Health Canada approves PLUVICTO™ as first targeted radioligand therapy for progressive PSMA positive metastatic castration-resistant prostate cancer

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- *Novel mechanism of action of PLUVICTO™ binds to target PSMA-positive cancer cells, delivering radiation treatment directly to those cells and nearby cells*[1]
- *Prostate cancer is the most diagnosed cancer among men*[2]*; new approaches are needed to treat patients with advanced forms of the disease*
- *Advanced Accelerator Applications is committed to reimagining medicine and cancer care with targeted radioligand therapy, a precision cancer treatment*

Mississauga, Ontario, September 7, 2022 - Advanced Accelerator Applications Canada Inc. is pleased to announce that Health Canada has approved PLUVICTO™ (lutetium (^{177}Lu) vipivotide tetraxetan injection) for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have received at least one androgen receptor pathway inhibitor (ARPI) and taxane-based chemotherapy[1].

The approval of PLUVICTO™ responds to the high unmet need for new targeted treatment options to improve outcomes for patients with mCRPC that has spread to other parts of the body despite multiple treatments. According to current statistics, men with metastatic prostate cancer currently have a 3 in 10 chance of surviving five years[3].

PLUVICTO™ is the first targeted radioligand therapy (RLT) approved in Canada for eligible patients with mCRPC, a precision cancer treatment that combines a targeting compound (ligand) with a therapeutic radioisotope (a radioactive particle). Once it is administered into the bloodstream, PLUVICTO™ binds to target PSMA-positive cancer cells to deliver radiation treatment directly to those cells and nearby cells, disrupting their ability to replicate and/or triggering cell death[1].

“The approval of PLUVICTO™ is a major step forward in precision medicine for patients whose cancer has progressed to mCRPC and who have limited treatment options. They now have the chance to receive a therapy that selectively seeks out cells that express PSMA and delivers targeted radiation,” said Dr. Urban Emmenegger, Medical Oncologist at the Odette Cancer Centre of Sunnybrook Health Sciences Centre in Toronto. “This pioneering approach is an advancement in the metastatic prostate cancer setting that gives new hope to these patients who have exhausted multiple avenues of treatment.”

Prostate cancer is the most diagnosed cancer among Canadian men and is the third leading cause of cancer-related death in men in Canada[4]. PSMA is an important biomarker that is found on the surface of most prostate cancer cells and is expressed in 80% of men with prostate cancer[5]. In metastatic prostate cancer, if cells have an abundance of the PSMA biomarker, it means the cancer is PSMA positive.

“This approval has the potential to alter the treatment paradigm for patients with metastatic prostate cancer. We are proud to be at the forefront of innovative precision medicine,” said Lyndal Walker, President & General Manager, Advanced Accelerator Applications Canada Inc. “The arrival of PLUVICTO™ demonstrates our strong commitment to making a meaningful difference for the lives of patients through ongoing research and advancements in nuclear medicine and targeted radioligand therapies.”

The Health Canada approval of PLUVICTO™ is based on the results of the pivotal Phase III VISION trial which randomized patients with PSMA-positive mCRPC who received ^{177}Lu-PSMA-617 in addition to best supportive/best standard of care (BSC/BSoC) versus patients treated with BSC/BSoC alone.

The full product monograph for PLUVICTO™ can be found at https://www.adacap.com/our-products/.

About PLUVICTOTM

PLUVICTO™ (lutetium (^{177}Lu) vipivotide tetraxetan injection) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have received at least one androgen receptor pathway inhibitor (ARPI) and taxane-based chemotherapy[1]. It is a type of precision cancer treatment combining a targeting compound (ligand) with a therapeutic radioisotope (a radioactive particle)[1]. After administration into the bloodstream, PLUVICTO™ binds to target cells, including prostate cancer cells that express PSMA, a transmembrane protein[1]. Once bound, energy emissions from the radioisotope damage the target cells and nearby cells disrupting their ability to replicate and/or triggering cell death[1].

About Advanced Accelerator Applications Canada Inc.

Advanced Accelerator Applications Canada Inc. (AAA), a Novartis company, specializes in 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: https://www.adacap.com.

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Pluvicto is a trademark.

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