PRESS RELEASE

Advanced Accelerator Applications Receives Positive CHMP Opinion for LysaKare® for Reduction of Kidney Exposure to Radiation During Peptide Receptor Radionuclide Therapy with Lutetium (^{177}Lu) Oxodotreotide (Lutathera®)

Saint-Genis-Pouilly, France, June 5, 2019 – Advanced Accelerator Applications S.A. (AAA), a Novartis company, today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization of LysaKare® 25g/25g (arginine hydrochloride/lysine hydrochloride) solution for reduction of renal (kidney) radiation exposure during peptide-receptor radionuclide therapy (PRRT) with lutetium (^{177}Lu) oxodotreotide (Lutathera®) in adults. If approved by the European Commission, LysaKare would be the first commercially registered arginine hydrochloride/lysine hydrochloride amino acid solution of this concentration available in Europe.

Lutathera, indicated for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adults, was the first PRRT ever approved by the European Commission in September 2017. Lutathera PRRT includes a targeting molecule attached to a radioactive component. The kidneys are the primary dose limiting organs for PRRT with Lutathera, and a lysine and arginine amino acid solution is co-administered to patients to reduce renal uptake and retention of Lutathera, thus reducing renal radiation exposure by approximately 50% and mitigating the risk for radiation-induced renal injury.

“LysaKare was developed to enhance patient safety and comfort during PRRT with Lutathera,” noted Germo Gericke, M.D., Head of Research and Development for Advanced Accelerator Applications. “This positive opinion by the CHMP supports our commitment to providing the best and most comprehensive care possible.”

Clinical efficacy and safety for arginine and lysine are based on published literature of studies using solutions with the same arginine and lysine content as LysaKare. There are limited data on the safety profile of arginine and lysine solution for infusion without concomitant administration of PRRT, which also includes the use of anti-emetics as pre-medication and often the concomitant use of short acting somatostatin analogues. The main adverse reactions which are related mainly to the amino acid solution are nausea (approximately 25%), vomiting (approximately 10%) and hyperkalaemia. These adverse reactions are mostly mild to moderate.

The European Commission (EC) takes binding decisions on the authorization of medicines valid throughout the EU. It bases its decisions on scientific assessments by the CHMP, ensuring that medicines comply with high quality, safety and efficacy standards. If approved by the EC, the centralized marketing authorization will be valid in the 28 countries that are members of the EU. Norway, Iceland and Liechtenstein, as members of the European Economic Area (EEA), will take corresponding decisions based on the EC's recommendation.

The European Commission will review the CHMP opinion and is expected to deliver its final decision within three months. The decision will be applicable to all 28 European Union member states plus Iceland, Norway and Liechtenstein.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Advanced Accelerator Applications S.A.

Advanced Accelerator Applications, a Novartis company, is an innovative radiopharmaceutical company developing, producing and commercializing radioligand theragnostics (pairings of therapeutic and diagnostic drugs based on the same targeting molecule) for oncology. AAA is an established leader in radiopharmaceuticals for Positron Emission tomography (PET) and Single-Photon Emission Computed Tomography (SPECT) diagnostic imaging. For more information, please visit: https://www.adacap.com/.

Media Relations Contacts:

Advanced Accelerator Applications
Rachel Levine
+1 917 375 2935 (mobile)
Rachel.Levine@adacap.com

Novartis Oncology
Julie Masow
+1 862 579 8456 (mobile)
Julie.Masow@novartis.com