Meeting summary
Lund, May 2014

The EVERREST project's 4th consortium meeting was hosted by the clinical team at the University of Lund. The main aims of the meeting were to gain final agreement for various aspects of the Clinical Trial protocol and to review the findings of interviews conducted in patients. The team also reviewed project progress, particularly with regards to the preclinical toxicology work and Prospective Study.

Anna Morka, Clinical Trial Manager at the Comprehensive Clinical Trials Unit at UCL, reported that four patients had been recruited to the prospective data collection study. This study will collate information the outcomes of pregnancies affected by severe Fetal Growth Restriction (FGR), including extensive information on maternal health and neonatal follow up, at the four participating clinical centres. The clinical centres in Spain and Sweden are also now ready to begin recruiting women to the study.

Dr Rebecca Spencer, Clinical Research Fellow at UCL, led the project team through a variety of different aspects related to finalising the Clinical Trial protocol. The team discussed the criteria for deciding whether or not a fetus has severe FGR. Rebecca reviewed the different approaches currently used by each clinical centre in the EVERREST project and described work she has undertaken with UCL Professor of Systems Medicine, Alexey Zaikin, to combine these approaches into the most conservative estimate possible for determining whether or not a fetus will reach a viable weight. The team also reviewed inclusion criteria related to ultrasound measurements of blood flow in the uterine artery and discussed the choice of trial design, possible doses for use in the preclinical toxicology study and clinical trial, and stopping rules that will be applied during the trial. Rebecca intends to present her work on protocol design and inclusion criteria at national and international conferences and submit it for publication in a leading obstetrics and gynaecology journal.

Plans for safety monitoring and assessment of participant experience during the clinical trial were also key areas of discussion. The team has identified the need for an internationally recognised set of definitions and grading criteria for pregnancy-related adverse events reported during clinical trials. This would be valuable not only for translational obstetric research, but also for the wider inclusion of pregnant women in research in general. The EVERREST consortium agreed to set up a working group in the next year to develop a provisional set of criteria, based on national and international guidelines and definitions.

Dr Jocelyn Brookes, interventional radiologist at UCLH, joined the meeting to discuss administration of the gene medicine in the clinical trial. He presented the

administration protocol and led a discussion of various aspects relating to fetal monitoring during and after the procedure.

Dr Maria Sheppard, post-doctoral fellow at Queen Mary and Westfield College, London, presented insights from interviews with parents in the UK and Spain. These interviews were designed to evaluate the ethical and societal acceptability of the EVERREST approach. At the time of the meeting, interviews were ongoing.

The next meeting will be held in spring 2015 at the Maternal-Fetal Unit of Hospital Clinic de Barcelona, Spain.