GILUPI - WE EXTRACT THE CELLS, YOU SEARCH FOR



The Situation

- The early detection of pathological changes is the decisive factor for an effective treatment
- Many established methods in current cell-based diagnostics only use a limited sample volumes (blood, tissue)
- The detection limits of rare cells in all types of specimen are often not reached, reducing the chances of detecting pathological changes
- Available isolation procedures are often associated with substantial physical and psychological stress for the patient (surgical procedures such as biopsy or amniocentesis, etc.)

Oncology:

- The optimal goal of diagnostic methods is to establish the basis of personalized concepts of therapy at the first evidence of a tumor disease
- With the Nanodetector diagnostic and therapeutic procedures could be optimized a real-time follow-up of therapy results would be possible
- The Nanodetector could significantly contribute to an improved prognosis for patients by enabling the optimization of therapy approaches

Prenatal:

- Currently used methods of prenatal diagnostics can be divided into non-invasive and invasive procedures
- If non-invasive screening tests (e.g. Triple Test) indicate a high risk of a chromosomal aberration or a gene defect invasive procedures are recommended (amniocentesis and chorionic villus biopsy) to confirm the diagnosis
- The newly developed GILUPI product will be able to replace all high-risk invasive procedures

The Medical Device

Functionalized Structured Medical Wire = FSMW

The GILUPI GmbH has developed a Nanodetector, which is an innovative diagnostic approach:

The cells are "fished" in vivo directly out of a peripheral vein. In the presently available methods a blood sample is taken to isolate the corresponding cells in order to characterize their genetic status.

Features of the GILUPI Nanodetector

In vivo detection and isolation of rare cells (e.g. trophoblasts, circulating tumor cells [CTC], etc.) out of an unlimited volume of blood for a comprehensive analysis of their molecular profile.



Figure 1: GILUPI Nanodetector for the isolation of rare cells

The Product's Novelties

- *In vivo* capture of target cells
- Reduced patient burden
- Low-risk application
- **Excellent biocompatibility**
- Efficient method for the *in vivo*-isolation of rare cells
- No limitation of sample volume
- Increased diagnostic sensitivity
- Significantly improved basis of information compared with other diagnostic methods

The Status of Development of the Product

The Nanodetector has been successfully used in several clinical studies:

Prenatal Study

Pregnant women: 36 subjects

Cancer studies

more than 30 subjects Breast cancer: more than 35 subjects Lung cancer: Prostate cancer: more than 15 subjects

The proof of concept for the detection of embryonic trophoblasts and CTCs was achieved!

In over 80% of the cancer patients CTCs could be detected and isolated!

The Method

Interaction of target cells with the Nanodetector is mediated through a biological functionalization using antibodies against surface markers of the desired cells.

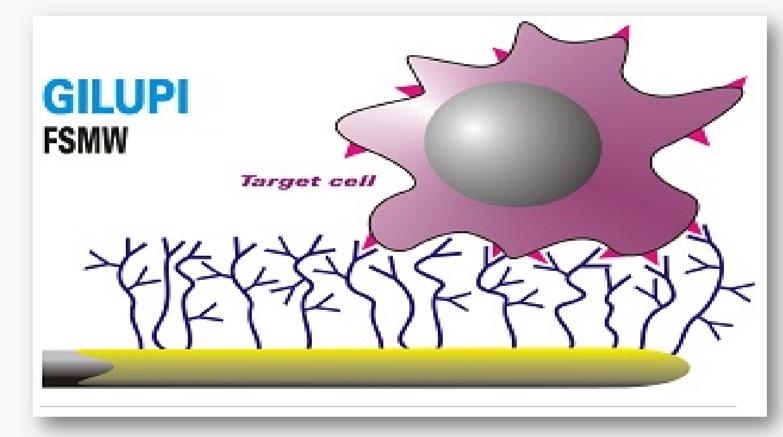


Figure 2: Schematic presentation of the Nanodetector

The Application

The Nanodetector is inserted into a patients arm vein through a cannula for a contact time of less than 60 min.



Figure 3: Nanodetector inserted into the arm vein

The Company

GILUPI GmbH - founded in 2006 as a medical technology company - has developed new medical devices for the isolation of rare cells out of the circulating blood on the basis of its own patented inventions in nanotechnology.

GILUPI's innovative products for prenatal and oncology diagnostics are expected to find worldwide acceptance and distribution in an important segment of the health care market.

The first certified product based on this technology is expected to be on the market by 2012. The product can now be used for *in vitro* tests.

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