PRESS RELEASE:

[^18F]FDG Dual radiotracer approved by FDA

Trasis and Shertech Laboratories, received FDA approval of the[^18F]FDG Dual process on AllinOne synthesizers.

Trasis and Shertech Laboratories “hand to hand” work was recently rewarded with approval of a supplemental abbreviated New Drug Application and thus receiving a Marketing Authorization from the U.S. Food and Drug Administration for the[^18F]FDG Dual process on AllinOne modules.

This regulatory approval will increase the U.S. market interest for this novel method of[^18F]FDG production allowing the preparation of two consecutive productions of[^18F]FDG on the “AllinOne” automated synthesizer using only one “Cassette” and one “Reagent kit”. Load once, run twice!

[^18F]FDG Dual is used in PET for diagnosing, staging and monitoring treatment of cancers, particularly in Hodgkin’s disease, non-Hodgkin’s lymphoma, colorectal cancer, breast cancer, melanoma and lung cancer.

This process can operate on any AllinOne model. It is now available for commercial use in the USA

Gauthier Philippart, Trasis CEO said: “We are very happy for receiving this approval. This endorses the fact that Trasis equipment and process are designed to fit all steps of the drug development from the R&D stage to the production level. We want to thank our partner (Shertech) for its reliability and its efficiency during all the regulatory process.”

Richard Sheriff, R.Ph. Shertech President/CEO said: “It took a product demonstration at the SNMMI meeting and a challenge from Gauthier to have the AllinOne synthesis platform be the first approved for use under a US based PET ANDA. We met the challenge and could not be more pleased with the performance of this unit and the potential of multi-product synthesis for our customers.”

Jean-Luc Morelle, Trasis CEO said: “It has been very rewarding to have a partner like Shertech taking advantage of new technologies to improve their operations. We look forward to continuing our relationship with Shertech to drive innovation through the industry. With increasing pressures on cost and productivity, the[^18F]FDG Dual exemplifies the commitment that Trasis has made to insure the success of our clients.”

James T. Davis, RPh Shertech Vice President Quality\R&D said: “The AllinOne unit offers excellent yields of 75-80% which has greatly improved our efficiency. The footprint of the unit fits the standard industry architecture and was easily installed. The unit along with Trasis research and development provides a robust selection of future products. We at Shertech look forward to a bright business relationship with Trasis.”

Product availability:
Trasis provides all the necessary components to manufacture the[^18F]FDG Dual within required conditions.
Performances

<table>
<thead>
<tr>
<th>Performance</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Cassette and reagents set up time</td>
<td>&lt; 1 min</td>
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<tr>
<td>Synthesis time</td>
<td>26 min</td>
</tr>
<tr>
<td>Typical production yield</td>
<td>70 ± 4% non decay corrected</td>
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<tr>
<td>Radiochemical purity</td>
<td>≥ 98%</td>
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About Shertech:

Since 1992, Shertech has been providing low energy radiopharmaceuticals to the Carolinas. Over 90 hospitals and outpatient centers are supported by our regional network of nuclear pharmacies. Through our partnership and affiliation with our customers, Shertech has expanded our deliverables past radiopharmaceuticals to include radiation safety services, clinical consultation, hazardous waste management and specialty ancillary supplies. A cyclotron facility doing business as Shertech Laboratories opened in 2006 to provide Positron Emission Tomography (PET) radiopharmaceuticals and services so that area physicians could more effectively manage patient disease with this advanced imaging technology. This facility is registered as a drug manufacturing site with the US FDA and is compliant with cGMP regulations.

For more information visit [www.shertechpharmacy.com](http://www.shertechpharmacy.com)

About Trasis:

At Trasis our primary focus is allowing the medical community to access new radiolabeled therapeutic and diagnostic substances easier and faster. To this end, we design, manufacture, sell and support high performance synthesizers, dose preparation equipment, their shielding and accessories. We also develop customized synthetic methods and instruments. We can provide GMP Active Pharmaceutical Ingredients (API) and assist our customers with their regulatory affairs. Our proven radiopharmaceutical expertise, coupled with our high end instruments allow us to provide fully integrated solutions for an effective tracer production and faster transition from drug development to marketing authorization.

**Trasis US representative:**
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Meet us at SNMMI - Booth #1002