

When time matters

Advanced Accelerator Applications (AAA), a market leader in the development of molecular nuclear medicine diagnostics and therapeutics, entrusts the shipment of LUTATHERA®*, a highly time-critical and sensitive radiopharmaceutical, to the forwarding agent PHSE and Swiss WorldCargo. From Northern Italy, via Zurich, to locations around Europe and the US in 48 hours.

Text by Silvia Cappelli

The radiopharmaceutical company AAA, which was recently acquired by Novartis, has been developing, producing and marketing innovative drugs in the area of nuclear medicine for over 15 years. One of the latest developments in the France-based company's therapeutic portfolio is "Lutathera" a prescription medicine used to treat adults with a rare cancer.

"Lutathera" is comprised of a targeting molecule which has a high affinity for a receptor over-expressed on these tumor cells and carries a radioactive isotope. Due to its small radioactive component, "Lutathera" cannot be kept in storage and must be administered to patients within 72 hours of production.

After in-depth clinical trials, the radiopharmaceutical was approved by the healthcare regulatory authorities in Europe in September 2017 and in the US a few months ago. "Lutathera" doses are delivered on a regular basis from AAA's manufacturing sites in the northern Italian regions of Piedmont and Emilia Romagna to far-flung destinations routinely and reliably.



From left: Fulvio Stolpe, Sales Executive Pharma & Food Specialist, Swiss WorldCargo Italy - Enrico De Maria, CEO, Advanced Accelerator Applications Italy, Alessandro Colasi, Head of International Department, PHSE

"Time is everything and logistics is of the essence for the effectiveness of this drug," explains Enrico de Maria, CEO of AAA Italy. "Cancer patients are scheduled for treatment at oncology centres around Europe and the US, and if the shipments do not reach them on time, the drug becomes useless." For this reason, building up effective partnerships with freight forwarders and cargo carriers specializing in pharmaceutical logistics is of vital importance."

For "Lutathera", AAA has selected a forwarding agent: PHSE, a global provider of customised logistics solutions, highly specialised in the biopharma and healthcare areas. "The col-

* (USAN: lutetium Lu 177 dotatate / INN: lutetium (177Lu) oxodotreotide)

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leagues from PHSE listened to us very patiently to understand our needs and find a customised solution together,” De Maria says. “In our partnership, we have developed an intimate understanding of each other’s business and established efficient and open communication lines which ensure the reliability of supplies to patients around the world. In particular, the experts at PHSE have acquainted themselves with the intricacies of the radiopharmaceutical business and its special constraints.”

According to Alessandro Colasi, Head of International Department at PHSE: “Air transportation is considered as the weakest link in the shipment of pharmaceuticals, so from our end it is also important that we work with a highly reputable airline which is able to offer ultra-fast transit times, and customised, care intensive solutions. In the specific case of “Lutathera”, due to the radioactive component, the highest quality standards in relation to handling dangerous goods are also a must.”

Even though the shelf life of “Lutathera” is 72 hours, shipments have to be delivered within 48 hours from production. PHSE and the Swiss WorldCargo’s Italian Sales team based in Milan were able to find a tailor-made solution for “Lutathera”. Space is blocked one week in advance. The shipments are picked up by temperature-controlled vans from PHSE’s fleet at the AAA manufacturing sites during the night and they are transported to Milan Malpensa MXP early in the morning to be loaded onto the first SWISS flights to Zurich to be further transferred onto connecting flights. “SWISS’s transfer times are unbeatable!”, Colasi comments.

In Colasi’s words: “At Swiss WorldCargo, we have always found support when facing the most difficult challenges. Their manageable size and dedication is a real advantage, they have always been able to find the best solutions for such a challenging, as well as during the development of the clinical study, showing an understanding for the ethical concerns of our business.”

“Moreover, the biotech logistics sector is increasingly oriented towards process standardisation. At PHSE we believe the CEIV Pharma Certification is an added value and the certification process is ongoing. Of course, we choose quality-oriented partners like Swiss WorldCargo which are also certified,” Colasi concludes.

Irregularities can always occur however. “It has only happened once,” De Maria remarks. “One day a “Lutathera” shipment had to be offloaded because of another shipment on board which could not be transported together with dangerous goods. Believe me, it was one of the saddest days of my life, thinking about the person who missed the chance of being treated.”

AAA

AAA has 20 production and research & development facilities which manufacture both diagnostic and therapeutic nuclear medicine products and over 650 employees in 13 countries (Belgium, Canada, France, Germany, Israel, Italy, the Netherlands, Poland, Portugal, Spain, Switzerland, the UK and the US). The company was acquired by Novartis in 2018.

More information at www.adacap.com

PHSE

PHSE is a family-owned international forwarding company headquartered in Legnano (Milan) whose aim is to create long-term relationships with its customers, providing a specialized, fast and reliable door-to-door service in the biopharma and healthcare sector. PHSE has over 250 of its own temperature-controlled vehicles (Vans, lorries and trucks) all GPS-equipped, 13 branches full GDP all over Italy and 3 branches overseas (USA-UK-Singapore). All the drivers are PHSE’s employees which guarantees the quality of service.

More information at www.phse.com

Dangerous Goods

Nuclear medicine uses very small amounts of radioactive materials (radio-pharmaceuticals or radiochemicals) to diagnose and treat diseases. Such materials can be shipped by air cargo in accordance to the IATA Dangerous Goods Regulations (DGR). Dangerous goods as defined in the IATA DGR are shipments which, owing to their chemical and/or physical characteristics, could, if uncontrolled, adversely affect the safety of the passengers, crew and/or aircraft on which they are carried.

SWISS’s compliance with the current IATA DGR, which are revised every year, is mandatory.

Therefore, all SWISS facilities worldwide have to be inspected at least once a year. Swiss WorldCargo’s Processes & Policies unit is responsible for the planning, coordination and performance of such inspections, for all associated record-keeping and for planning any actions or improvements required. All staff involved in handling dangerous goods must undergo a 5-day training course. One day is entirely dedicated to radioactive materials.