Dilafor
Healthier labor for healthier lives

Dilafor announces positive results from a phase 2b study of tafoxiparin

STOCKHOLM, SWEDEN 1 June 2021. Dilafor has concluded a phase 2b study with its drug candidate tafoxiparin which showed a significant positive impact on cervical ripening in first-time mothers receiving treatment to induce labor. Further and full analysis of data will be done by the company. Market analyses show that a drug that can induce cervical ripening has the potential to reach annual sales in excess of USD 1 billion in the US market alone.

About a quarter of all pregnant women are subject to labor induction, however more than half of these experience failed induction. This leads to a prolonged birth process that increases the need for a caesarean section and the risk of complications in both mother and child.

Dilafors' double-blind, placebo-controlled phase 2b study of the drug candidate tafoxiparin includes 170 first-time mothers with unripe cervix, who received treatment to ripen the cervix and thereby facilitate the onset of labor. The patients in the study were treated with either a subcutaneous injection of tafoxiparin or placebo once daily for up to one week before the planned labor induction. The primary objective of the study was to document the effect of tafoxiparin on cervical ripening measured as the degree of ripening according to an internationally established scale, the Bishop score.

The study results showed that tafoxiparin had a positive effect on the cervical ripening compared with placebo, a difference that was highly statistically significant ($p < 0.009$). Based on these positive results, Dilafor plans to extend the phase 2b study in order to document the effect of tafoxiparin also in two lower doses.

“We are very pleased to see the positive results on cervical ripening. We are looking forward to evaluating more deeply the efficacy data. These results are an important milestone for Dilafor and its dedicated team. We would like to thank the patients, their families, and the clinical sites who have participated in the study” says Lena Degling Wikingsson, CEO of Dilafor.

“The convincing effect of tafoxiparin on cervical ripening opens up for a possible new treatment alternative in obstetrical care. There is a huge medical need due to increased number of labor inductions. Furthermore, current medical practice is related to negative influence on the fetus due to hyperstimulation. Therefore, I am pleased to see the current fetal safety profile of tafoxiparin” says professor Gunvor Ekman Ordeberg, Chief Medical Officer and founder of Dilafor.

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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 Opocrin S.P.A and the Foundation for Baltic and European Studies (Östersjöstiftelsen). For more information, please visit: www.dilafor.com

About tafoxiparin

Tafoxiparin is a proprietary polysaccharide based drug developed by Dilafor. Women that experience protracted and complicated labor have deficiency in a naturally occurring submucosal molecule that plays an important role in labor. Preclinical and clinical data show that tafoxiparin fulfills the role of this molecule and works in conjunction with naturally occurring molecules important in childbirth. Slow progress of labor has an incidence of approximately 40 per cent of all pregnant women and can cause complications both during and after the labor for both the mother and child.
Examples of maternal complications are emergency caesarean sections, postpartum hemorrhages, vaginal tears, anal ruptures and an increased risk of infection in the uterus after the labor. Slow progress of labor creates a tension on the fetus and can cause lower oxygenation of the fetus but also an increased risk of an infection in the child. These complications lead to short- and long-term consequences for the mother and the newborn in addition to substantial health care costs.