

## PRESS RELEASE

# Advanced Accelerator Applications Announces Health Canada Approval of NETSPOT<sup>®</sup> Diagnostic Imaging Agent Kit to Detect Neuroendocrine Tumours

- NETSPOT<sup>®</sup> is the first and only kit for the preparation of gallium (<sup>68</sup>Ga) oxodotreotide injection for diagnostic imaging of neuroendocrine tumors
- The safety and clinical benefit of NETSPOT<sup>®</sup> was based on a systematic review of the scientific literature on the use of gallium (68Ga) oxodotreotide as a radiodiagnostic agent in the management of patients with neuroendocrine tumours (NETs)
- Despite vast improvements in diagnostic techniques, neuroendocrine tumours remain one of the most elusive cancers to diagnose<sup>1</sup>

**Saint-Genis-Pouilly, France, April 7**, **2020** - **Advanced Accelerator Applications S.A. (AAA)**, a Novartis company, today announced that Health Canada has approved **NETSPOT**<sup>®</sup> (kit for the preparation of gallium (<sup>68</sup>Ga) oxodotreotide injection) for the evaluation of neuroendocrine tumours ("NETs"). NETSPOT<sup>®</sup> is the first and only kit for the preparation of gallium (<sup>68</sup>Ga) oxodotreotide injection, a radioactive diagnostic agent for *positron emission tomography* (PET) imaging of somatostatin receptor overexpression in adult patients with confirmed or suspected somatostatin receptor positive neuroendocrine tumors (NETs) for localizing primary tumours and their metastases.

This innovative technology supports a more accurate diagnosis and staging of NETs and a more tailored treatment plan. Following this approval, NETSPOT<sup>®</sup> will be available in Canada.

"The diagnosis of neuroendocrine tumours is often delayed by years, because the symptoms associated with NETs are also typical for dozens of other diseases and conditions," said Dr. Stephan Probst, Chief of Nuclear Medicine, Jewish General Hospital in Montreal. "NETSPOT<sup>®</sup> represents an advance in diagnostic imaging that provides us with higher quality images, allowing for enhanced decision making when it comes to choosing amongst therapeutic options, potentially resulting in better patient management."

The availability of NETSPOT<sup>®</sup> in Canada is expected to benefit NETs patients by reducing their exposure to radiation and alleviating the discomfort they experience by lowering the amount of time to conduct the scan.<sup>2</sup>

"We applaud Health Canada in approving the NETSPOT<sup>®</sup> kit and this innovative technology as an important adjunct to helping physicians identify the precise location and extent of the tumour and plan staging and

the best course of treatment," stated Jackie Herman, President & Director of Treatment Access & Health Policy of CNETS Canada.

"We are excited about the approval of NETSPOT<sup>®</sup> as it offers physicians additional insight into the patient's disease burden, enabling them to optimize treatment and care. In addition, the approval reflects our ongoing commitment to the Canadian neuroendocrine tumour community, including patients, their families and the healthcare professionals dedicated to their care," said Lyndal Walker, General Manager of Advanced Accelerator Applications in Canada.

## About Neuroendocrine Tumours (NETs)

Neuroendocrine tumours, also known as NETs, are a group of tumours that can originate in the neuroendocrine cells of many different organs such as the stomach, intestines, pancreas, lungs and other locations. NETs can remain clinically silent for years thus delaying diagnosis. These cancers are the second most common type of gastrointestinal malignancy and NETs are now the fastest growing class of cancers worldwide, accounting for approximately 2% of cancers. The increased incidence refutes the reference to these cancers as rare.<sup>3</sup> The prevalence of neuroendocrine tumours (NET) is estimated at 35 per 100,000 but may be considerably higher if undiagnosed tumours are included. Alarmingly, of the approximately 12,000-15,000 Canadians with NETs, only 10% have a complete and accurate diagnosis.<sup>4</sup> Because NETs can be misdiagnosed or where there is a delay in diagnosis, the tumour is likely to spread to other parts of the body.<sup>5</sup> This is why faster, accurate diagnosis is essential to offering patients the best possible outcome.

## 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," "may," "could," "would," "expect," "anticipate," "seek," "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, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19: safety, guality, data integrity 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, S.A. (AAA), a Novartis company, is developing targeted radioligand therapies and precision imaging radioligands for oncology indications. We are committed to transforming

patients' lives by leading innovation in nuclear medicine. AAA has a legacy as a leader in radiopharmaceutical drugs for Positron Emission Tomography (PET) and Single-Photon Emission Computed Tomography (SPECT) diagnostic imaging. For more information, please visit: <a href="https://www.adacap.com">https://www.adacap.com</a>.

#### References

1. CNETS Canada, Obtaining a Neuroendocrine Tumour Diagnosis, <u>https://cnetscanada.org/patients-caregivers/net-diagnosis-and-treatments/symptoms-and-diagnosis/</u>

2. CNETS Canada, Ga68 PET Scan, <u>https://cnetscanada.org/patients-caregivers/net-diagnosis-and-treatments/symptoms-and-diagnosis/scans/ga68-scan/</u>

- 3. CNETS Canada, NET One Page Facts, https://cnetscanada.org/patients-caregivers/resources/489-2/
- 4. CNETS Canada, https://cnetscanada.org/patients-caregivers/resources/489-2/
- 5. US National Library of Medicine, National Institutes of Health

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6240263/

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