 | 2,278 |
| Trade and other receivables | 23,625 | 20,053 | 16,143 |
| Other current assets | 14,800 | 10,160 | 7,997 |
| Cash and cash equivalents | 118,886 | 45,096 | 13,610 |
| **TOTAL ASSETS** | **274,103** | **186,514** | **143,477** |

| EQUITY AND LIABILITIES (In € thousands) | 12.31.2015 | 12.31.2014 | 12.31.2013 |
|---|---|---|---|
| **Equity attributable to owners of the Company** | **169,754** | **85,187** | **55,723** |
| Share capital | 7,856 | 6,323 | 5,415 |
| Share premium | 213,982 | 118,421 | 76,594 |
| Reserves and retained earnings | (35,083) | (30,058) | (14,134) |
| Net loss for the year | (17,001) | (9,499) | (12,152) |
| **Non-controlling interests** | **-** | **-** | **1,360** |
| **Total equity** | **169,754** | **85,187** | **57,083** |
| **Non-current liabilities** | **68,341** | **70,709** | **62,052** |
| Non-current provisions | 9,968 | 8,011 | 6,029 |
| Non-current financial liabilities | 16,205 | 20,971 | 20,359 |
| Deferred tax liabilities | 2,804 | 4,460 | 4,187 |
| Other non-current liabilities | 39,364 | 37,267 | 31,477 |
| **Current liabilities** | **36,008** | **30,618** | **24,342** |
| Current provisions | - | 128 | 115 |
| Current financial liabilities | 5,560 | 5,915 | 5,458 |
| Trade and other payables | 14,710 | 12,156 | 9,218 |
| Other current liabilities | 15,738 | 12,419 | 9,551 |
| **Total liabilities** | **104,349** | **101,327** | **86,394** |
| **TOTAL EQUITY AND LIABILITIES** | **274,103** | **186,514** | **143,477** |

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

## YEAR ENDED DECEMBER 31, 2015

| | Attributable to the Company | | | | | |
|---|---|---|---|---|---|---|
| **In € thousands** | **Share capital** | **Share premium** | **Translation reserve** | **Net Income / (loss) for the year** | **Group reserves** | **Total** |
| **At January 1, 2015** | **6,323** | **118,421** | **1,620** | **(9,499)** | **(31,678)** | **85,187** |
| **Comprehensive income for the year** | | | | | | |
| Loss for the year | - | - | - | (17,001) | - | (17,001) |
| Other comprehensive income / (loss) for the year | - | - | 3,239 | - | (559) | 2,680 |
| **Total comprehensive income** | **-** | **-** | **3,239** | **(17,001)** | **(559)** | **(14,321)** |
| **Transactions with owners of the Company** | | | | | | |
| Issue of ordinary shares | 1,533 | 102,209 | - | - | - | 103,742 |
| Share issue costs | - | (6,648) | - | - | - | (6,648) |
| Appropriation of 2014 net loss | - | - | - | 9,499 | (9,499) | - |
| Equity-settled share-based payments | - | - | - | - | 1,794 | 1,794 |
| **Total transactions with owners of the Company** | **1,533** | **95,561** | **-** | **9,499** | **(7,705)** | **98,888** |
| **At December 31, 2015** | **7,856** | **213,982** | **4,859** | **(17,001)** | **(39,942)** | **169,754** |

## CONSOLIDATED STATEMENTS OF CASH FLOWS
### YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013

| In € thousands | 12.31.2015 | 12.31.2014 | 12.31.2013 |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| Net loss for the year | (17,001) | (10,803) | (12,781) |
| Adjustments: | | | |
| Depreciation, amortization and impairment of non-current assets | 11,321 | 11,993 | 9,545 |
| Share based payment expense | 1,794 | 2,278 | 2,281 |
| Loss / (Gain) on disposal of property, plant and equipment | 367 | 10 | (62) |
| Financial result | 6,696 | 1,800 | 9,768 |
| Income tax expense | 771 | 404 | 1,158 |
| Negative Goodwill recognized in other operating income | - | 94 | - |
| **Subtotal** | **3,948** | **5,776** | **9,909** |
| Increase in inventories | (742) | (1,085) | (445) |
| Increase in trade receivables | (3,572) | (3,910) | (606) |
| Increase / (decrease) in trade payables | 156 | 2,938 | (639) |
| Change in other receivables and payables | (1,436) | (58) | (442) |
| Increase in provisions | 752 | 153 | 253 |
| **Change in working capital** | **(4,842)** | **(1,962)** | **(1,879)** |
| Income tax paid | (2,902) | (1,451) | (663) |
| **Net cash used in operating activities** | **(3,796)** | **2,363** | **7,367** |
| **Cash flows from investing activities** | | | |
| Acquisition of property, plant and equipment | (11,286) | (8,860) | (9,289) |
| Acquisition of intangible assets | (910) | (394) | (634) |
| Acquisition of financial assets | (99) | (745) | (116) |
| Interest received | 200 | 265 | 379 |
| Repayment on financial assets | 278 | 1,122 | - |
| Proceeds from disposal of property, plant and equipment | 118 | 113 | 130 |
| Proceeds from government grants | - | 623 | - |
| Acquisition of subsidiaries, net of cash acquired | - | (561) | (1,395) |
| **Net cash used in investing activities** | **(11,699)** | **(8,437)** | **(10,925)** |
| **Net cash from financing activities** | | | |
| Payment of deferred and contingent liabilities to former owners of acquired subsidiaries | (1,494) | (1,884) | - |
| Issuance of share capital | 97,094 | 40,666 | 4,820 |
| Transactions with shareholders | - | (1,464) | - |
| Proceeds from borrowings | 210 | 8,041 | 3,496 |
| Repayment of borrowings | (4,852) | (7,016) | (4,058) |
| Interests paid | (827) | (906) | (1,029) |
| **Net cash from financing activities** | **90,131** | **37,437** | **3,229** |
| **Net increase / (decrease) in cash and cash equivalents** | **74,636** | **31,363** | **(329)** |
| Cash and cash equivalents at the beginning of the year | 45,096 | 13,611 | 13,947 |
| Effect of exchange rate changes on cash and cash equivalents | (846) | 122 | (7) |
| **Cash and cash equivalents at the end of the year** | **118,886** | **45,096** | **13,611** |