Orphan Drug Designation granted by European Commission for Tetrofosmin for Diagnosis of Glioma

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proACTINA SA, a research-driven and innovation-focused Small-Medium Enterprise in Athens-Greece, today announced that European Commission (EC) has granted Orphan Designation for tetrofosmin for the diagnosis of glioma, following a positive opinion by European Medicines Agency (EMA). The Decision was published in the Community Register of Orphan Medicinal Products and the product has received EU orphan designation number: EU/3/16/1764

"This is a significant achievement for proACTINA as it will advance our development and commercialization plans. We are glad that both EMA and EC have recognized the unmet medical need for glioma diagnosis and that our product will be of significant benefit for those affected by the condition" said Dr. Alex Strongilos, President and CEO of proACTINA SA. "Glioma is a devastating disease whose diagnosis represents a significant unmet medical need, particularly for those patients with suspicion of recurrence."

Tetrofosmin, used in Single-Photon Emission Computed Tomography (SPECT) brain imaging, can provide a highly accurate non-invasive diagnostic solution for the differential diagnosis of glioma. Currently, a Phase II clinical trial designed to assess the technical and diagnostic performance of tetrofosmin/ SPECT for the differential diagnosis of recurrence of high-grade glioma from treatment-induced necrosis is recruiting patients (EudraCT No: 2015-005573-21).

Orphan Drug Designation is granted by the EC for a product intended to diagnose or treat a life-threatening or chronically debilitating disease that affects no more than 5 in 10,000 people in EU, and for which there is no (or only unsatisfactory) treatment options, or the medicine will be of significant benefit to those affected by that condition.

About Glioma

Gliomas are tumours arising from glial cells of the nervous system. Glioma is estimated to be affecting approximately 1.6 in 10,000 persons in the European Union. The most aggressive form of glioma is High Grade Glioma, which, despite successful treatment, recurs in 90% of cases.

Gliomas may cause severe damage to the brain, thus being characterised as debilitating & life-threatening associated with poor long-term survival. Symptoms are caused by compression by the tumour on the surrounding brain tissue and depend on which part of the brain is affected. They include: headache, anorexia, nausea, vomiting, seizures, neurological deficits, personality and cognitive impairment.

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About Tetrofosmin/ SPECT

Tetrofosmin is a ligand reconstituted with Sodium Pertechnetate (99mTc) to prepare Technetium-99m-tetrofosmin (Tc99m-TF) injection for intravenous administration. It is used as a tracer for Single-Photon Emission Computed Tomography (SPECT) imaging of the brain.

Although Tc99m-TF does not cross the blood brain barrier (BBB) in healthy brain tissue, the conditions associated with glioma indicate that BBB permeability is disrupted and there is tracer uptake at the tumour site, leading to a strong signal visualised by SPECT imaging. Therefore, Tc99m-TF provides a powerful non-invasive tool in glioma diagnosis.

About proACTINA

proACTINA's vision is to become a leader in the diagnostics for brain abnormalities by building both in-house expertise as well as establishing robust collaborations for the development of novel non-invasive diagnostic tools as integrated parts of precision-medicine approaches. proACTINA is currently partnering with both academia and industry for the implementation of GLIOMARK, a "Horizon 2020" 4-year project for the clinical validation of an *in vivo* biomarker for brain tumour (glioma) diagnosis. The end-product will consist of a diagnostic radiopharmaceutical kit, containing tetrofosmin, repositioned (by both clinical & pharmaceutical development) specifically for brain imaging. This non-invasive diagnostic technique will provide reliable glioma diagnosis with high sensitivity & specificity aiming to reduce the need for invasive and costly biopsy. http://www.gliomark.eu/.

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Partners:
Consultech GmbH, Berlin Germany (http://www.consultech.de/en)
University of Ioannina, Greece (http://www.uoi.gr)

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