



PRESS RELEASE

NETSPOT™ Gallium Ga 68 Dotatate Kit Approved By FDA Using The GalliaPharm® Ge-68/Ga-68 Generator As The Source Of Gallium-68

June 2, 2016 – Advanced Accelerator Applications (AAA - The radiopharmaceutical company headquartered in SAINT-GENIS-POUILLY, France) have obtained approval from the US FDA for their diagnostic imaging NETSPOT™ Gallium Ga 68 dotatate kit. The kit will be used for the labeling of Ga-68 dotatate for injection, for the localization of somatostatin receptor positive neuroendocrine tumors in adult and pediatric patients using Positron Emission Tomography (PET).

NETSPOT™ is the first kit approved by the FDA that will utilize the improved imaging enabled by the PET emitting Ga-68, which is conveniently obtained from Eckert & Ziegler Radiopharma's GalliaPharm® Ge-68/Ga-68 generator.

This successful kit approval links the Eckert & Ziegler GalliaPharm® Ge-68/Ga-68 generator as the source of the Ga-68 in the kit's package insert (PI).

GalliaPharm® is the only Ge-68/Ga-68 generator registered as a medicinal product in several countries of the European Union. For the USA a Type II Drug Master File (DMF No. 28741) was filed with the FDA.

GalliaPharm® meets all the strict requirements of the relevant EU pharmacopoeia monograph including sterility over the entire one-year shelf-life and the Ge-68 breakthrough limit (< 0.001%). These are essential factors for the patient safety and enable the usage of the GalliaPharm® generator for kit labeling for its appropriate medicinal use for PET.

Please read the following press release:



Advanced Accelerator Applications Announces FDA Approval of NETSPOT™ (Somakit-TATE), a Kit for the Preparation of Gallium Ga 68 Dotatate for Neuroendocrine Tumor Detection

NETSPOT™ will be the new name for Somakit-TATE, a PET (Positron Emission Tomography) Diagnostic

Saint-Genis-Pouilly, France – June 2, 2016 – Advanced Accelerator Applications S.A. (NASDAQ:AAAP) (“AAA” or “the Company”), an international specialist in molecular nuclear medicine, today announced that the US Food and Drug Administration (FDA) has approved NETSPOT™ (Somakit-TATE) for the localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients. NETSPOT™ received approval following a Priority Review from the FDA.

NETSPOT™ is the new market name for Somakit-TATE (a kit for the preparation of gallium Ga 68 dotatate injection) in the US. NETSPOT™ is the first approved drug using Ga 68 as a positron emitter. Gallium Ga 68 dotatate received Orphan Drug Designation from both the FDA and European Medicines Agency (EMA) in March 2014.

Following today’s approval, NETSPOT™ will be made available to the US market as soon as possible. AAA intends to commercialize the product in the US in two forms: As a kit for reconstitution using a Ga 68 generator, and as NETSPOT™ Injection, a ready-to-use dose delivered from a local radiopharmacy in selected metropolitan areas.

NETSPOT™ is currently approved for use with the GalliaPharm Ga 68 generator from Eckert & Ziegler.

“The FDA approval of NETSPOT™ is a key milestone in our mission of improving the lives of NET patients,” said Stefano Buono, Chief Executive Officer of AAA. “NETSPOT™ has the potential to significantly improve the accuracy of NET diagnosis, while reducing radiation exposure for patients. We believe that the use of NETSPOT™ should also offer increased comfort for patients by potentially shortening a procedure that is currently performed over 24 hours or more to just a few hours.”

The estimated incidence of NETs for the combined populations of the United States and the European Union is approximately 47,300 patients/year.¹ Even though NETs have historically been considered as rare tumors (orphan disease) their incidence has grown over 500% over the last 3 decades.^{1,2,3}

About Neuro Endocrine Tumors (NETs)

Neuro Endocrine Tumors, also known as NETs, are a group of tumors originating in the neuroendocrine cells of many different organs. NETs can remain clinically silent for years delaying the diagnosis in a large number of patients. These cancers are rare but they are the second most common type of gastrointestinal malignancy and their incidence is increasing. [...]