

PRESS RELEASE:

Trasis leads the way on Fibroblast Activation Protein Inhibitor [¹⁸F]AIF-FAPI-74 radiotracer production

Liège, Belgium, 18 May 2021 – Trasis, a leading manufacturer of instruments and consumables for the preparation of radiopharmaceuticals, is thrilled to announce its latest process development with the [¹⁸F]AIF-FAPI74 radiotracer, a Sofie Co. proprietary multicancer PET tracer.

The emergence of tracers targeting Fibroblast Activation Protein (FAP) which exhibit low uptake in normal tissues and high uptake in many cancers, named FAP Inhibitors (FAPIs), are believed to have the potential for widespread applicability as a diagnostic tracer^{1 2}.

Featuring unmatched yields at large production scale, the innovative process developed by Trasis will bring [¹⁸F]AIF-FAPI-74 to the next level.

FAP is an appealing target for the development of new radiotracers to improve cancer diagnosis with positron emission tomography imaging (PET). Such tracers, called FAPIs, were initially developed with gallium-68, and have shown promising diagnostic use in 28 different types of cancer.¹ Nevertheless, the inherent limitations of gallium-68 (short half-life, lower image resolution and production scale) prompted the development of fluorine-18 labelled analogues. [¹⁸F]AIF-FAPI-74, with the added benefit of ¹⁸F, retains the properties of the ⁶⁸Ga version.³

Collaboration with Sofie Co.

In this context, Sofie Co., exclusive licensee of several FAPI compounds, established a collaboration with Trasis for the GMP production of [¹⁸F]AIF-FAPI-74. The result of this collaboration is a reliable, high-yield and scalable automated process suitable for the cGMP manufacturing of [¹⁸F]AIF-FAPI-74. The end product exhibits excellent stability over time (up to 10h), allowing for production in large quantities and subsequent shipment to distant sites.

¹ ⁶⁸Ga-FAPI PET/CT: Tracer Uptake in 28 Different Kinds of Cancer. *Journal of Nuclear Medicine*, 2019; 60 (6): 801

² state-of-the-Art: FAPI PET/CT-Will it end the hegemony of FDG in oncology? *Journal of Nuclear Medicine*, 2021, 62 (3): 296

³ FAPI-74 PET/CT Using Either ¹⁸F-AIF or Cold-Kit ⁶⁸Ga Labeling: Biodistribution, Radiation Dosimetry, and Tumor Delineation in Lung Cancer Patients, *Journal of Nuclear Medicine*, 2021, 62 (2): 201



KEY RESULTS

- ▶ Initial [¹⁸F]fluoride average load of 152 GBq;
- ▶ High radiochemical yields: 50±5% non-decay-corrected
- ▶ Radiochemical purity (RCP): 96 ± 0.5% at End of Synthesis (EOS)
- ▶ Stability: up to 10 hours post EOS with compliant QC (pH, endotoxin, residual solvent, RCP)
- ▶ Easy quality control: no complex residual solvent/impurity analysis
- ▶ Compatible with miniAllinOne and AllinOne Trasis synthesizers

Conclusion

Drawing on its extensive experience in fluorine chemistry, Trasis has developed and automated a process for radiosynthesis of [¹⁸F]AlF-FAPI-74 that complies to production expectations. This process has been demonstrated at high activity in close collaboration with Sofie Co.

This breakthrough will pave the way to a wider use and global distribution of this promising tracer, ultimately improving patient access.

This achievement also demonstrates the commitment and expertise of Trasis in this recent and growing field of radiotracers labelled with [¹⁸F]AlF.

About Trasis

Trasis is a Belgian company specialized in the development and manufacturing of innovative and high-quality radiopharmaceutical equipment. Trasis focuses on helping the medical community access new radio-labelled therapeutic and diagnostic substances easily and faster. Trasis designs, manufactures, and sells state-of-the-art solutions addressing the evolving needs of the radiopharmaceutical industry, including synthesizers, radiopharmaceutical quality control, dose preparation and dispensing equipment, their consumables and accessories, as well as related maintenance, quality and regulatory services.

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