

Dilafor announces positive results from a multi dosing safety and pharmacokinetic clinical study.

STOCKHOLM, SWEDEN – February 5, 2015. Dilafor AB announced today completion of a safety and pharmacokinetic multi dosing phase I study with their lead product tafoxiparin. The purpose of the study was to evaluate different clinical administration routes and different dose levels of tafoxiparin in healthy female volunteers. The results will give guidance on the dosages to be used in the phase II trial in Asia in Labor induction expected to start in end year 2015.

Dilafor is a Karolinska Development portfolio company.

The phase I study was focused on the evaluation of the safety and pharmacokinetics of tafoxiparin using a multidosing schedule of tafoxiparin. The study demonstrated tafoxiparin to be safe and well tolerated and with a predictive pharmacokinetic profile. The outcome of the study will be used in the planning of the global clinical trial program in two major indications; Labor induction and Labor arrest. As a next step and as part of the clinical development program in Asia together with Lee's Pharmaceuticals, tafoxiparin will be used in a phase II clinical trial in pregnant women that are induced into labor. Initiation of the study is expected in end of 2015. Decision on the study start is depending on approval from Chinese FDA. Meanwhile during 2015, a phase I clinical safety study is planned in Asian women to support the start of the phase II study and to support the use of Asian clinical data in global clinical development.

Including this study, tafoxiparin has been used and shown to be safe in totally three clinical trials involving 335 subjects of whom 263 were term pregnant women.

“This study is an important milestone in the clinical strategy for development of tafoxiparin for obstetrical indications. The generated pharmacokinetic data and the supportive safety data give us excellent tools to decide about the design of the phase II clinical trial” says Lena Degling Wikingsson, CEO at Dilafor AB

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TO THE EDITORS

About Dilafor AB

Dilafor AB is a Swedish drug development company focusing on the development of tafoxiparin for obstetric indications. The company's primary goal is to decrease the incidence of slow progress of labor both after induction of labor and after spontaneous onset of labor. The main owner of Dilafor is KDev Investments AB, which is jointly owned by Karolinska Development AB (publ) and Rosetta Capital IV. The other main owners are The Foundation for Baltic and European Studies (Östersjöstiftelsen) and Praktikerinvest. For more information, please visit: www.dilafor.com.

About tafoxiparin

Tafoxiparin is a heparan sulphate mimetic, a propriety polysaccharide based drug developed by Dilafor. Women that experience protracted and complicated labor have deficiency in heparan sulphate which is a naturally occurring polysaccharide and plays an important role in labor. Preclinical and clinical data show that tafoxiparin fulfills the role of heparan sulphate and works in conjunction with naturally occurring molecules important in child birth. Slow progress of labor has an incidence of 45% of all pregnant women. It is associated with a number of both long and short term maternal and fetal complications such as emergency caesarean sections, postpartum hemorrhages, vaginal tears, anal ruptures, meconium-stained amniotic fluid and asphyxia. These complications lead to short and long term consequences for the mother and the newborn in addition to substantial health care costs.