P R E S S R E L E A S E

FOR IMMEDIATE RELEASE

Consortium lead by Prophylix Pharma AS receives up to €6 M in EU-funding

The EU grant is for development of a prophylactic treatment to prevent severe bleeding and death in newborns caused by Fetal/Neonatal Alloimmune Trombocytopenia.

May 8, 2012 (Tromsø, Norway).
Prophylix Pharma AS today announced that its project proposal for developing a new therapy to prevent Fetal/Neonatal Alloimmune Trombocytopenia (FNAIT) has been favorably evaluated by the EU Commission and will receive up to €6 million in funding under the Seventh Framework Programme (FP7-HEALTH). The project with the acronym PROFNAIT will be carried out by a consortium consisting of academic and commercial organizations from Norway, Sweden, Denmark and Germany.

FNAIT is a rare but potentially very serious condition that occurs in about 1 out of 2,000 pregnancies. FNAIT is most commonly caused by incompatibility between mother and foetus for the Human Platelet Antigen 1a (HPA-1a). If a mother is negative for the HPA-1a antigen, she may develop antibodies against HPA-1a antigen from her foetus. Transferral of these antibodies to the foetus can destroy the foetus' blood platelets and increase the risk of severe and potentially fatal bleeding. Currently no satisfactory preventive measures or treatment exist.

Rare plasma donors needed

The new prophylactic therapy consists of a so-called hyperimmune - a specific IgG antibody fraction isolated from human plasma of rare donors who are carrying antibodies against the HPA-1a antigen. The objective of the PROFNAIT consortium is to secure sufficient plasma to manufacture the hyperimmune and to conduct clinical development of the product until registration. The plasma will be obtained from female donors that have given birth to a child suffering from FNAIT but also women who are known to be immunized against HPA-1a, for example from screening programmes, are potential donors. Less than 1 in 100 women is likely to be a donor and the right plasma therefore extremely rare. Thus, the consortium invites all women who know they are immunized, or would like to be tested to see if they are immunized against HPA-1a, to sign up as potential donors at www.prophylixpharma.com

When the hyperimmune product has been produced from donor plasma, it will be offered in a clinical study as prophylaxis to pregnant women who are HPA-1a negative and thus at risk of developing antibodies against the HPA-1a antigen from their fetus. Once the prophylactic treatment has been approved by the regulatory authorities, it should be offered to 1 in 50 pregnant women or approximately 170,000 women annually in Europe.

Orphan drug status
In October 2011, the European Medicines Agency's (EMA's) Committee for Orphan Medicinal Products (COMP) granted the prophylactic treatment Orphan Medicinal Product Designation (EU/3/11/922). This designation secures Prophylix Pharma market exclusivity in Europe for 10 years, the possibility of free scientific advice from EMA and other advantages that will facilitate the clinical development of the prophylaxis.

The Consortium
Prophylix Pharma will be leading the consortium as Coordinator and also be responsible for the commercialization of prophylactic therapy once the product has been registered. The other members of the PROFNAIT consortium are Larix ApS (DK), Biotest AG (DE), DRK-Blutspendedienste (DE), University of Tromsø (NO), Oslo University Hospital (NO), Karolinska University Hospital (SE), University of Lund (SE) and Aalborg Hospital (DK).

Prophylix Pharma AS
Is a Norwegian company founded in 2008 by a group of scientists, Norinnova Technology Transfer AS and University Hospital of Northern Norway in Tromsø . The company is dedicated to develop a new prophylactic treatment of Foetal/Neonatal Alloimmune Thrombocytopenia (FNAIT). Norinnova Invest AS and Sarsia Seed AS are lead investors in the company.

The Danish life science consultancy firm Wiborg ApS was assisting Prophylix Pharma in the FP7 grant application process.

For more information, please visit www.prophylixpharma.com or contact:

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