



# A new medical device for *in vivo* fetal cells isolation from maternal blood - preliminary results of safety evaluation

M. Madejczyk<sup>2</sup>, B. Długaszewska<sup>1</sup>, M. Mayer<sup>1</sup>, G.H. Bręborowicz<sup>2</sup>, K. Lücke<sup>1</sup>

<sup>1</sup>GILUPI GmbH, Am Mühlberg 11, 14476 Potsdam, Germany

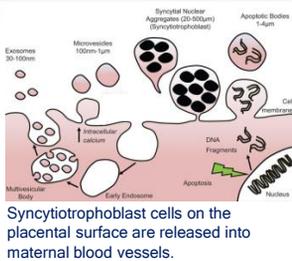
<sup>2</sup>Klinika Perinatologii i Ginekologii UM w Poznaniu, Polna 33, 60-535 Poznań, Poland



## Abstract

Prenatal diagnosis based on rare fetal cells is still a challenge. We present a novel medical device - GILUPI CellCollector™ that offers minimal invasive alternative to capture and immobilize trophoblast cells *in vivo*. Results of an open phase 1 study performed in 12 healthy, non-pregnant women are shown. The aim of the study was safety determination of the new prenatal device. CellCollectors were functionalized with a combination of two murine antibodies 1C10 and anti-HLA-G (G233) on the surface, to capture trophoblast fetal cells. The CellCollector was inserted through a standard cannula in a subject's cubital vein for 45 minutes. The device was well tolerated in all 12 applications without side effects. In the 4 weeks (follow up) after the device application no AEs/SAEs in any causal relationship to the product were observed. The results of HAMA-ELISA tests after the device application showed that no immune response concerning the development of HAMAs (Human anti-mouse antibodies) was measured in any of the 12 non-pregnant subjects in the control group. The application of the new prenatal device is expected to be safe and without risks for pregnant subjects participating in the study.

## GILUPI CellCollector™- an *in vivo* fetal cells isolating method



Insertion of the GILUPI CellCollector™ through 20G indwelling cannula in a peripheral arm vein.



*In vivo* isolation of fetal trophoblasts within 45 minutes application time.

- Sex determination
  - Aneuploidy detection
- Downstream diagnostics

## GILUPI CellCollector™ innovative structure



- 4cm functionalized tip
- 3 thin braided stainless steel wires
- Gold and hydrogel coating
- Incorporated antibodies: 1C10 and G233 (against trophoblast cells)
- Increased surface and better hemodynamics

## Study design

**Phase 1**  
n=12, Caucasian population  
non-pregnant subjects

ENDPOINT

**Safety and tolerability**

- Observation vital signs: before, during and after CellCollector application
- Adverse events (AEs)/serious adverse events (SAEs) with/without a causal relationship to the device
- HAMA-test before and 4 weeks after application
- Subjective evaluation of the procedure (subject)

ENDPOINT

**Phase 2**  
n=24, Caucasian population  
pregnant subjects

**Functionality**

- Fetal sex determination

ENDPOINT

## Phase 1 safety evaluation results

- Vital signs (blood pressure, heart frequency, temperature) before, during and after the application within normal range
- No AEs/SAEs in any causal relationship to the GILUPI CellCollector™ occurred
- HAMA-test results were negative in all 12 non-pregnant subjects
- No discomfort or pain was reported, procedure was assessed as comparable to venipuncture for blood taking

## Conclusions

The GILUPI CellCollector™ 1C10/G233 with two murine antibodies on the surface was applied for the first time *in vivo*. Safety and tolerability was proved. New GILUPI medical device can be safely used in the second phase of the trial and applied in pregnant subjects.