Press release

Fludarabine labelled with Fluor 18: a new radiotracer for onco-hematology

Paris (France) and New York, N.Y (USA), June 20, 2019 – The CEA and Zionexa have signed an exclusive license agreement for Fludarabine labelled with Fluor 18 ([^{18}F] Fludarabine), an innovative radiopharmaceutical. Used in combination with a PET exam (Positron Emission Tomography), this radiotracer may allow better visualization of the tumor cells in lymphoproliferative diseases. A phase I study (NCT 021 28 945) has led to a proof of concept of the molecule for humans. A phase III multicentric clinical study will follow this license agreement, which is the prerequisite before marketing authorization request, in Europe and in the United-States.

Imaging biomarkers are key for the care of patients with malignant diseases (for diagnosis, treatment response or recidivism assessment). PET imaging uses a radiopharmaceutical biomarker which targets the tumor cell and allows to visualize the treatment response along the patient's pathway.

The CEA[1] has developed an innovative radiopharmaceutical: [^{18}F] Fludarabine. The molecule, developed by the LDM-TEP (Cyceron platform), is covered by a European patent delivered on September 27th, 2017. This patent will be used by Zionexa as part of the license agreement signed on May, 22nd 2019 with the CEA.

[^{18}F] Fludarabine shows a high potential in PET imaging for the evaluation of malignant blood disorders, especially lymphomas. This radiopharmaceutical may allow to visualize lymphoid tumor cells where other current diagnostic techniques are limited in terms of specificity and sensitivity[2].

Preclinical studies show that this radiotracer may allow to avoid interpretation difficulties encountered with current imaging methods for lymphomas. According to the phase I study, [^{18}F] Fludarabine's higher specificity on the tumor tissue and its low affinity for peripheral inflammatory tissue may allow to visualize the tumor tissue with a higher contrast, reducing the false positive risk. The phase I study included 10 patients with diffuse large cells lymphomas and chronic lymphoid leukemia.

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[1] *Laboratory for methodological development in PET (CEA-Institut Joliot, DRF/JOLIOT/SHFJ/LDM-TEP, Caen)*

[2] *This innovative drug has proven its better efficacity for diagnosis in lymphoproliferative diseases in terms of specificity and sensitivity compared to its homolog currenly used ([18F] FDG). http://jnm.snmjournals.org/content/59/9/1380*

A phase III clinical study will be launched in 2020, in order to submit a marketing authorization application for [^{18}F] Fludarabine, in Europe and in the United-States. With this innovative project, Zionexa's objective is to bring new information to hematologists to improve the pathway of patients with lymphoproliferative diseases.

***About Zionexa* – www.zionexa.com**

Zionexa is an international and innovative company developing and commercializing molecular imaging solutions, companion diagnostics (CDx) for targeted therapies in oncology, to improve patients' pathway and provide them a better quality of life.

***About the CEA* - www.cea.fr/english/ | @CEA_Officiel**

CEA is a public multidisciplinary research organization whose research fields range from nuclear industry to bio-sciences, fundamental physics, and information and communication technologies. CEA represents 16,110 employees, B€4.4 budget, 1,689 patents registered or active, 1,300 contracts signed with industry, 178 new companies created since 1972 in high technologies sectors, and 9 research centers located in France.

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