

Biosensor for timely diagnosis of VEGF concentration in retinal disorders

Biosensor for *in vitro* or *in vivo* application / Measurement of a patient's VEGF concentration for timely coordination with therapeutic decisions / Optional: System for inducible synthesis of anti-VEGF molecules *in vivo* could be integrated

DESCRIPTION OF TECHNOLOGY

The technology comprises a method for determination of VEGF (vascular endothelial growth factor) concentration *in vitro* or directly *in vivo* in the eye by use of a single-molecule biosensor.

The measurement of VEGF is based on binding of VEGF molecules to the biosensor, wherein binding triggers a bioluminescence resonance energy transfer (BRET) signal that can be detected and quantified.

Furthermore, the biosensor can optionally be combined with cells comprising an inducible vector for synthesis of anti-VEGF molecules that subsequently downregulate VEGF concentration in the eye as a therapeutic response to an increased concentration of VEGF.

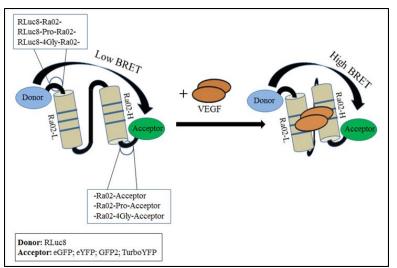




Fig. 1: When VEGF binds to the biosensor molecule, a conformational change occurs in the biosensor, which reduces the distance between donor (RLuc8) and acceptor (GFP2) and thus enables energy transfer. In *in vitro* methods, VEGF concentrations of unknown samples can be measured by linear regression using a VEGF standard and calculated using the BRET ratio.

AT A GLANCE ...

Application Fields

 Diagnosis and therapy of retinal disorders, like AMD, DME, and others

Business

Pharma / Biotech / Medical Technol.

USP

- Biosensor for timely measurement of VEGF concentration and linking to therapeutic decisions
- In vivo measurement of VEGF possible by use of a minimally invasive procedure
- Optional: Combination with inducible system for *in vivo* synthesis of anti-VEGF molecules depending on actual VEGF concentration

Development Status

- All biosensor components available and functional
- Next steps: Preclinical and clinical development and evaluation

Patent Status

- Priority application filed on 23/02/2016 in EP, pending, published as EP 3211422 A1.
- PCT application filed on 20/02/2017, published as WO 2017/144416.
- US application filed on 23/08/2018, pending.

APPLICATION FIELDS

The technology provides a method for determination of intraocular VEGF concentration that allows for a decision if therapeutic intervention with anti-VEGF antibodies of patients with a retinal disorder, like

- age-related macular degeneration (AMD),
- diabetic macular edema (DME),
- diabetic retinopathy,
- retinopathy of prematurity, or
- retinal vein occlusion (RVO),

is necessary due to the measured prevalent VEGF concentration.

ADVANTAGES OVER THE PRIOR ART

The state of the art lacks a highly sensitive assay in the range of femtogram per milliliter (fg/ml) for *in vitro* determination of VEGF concentration with a small sample volume that is provided by the new technology.

The method is moreover suitable for *in vivo* application and for combination with a system for on site *in vivo* control of VEGF concentration by synthesis of anti-VEGF molecules that is activated dependent on the measured VEGF concentration.

STATE OF THE PRODUCT DEVELOPMENT

All components of the biosensor for diagnostic measurement of VEGF concentration and for synthesis of anti-VEGF molecules for therapeutic intervention are available and functional.

Further steps for preclinical and clinical evaluation have not been performed so far.

MARKET POTENTIAL

The number of patients with retinal disorders is constantly growing due to the demographic development. Alone in the US, the revenues of retinal therapeutics for AMD, DME, and RVO were 2.5 billion US\$ in 2012, based on a patient number of 3.5 million. It is expected that the revenues will further increase drastically. In Germany, actually about 1 million people suffer from AMD.

COOPERATION OPPORTUNITIES

On behalf of its shareholder Justus-Liebig-Universität Giessen TransMIT GmbH is looking for cooperation partners for further development or licensees.

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