Dilafor initiates phase IIb clinical trial with tafoxiparin in women with slow progress of labor

STOCKHOLM, SWEDEN – January 4 , 2017. Dilafor AB, a drug development company focusing on the development of tafoxiparin for obstetric indications, today announces that the first subject has been enrolled in the Phase IIb study with tafoxiparin in pregnant women who experience slow progress of labor or labor arrest after spontaneous onset.

Tafoxiparin is in clinical development as a new treatment designed to decrease the incidence of protracted labor (i.e labor that lasts more than 12 hours), which is the main cause of emergency surgical deliveries such as caesarian section. The condition is often associated with complications for both mother and child. Tafoxiparin has shown in a Phase II clinical trial encouraging evidence that it can decrease the proportion of women with labor more than 12 hours.

The Phase IIb study is a multi-center, double blind, placebo-controlled dose-finding study in term-pregnant first-time mothers that after spontaneous onset of labor require labor augmentation due to primary slow progress or labor arrest. The pregnant women will be randomized to receive one of three different dosages of tafoxiparin or placebo. The treatment will be as an adjunct to standard of care, which is intravenous infusion of oxytocin. The target is to enroll 360 pregnant women in the Phase IIb study.

This proof of concept study is designed to demonstrate reduced time to vaginal delivery defined as time from start of tafoxiparin treatment until delivery. Secondary endpoints include safety, proportion of women with labor time more than 12 hours, number of women with instrumental deliveries such as vacuum extraction and number of caesarian sections. The study is planned to be performed in two countries in Europe including up to 14 delivery clinics. Sweden is the first country to be included.

Lena Degling Wikingsson, CEO of Dilafor, said: “We are excited to initiate this proof of concept study with tafoxiparin in this important indication. The only option for pregnant women who experience protracted labor and do not respond to current clinical practice is acute caesarian sections, which are often associated with complications for both mother and child. We have already seen encouraging results in a completed clinical study with tafoxiparin and look forward to the results of this new trial, which if positive, will pave the way for a pivotal trial and potentially a new treatment option for patients.”

Gunvor Ekman-Ordeberg, CMO and co-founder of Dilafor, said: “I am delighted that my 40 years’ preclinical and clinical research within obstetrics have reached this significant milestone. There is a great medical need for new treatments to address protracted labor and I hope that tafoxiparin will make a difference for all these pregnant women.”

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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 proprietary polysaccharide based drug developed by Dilafor. Women that experience protracted and complicated labor have deficiency in heparan sulphate which is a naturally occurring polysaccharide that 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 approximately 40% 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.