SOFIE and GE HealthCare Enter Licensing Agreement to Develop FAP PET Radiotracers

October 11, 2023

- A global licensing agreement has been signed for the development and commercialization of SOFIE's two investigational Gallium-68 and Fluorine-18 Fibroblast Activation Protein Inhibitors (FAPI) radiopharmaceutical diagnostics - [^{68}Ga]FAPI-46 and outside-U.S. rights for [^{18}F]FAPI-74
- FAP is highly expressed in cancer associated fibroblasts (CAF), which supports the growth and spread of cancerous cells across many tumor types[1]
- SOFIE will maintain clinical development and commercialization rights for [^{18}F]FAPI-74 in the U.S. building on momentum from its FAPI Global Outreach Program

CHALFONT ST GILES, England--(BUSINESS WIRE)--Oct. 11, 2023-- GE HealthCare today announced an exclusive global licensing agreement with SOFIE Biosciences (SOFIE), a Virginia, U.S.-based company, to develop, manufacture and commercialize SOFIE's Gallium-68 and Fluorine-18 labelled diagnostics targeting fibroblast activation protein (FAP). Financial terms were not disclosed. Based on this agreement, GE HealthCare will take on global rights for [^{68}Ga]FAPI-46 and outside-US rights for [^{18}F]FAPI-74, originally developed at Heidelberg University in Germany, and both currently in Phase II clinical trials in the U.S. ([^{68}Ga]FAPI-46 (NCT05262855)[2] and [^{18}F]FAPI-74 (NCT05641896)[3]). SOFIE will continue its clinical development and commercialization program with [^{18}F]FAPI-74 in the U.S.

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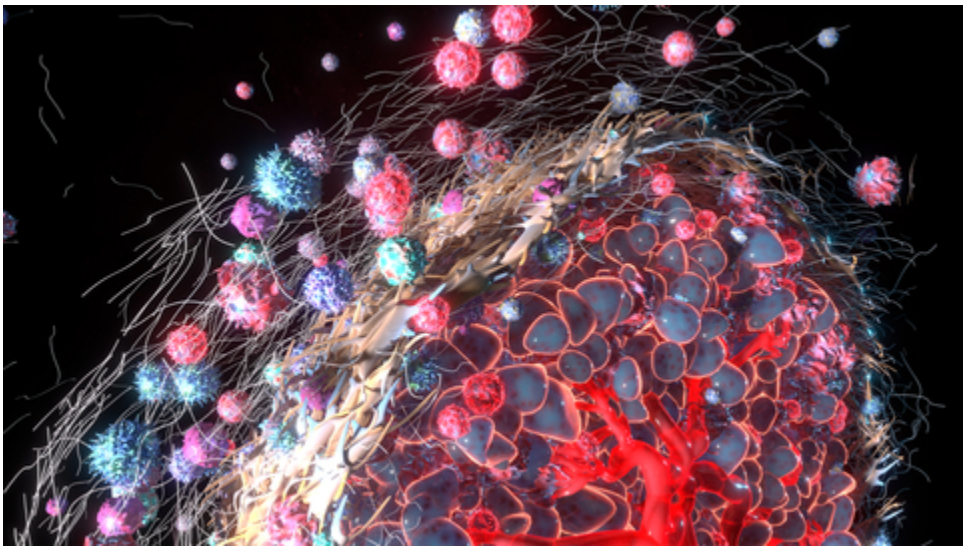

Illustrative example: cancer associated fibroblasts (CAFs) and the tumor microenvironment. (Photo: Business Wire)

FAP is an enzyme highly expressed in cancer associated fibroblasts (CAF), a key component of the tumor microenvironment which supports the growth and spread of cancerous cells. With CAF present in most tumor types including, for example, breast, pancreatic, colorectal, lung, liver and gastric, the development of FAP-targeted diagnostics holds great potential in oncology as well as other conditions including inflammation, fibrosis and arthritis[4].

Building on the momentum created by SOFIE's sponsored trials in the U.S. and FAPI Global Outreach Program which engages with 130 academic institutions in 39 countries to unlock FAPI's clinical utility, GE HealthCare aims to develop FAP imaging products through clinical trials and towards regulatory submission, and potential commercialization in various regions. SOFIE and GE HealthCare will collaborate on both the development and commercialization processes through a joint steering committee.

Usankar Thiru, Strategy & Evaluation Director with GE HealthCare's Pharmaceutical Diagnostics segment said: "Working with SOFIE to add these FAPI assets to our next generation portfolio of investigational targets is a significant milestone and aligns with our vision to expand our innovation pipeline to enable precision care for personalized treatment decision making. As a standalone company, we are keen to collaborate with companies like SOFIE in this way – bringing our size, scale and unique perspective as a developer, of both radiopharmaceuticals and the scanners needed to utilize them, to drive innovation in healthcare to benefit patients and clinicians."

Sherly Mosessian, Ph.D, SOFIE's Chief Scientific Officer, added: "The FAPI family of compounds have shown to have tremendous potential in diagnostic and companion diagnostic use in various oncologic and non-oncologic indications. I am very excited that we are collaborating with GE HealthCare, on a worldwide scale, to help jointly unlock the full promise of these products."

GE HealthCare's Pharmaceutical Diagnostics segment is a global leader in imaging agents used to support around 100 million procedures per year globally, equivalent to three patient procedures every second. Its Molecular Imaging portfolio combines established proprietary products across cardiology, neurology and oncology.

About GE HealthCare Technologies Inc.

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 100 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from diagnosis, to therapy, to monitoring. We are an $18.3 billion business with 50,000 employees working to create a world where healthcare has no limits.

Follow us on Facebook, LinkedIn, Twitter, Instagram, and Insights for the latest news, or visit our website https://www.gehealthcare.com/ for more information.

About SOFIE Biosciences (SOFIE)

SOFIE's vision is to improve patient outcomes by developing and delivering molecular diagnostics and therapeutics (theranostics). With its robust radiopharmaceutical production and distribution network, mature contract manufacturing services and high value theranostic intellectual property, SOFIE is poised to deliver on the promise of radiopharmaceuticals. For more information visit our website, https://sofie.com/ or contact us by email at info@sofie.com.

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[1] Xing, F., Saidou, J. and Watabe, K. (2010) Cancer associated fibroblasts (cafs) in tumor microenvironment, Frontiers in bioscience (Landmark edition). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2905156/ (Accessed: 28 July 2023).

[2] Study of [68Ga]FAPI-46 PET in Patients With Pancreatic Ductal Carcinoma (FAPI-46 PDAC) - Full Text View - ClinicalTrials.gov. (n.d.). https://classic.clinicaltrials.gov/ct2/show/NCT05262855 (Accessed: October 4 2023).

[3] Study of [18F]FAPI-74 PET in Patients With Gastrointestinal Cancers - Full Text View - ClinicalTrials.gov. (n.d.). https://classic.clinicaltrials.gov/ct2/show/NCT05641896 (Accessed: October 4 2023).

[4] Dendl, K., Koerber, S. A., Kratochwil, C., Cardinale, J., Finck, R., Dabir, M., Novruzov, E., Watabe, T., Kramer, V., Choyke, P. L., Haberkorn, U., & Giesel, F. L. (2021). FAP and FAPI-PET/CT in Malignant and Non-Malignant Diseases: A Perfect Symbiosis? Cancers, 13(19), 4946. https://doi.org/10.3390/cancers13194946. Available at: https://www.mdpi.com/2072-6694/13/19/4946 (Accessed: October 4 2023).

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GE HealthCare Media Contact:
Mathilde Bouscaillou
M 033 647 008 271
Mathilde.Bouscaillou@ge.com

SOFIE Biosciences:
Dawn Allen
Marketing Manager
dawn.allen@sofie.com

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