# Karolinska Development's portfolio company Dilafor advances tafoxiparin following successful meetings with FDA and European regulatory authorities

STOCKHOLM, SWEDEN – January 30, 2025. Karolinska Development AB (Nasdaq Stockholm: KDEV) today announces that its portfolio company Dilafor has successfully completed regulatory meetings with the U.S. Food and Drug Administration, FDA, and European Health Agencies, regarding the continued development of the company's drug candidate tafoxiparin. The completed meetings mark the end of a comprehensive dialogue with regulatory authorities in the US and EU to reach an alignment between the authorities on designing pivotal clinical Phase 3 studies in Europe and the US to evaluate tafoxiparin as a new potential treatment for priming of labor.

Dilafor has completed interactions with US and European authorities during 2023 – 2024 to achieve an alignment in the regulatory process ahead of the upcoming clinical phase 3 trials with the company's drug candidate tafoxiparin, developed for priming of labor. Positive outcomes from scientific advice meetings with the FDA and the EMA, were followed by a Simultaneous National Scientific Advice, SNSA, including five key national EU authorities, in December 2024. The meetings resulted in an agreement on the overall study design; in particular the primary endpoint, inclusion criteria, and the performance of the study. Following this positive development, Dilafor will now finalize the detailed planning for pivotal Phase 3 studies in the US and Europe.

"There is generally a lack of new product development in the obstetrical area, and tafoxiparin represents a new principle and mode of action compared to available therapies. The extensive interactions with regulatory bodies in the US and Europe have been extremely helpful and have led to an alignment on the design of a Phase 3 program. Along the way, the FDA has been clear that they share the view on tafoxiparin's mode of action resulting in priming of labor," says Lena Degling Wikingsson, CEO, Dilafor.

Currently, more than 30 percent of term pregnant women are induced into labor. Existing interventions require fetal and maternal surveillance in hospital due to maternal and fetal high risk of complications, generating high healthcare costs. National guidance for labor induction have recently been revised to encourage delivery at 39 weeks of gestation in the US and at 40–41 weeks in Europe. The change in routines is supported by strong scientific publications and has been shown to reduce the risk of stillbirth, neonatal complications, operative deliveries leading to improved maternal and neonatal outcomes. The new guidance will lead to a further increase in the number of deliveries requiring labor induction. To reduce the constraints at the obstetrical clinics a new, safe home-based treatment option for labor priming may be a future solution.

Tafoxiparins novel mechanism of action represents a potential breakthrough in obstetrical care by mimicking the natural priming of labor process. The drug candidate uniquely initiates both cervical ripening and myometrial remodeling over several days, initiating a spontaneous onset of labor leading to a vaginal delivery without traditional mechanical or pharmacological interventions. Tafoxiparin is the first drug developed for self-administration by the mother using a daily autoinjector at home, marking a possible improvement in quality of life for the pregnant woman and her family. Moreover, the tafoxiparin drug candidate has in Phase 2 studies demonstrated potential to reduce fetal and maternal complications and associated healthcare expenses.

“We are seeing a clear trend towards earlier induction of labor in both Europe and the US as it has been shown to reduce infant mortality and the risk of complications during delivery radically. This is putting pressure on an already strained maternity care system with increased hospitalization. The aim of tafoxiparin is to enable treatment at home to start a natural process of labor priming resulting in spontaneous onset of labor,” says Viktor Drvota, CEO, Karolinska Development.

Karolinska Development's direct ownership in Dilafor amounts to 3% and indirect ownership interest via KDev Investment in Dilafor amounts to 29%.

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**TO THE EDITORS**

**About Karolinska Development AB**

Karolinska Development AB (Nasdaq Stockholm: KDEV) is a Nordic life sciences investment company. The company focuses on identifying breakthrough medical innovations in the Nordic region that are developed by entrepreneurs and leadership teams. The Company invests in the creation and growth of companies that advance these assets into commercial products that are designed to make a difference to patient’s lives while providing an attractive return on investment to shareholders.

Karolinska Development has access to world-class medical innovations at the Karolinska Institutet and other leading universities and research institutes in the Nordic region. The Company aims to build companies around scientists who are leaders in their fields, supported by experienced management teams and advisers, and co-funded by specialist international investors, to provide the greatest chance of success.

Karolinska Development has a portfolio of eleven companies targeting opportunities in innovative treatment for life-threatening or serious debilitating diseases.

The Company is led by an entrepreneurial team of investment professionals with a proven track record as company builders and with access to a strong global network.

For more information, please visit www.karolinskadevelopment.com.