GLIOMARK

www.gliomark.eu

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Biomarker validation for brain tumor diagnosis: Repositioning of an imaging radiotracer

The GLIOMARK project objective is the **clinical validation** of the permeability of the BBB as an *in vivo* **biomarker** for brain tumor (glioma) diagnosis and grading of gliomas. This will accomplished by means of the **radiotracer** 99mTc-tetrofosmin and the imaging technique Single-Photon Emission Computed Tomography (**SPECT**).

The outcome of GLIOMARK is a **diagnostic radiopharmaceutical kit**, containing tetrofosmin, repositioned specifically for **brain imaging** used in combination with SPECT as a non-invasive method. The diagnosis has an immediate **impact** on the type and aggressiveness of **subsequent therapies**.

pro-ACTINA SA is a research-driven SME based in Athens, Greece, whose vision is to become a leader in the diagnostics for brain abnormalities.
ConsulTech GmbH is a life sciences consulting SME based in Berlin, Germany.

GLIOMARK is an SME instrument Phase 2 project funded by the EC´s Horizon 2020 programme.

Start date: July 1st, 2015
Duration: 48 months
Contact: gliomark@consultech.de

pro-Actina

www.proactina.gr

Dr. Alex Strongilos
President and CEO, pro-ACTINA SA, Athens (GR)

Dr. Eva Levi
Clinical Operations Manager, pro-ACTINA SA

In cooperation with:
Prof. Andreas Fotopoulos and Dr. George Alexiou
University Hospital of Ioannina

ConsulTech GmbH

www.consultech.de

Dr. Daniel Schubart
CEO, ConsulTech GmbH, Berlin (DE)
Project coordinator

This project receives funding from the European Union´s Horizon 2020 Research and innovation programme under grant agreement No. 673737.

Next Generation of Glioma Diagnostics

Validation of blood-brain-barrier permeability as a glioma biomarker by means of the radiotracer 99mTc-tetrofosmin and single-photon emission computed tomography

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Disease and Aim

Disease

- Gliomas are brain tumors arising from glial cells of the nervous system.
- Glioma is a long-term debilitating and life-threatening disease.
- There is a significant unmet medical need for the diagnosis of gliomas.

Aims

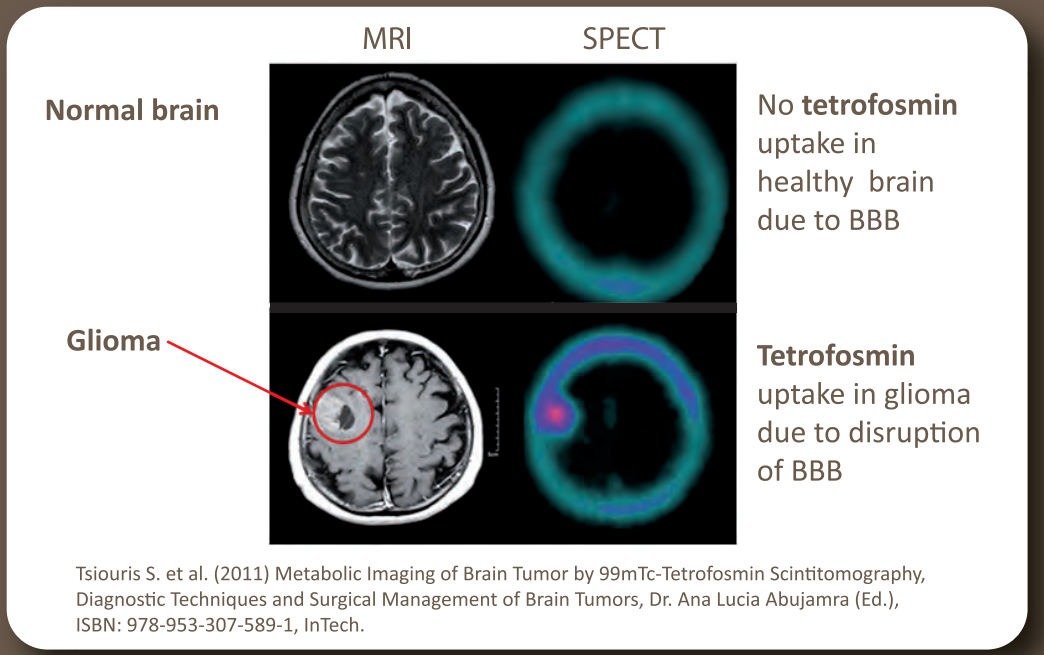
- Clinical validation of imaging biomarker for glioma
- Development of novel diagnostic tool for differential diagnosis and grading of brain tumors
- Repositioning of well-established diagnostic product
- Contribution to the goals of the "International Rare Diseases Research Consortium" (IRDiRC)

Steps of the GLIOMARK project

- ▶ **Clinical Development**
  Phase II clinical trial
  (EudraCT No: 2015-005573-21)
  Phase III clinical trial
- ▶ **Manufacturing (GMP)**
- ▶ **Regulatory development**
  Scientific advices by EU authorities
  Orphan designation
  Paediatric Investigation Plan

Solution

- Non-invasive diagnostic approach to avoid surgery / biopsy
- Improved accuracy compared to standard imaging procedures
- Widespread availability of both tracer and γ-cameras (SPECT)
- Lower cost compared to PET imaging
- Alleviation of healthcare burden



Tsiouris S. et al. (2011) Metabolic Imaging of Brain Tumor by 99mTc-Tetrofosmin Scintitomography, Diagnostic Techniques and Surgical Management of Brain Tumors, Dr. Ana Lucia Abujamra (Ed.), ISBN: 978-953-307-589-1, InTech.

Blood-brain-barrier (BBB) permeability disrupted in Glioma

Commercialisation

- Orphan designation granted by the EC (EU/3/16/1764)
- 10 years of market exclusivity
- Promoting personalised treatment for glioma patients worldwide
- Commercialisation of a radiopharmaceutical kit for brain imaging by SPECT

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Next step

- ▶ Commercialisation of the diagnostic kit with the indication under development (differential diagnosis of recurrence of high-grade glioma from treatment-induced necrosis)

Future perspectives

- ▶ Expansion to other indications related to brain abnormalities both tumor-related and unrelated (new clinical trials)

C & T ConsulTech GmbH

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