Development of a prophylactic treatment for the prevention of fetal/neonatal alloimmune thrombocytopenia (FNAIT)

From 2012-08-01 to 2018-07-31, closed project

Project details

<table>
<thead>
<tr>
<th>Total cost:</th>
<th>Topic(s):</th>
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<tbody>
<tr>
<td>EUR 7 837 467,18</td>
<td>HEALTH.2012.2.4.4-1 - Preclinical and/or clinical development of substances with a clear potential as orphan drugs</td>
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<tr>
<th>EU contribution:</th>
<th>Funding scheme:</th>
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<tbody>
<tr>
<td>EUR 5 986 000</td>
<td>CP-FP - Small or medium-scale focused research project</td>
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<th>Coordinated in:</th>
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<tr>
<td>Norway</td>
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Objective

Objective--The project aims to develop an anti HPA-1a immunoglobulin (IgG), Tromplate® that can prevent post delivery immunisation of the mother against the Human Platelet Antigen-1a (HPA-1a). This prophylactic treatment will prevent Fetal/Neonatal Alloimmune Thrombocytopenia (FNAIT) in the fetus/newborn in subsequent pregnancies.

FNAIT--FNAIT is a rare but potentially serious condition which affects about 4,000 fetuses and newborns a year in EU-27 and which may result in severe bleeding, intracranial hemorrhage, fetal death or lifelong disability. FNAIT may develop when the mother and the fetus have different platelet surface antigens, most commonly HPA-1a. Transferral of HPA-1a antigen from the fetus may cause immunisation of the mother and the anti-HPA-1a antibodies she develops may in turn destroy the platelets of subsequent HPA-1a positive fetuses/newborns and cause FNAIT. Today, no good treatment of FNAIT exists.

Rationale--Previously, it was believed that the pregnant woman develops antibodies early in the first pregnancy with the implication that FNAIT could not be prevented. However, a study conducted by the applicants of more than 100,000 pregnancies revealed that HPA-1a antibody formation most often takes place in association with or after delivery. Therefore, anti-HPA-1a IgG given to the mother shortly after birth should prevent her immune system from generating harmful anti-HPA-1a antibodies. This concept is analogous to the use of anti(D) for Rhesus D prophylaxis.

Activities--The project elements: manufacturing of Tromplate® using the process for producing anti(D); screening for HPA-1a negative and pregnant women and clinical Phase II/III studies investigating the efficacy and safety of Tromplate®.

Relevance to the work program—The prophylactic Tromplate® treatment has obtained orphan drug status in Europe. FNAIT represents a significant health care expense for the society and a great burden for the affected children and their families.

Related information

<table>
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<tr>
<th>Report Summaries</th>
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<tbody>
<tr>
<td>Final Report Summary - PROFNAIT (Development of a prophylactic treatment for the prevention of fetal/neonatal alloimmune thrombocytopenia (FNAIT))</td>
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<tr>
<td>Periodic Report Summary 1 - PROFNAIT (Development of a prophylactic treatment for the prevention of fetal/neonatal alloimmune thrombocytopenia (FNAIT))</td>
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<tr>
<td>Periodic Report Summary 2 - PROFNAIT (Development of a prophylactic treatment for the prevention of fetal/neonatal alloimmune thrombocytopenia (FNAIT))</td>
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<tr>
<td>Periodic Report Summary 3 - PROFNAIT (Development of a prophylactic treatment for the prevention of fetal/neonatal alloimmune thrombocytopenia (FNAIT))</td>
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</tbody>
</table>
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**EU contribution:** EUR 237,439,22

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**EU contribution:** EUR 108,326,40

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**EU contribution:** EUR 585,193,06

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**EU contribution:** EUR 18,900
Activity type: Research Organisations

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