



Dilafor Background

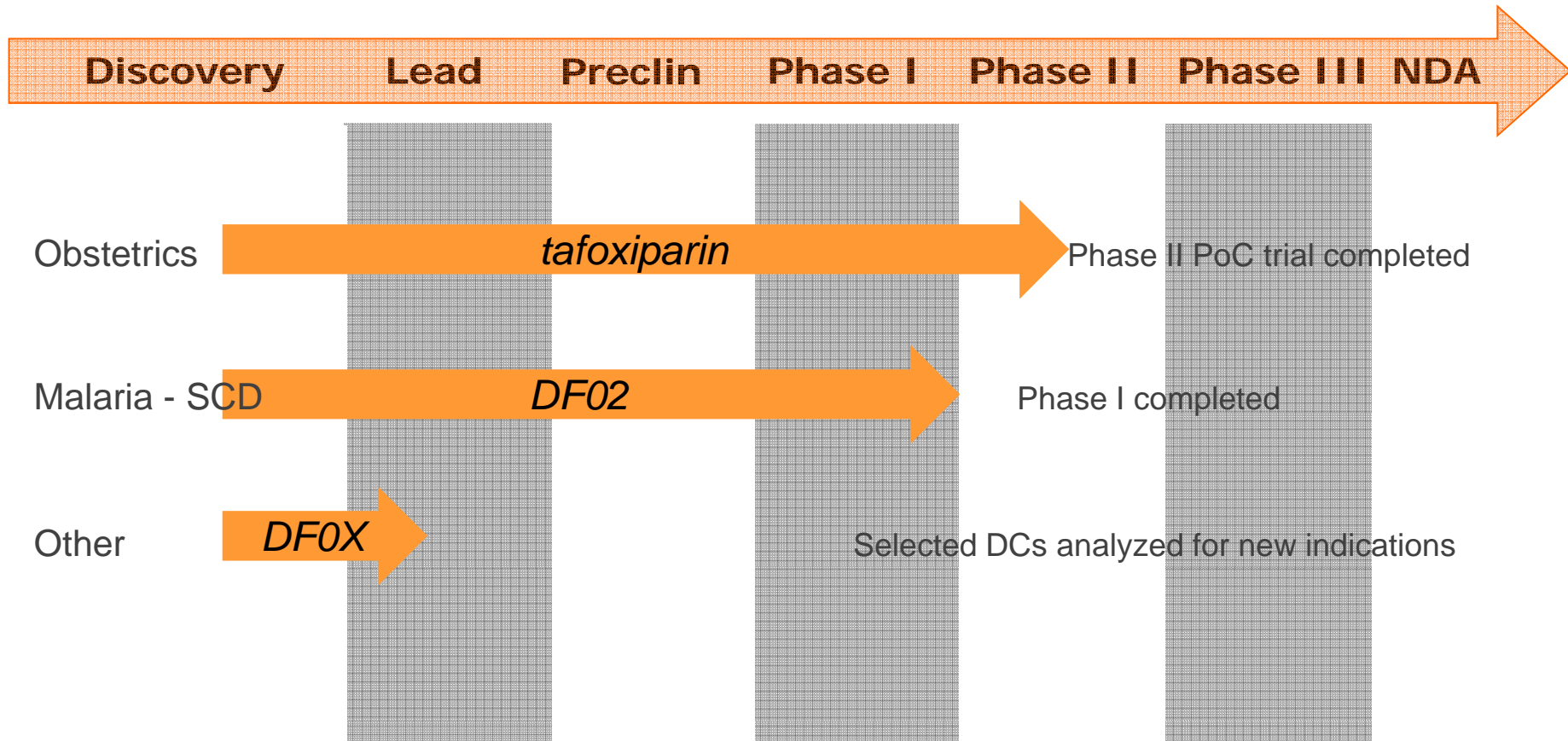
- Established in 2003
- Karolinska
Development
- Promising results
from Phase II trial of
lead DC *tafoxiparin*
presented in
September '09
- Phase I completed
with a second DC



Business Focus

Exploiting the Pharmacological Properties of
LAH
Low Anticoagulant Heparin

R & D Pipeline



The Origin of Tafoxiparin

25 years
of
Research Of The
Extra Cellular Matrix
In The Reproductive Tract
Combined With
Clinical Observations



The Clinical Observation

- LMWH prophylaxis associated with
 - Effective labor
 - Softening (ripening) of cervix

LMWH Unsuitable During Labor

- Risk for bleeding complications
- Epidural analgesia contraindicated

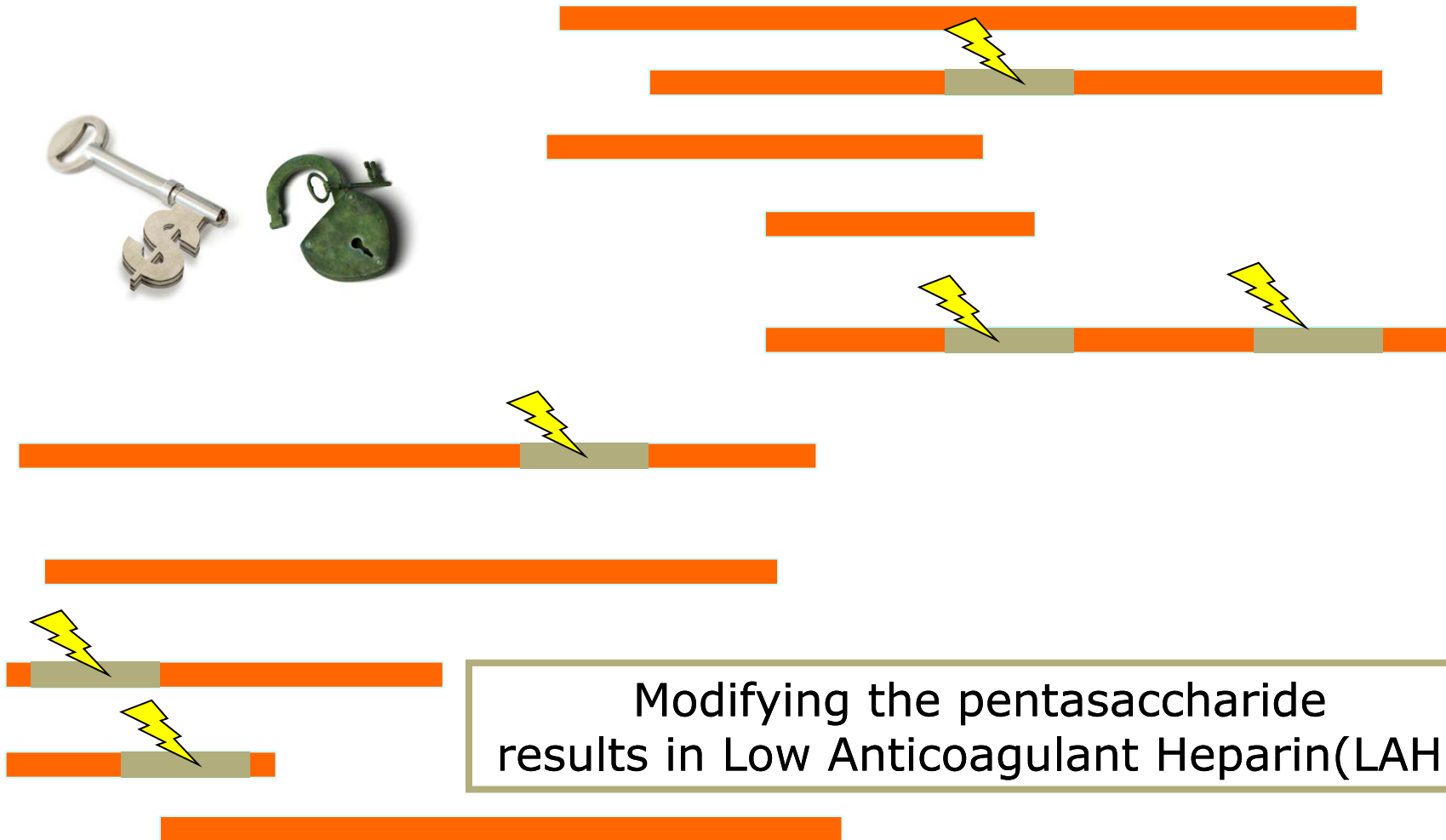


Need for a Low Anticoagulant Heparin
(LAH)

tafoxiparin



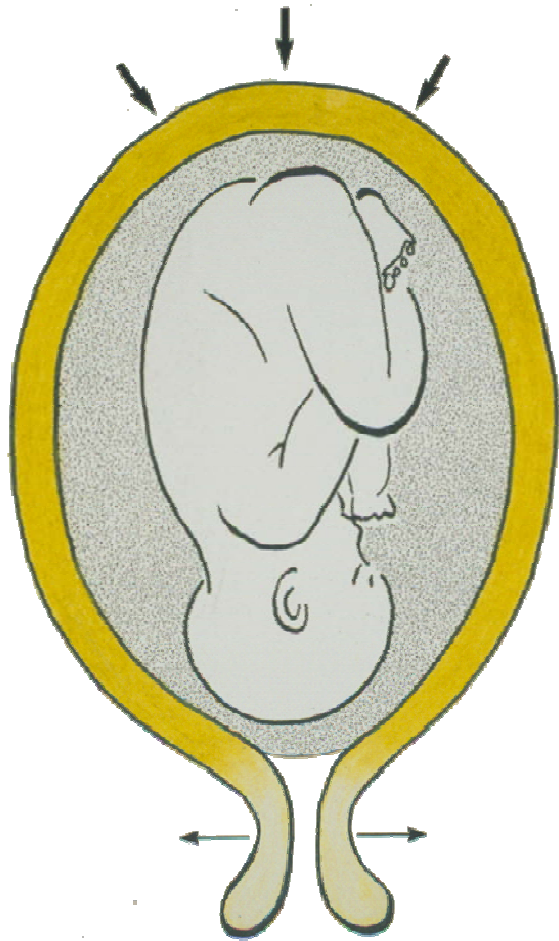
LAH Derived From Heparin



Protracted Labor

- Protracted labor occurs in up to 50% of all deliveries
- Mother and child at risk for emergency interventions and cesarean section, instrumental assistance and serious complications
- Interventions reported in 20 to 25% of all deliveries in high income countries

Labor Challenges



 Effective contractility

 Softening of the cervix

Population & Births

Territory	Population	Annual births
NA (US/Canada)	340.7	4.6
EU	491.5	4.9
Japan	127.1	1.0
Sum	959.4	10.4
RoW	5 830.7	125.0
Target (NA/EU/Japan)	Incidence	Annual births
Induced births	21%	2.2
Millions		

2.2

Consequences of Protracted Labor

Exhausted myometrium



Exhausted mother



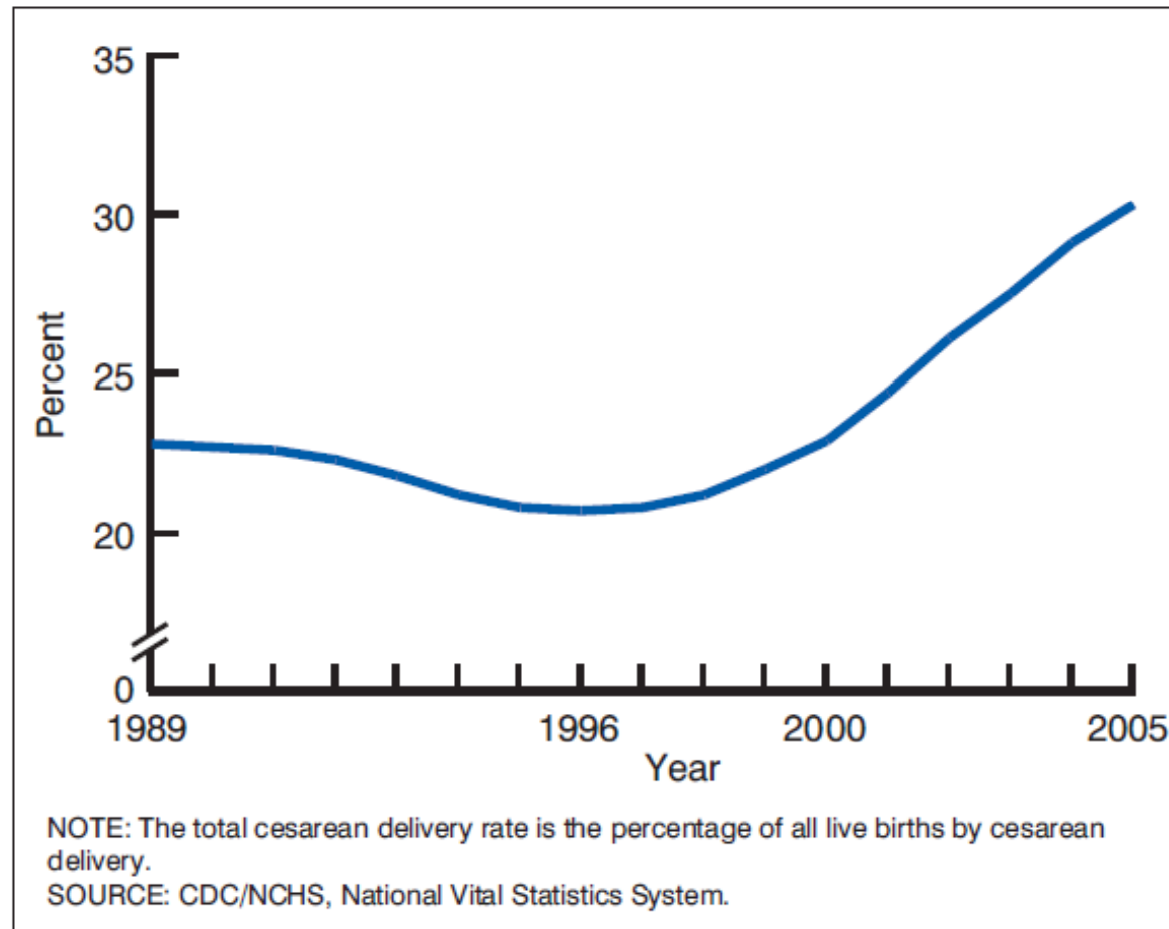
Exhausted fetus



ASFYXIA



Cesarean Delivery Rates - USA



Induction of Labor Increases with Gestational Age

USA - Singelton births

Gestational age	2005	2004	2003	2002	2001	2000	1995	1990
	Percent							
All gestatons	22.8	21.7	21.1	21.1	20.8	20.2	16.2	9.6
Under 32 weeks	8.9	8.7	8.6	8.8	8.9	9.2	7.8	5.0
32–33 weeks	13.4	13.0	12.8	12.8	12.8	13.3	10.6	6.4
34–36 weeks	17.3	16.7	16.0	16.2	16.2	16.2	12.6	7.5
Total under37 weeks	15.6	15.1	14.5	14.7	14.7	14.8	11.6	6.9
Total 37 weeks and over	23.7	22.5	21.9	21.8	21.6	20.8	16.7	9.9
37–39 weeks	21.7	20.6	19.8	19.8	19.6	18.9	14.3	7.9
40–41 weeks	26.8	25.3	24.8	24.6	24.1	22.9	18.5	10.7
42 weeks and over	26.2	25.4	24.3	24.3	24.4	24.4	21.3	14.9

Proof of Concept Study in Humans

Prevention of Protracted Labor

PPL02



Study Objectives

- **Primary**
 - Evaluate the effect of *tafoxiparin* on labor time in vaginal delivery
- **Secondary**
 - Safety and tolerability
 - Complications of labor
 - Overall assessment of the treatment

Study Population & Dose

- **Nulliparous women:**
 - # 263
- **Tafoxiparin:**
 - 60 mg, subcutaneously (3-28 doses)

Women Disposition

#	Placebo	<i>tafoxiparin</i>
Randomized	125	138
Withdrawn	2	4
Per-protocol	115	117

Labor Time

Vaginal delivery	Placebo		<i>tafoxiparin</i>	
	n	Mean (h)	n	Mean (h)
Expectancy	93	7.5	96	6.7
Labor induction	16	7.3	14	4.7 p = 0.06

Tafoxiparin Reduces Protracted Labor

Delivery time	Placebo n=93	<i>tafoxiparin</i> n=96	p-value
>10h	22	18	0.41
>11h	18	10	0.09
>12h	15	6	0.03

Tafoxiparin Reduces The Use of Vacuum Extraction & Neonatal Acidosis

Labor time >12h

	Placebo n=15	<i>tafoxiparin</i> n=6
Acidosis ¹⁾	2	0
Vacuum extraction	9	2 p<0.001

¹⁾ Indicative of poor neonatal oxygenation

Maternal Adverse Events

Injection site	Placebo n=125	<i>tafoxiparin</i> n=138
Hematoma	17 (13.6%)	38 (27.5%)

Hematoma

No clinical significance

- Tafoxiparin has $\approx 1/20$ th of the anti-coagulative effect of ordinary LMWHs
- All LMWHs associated with hematomas
- Injection concentration/volume dependence
 - 0.4 ml injected causes ruptures of small vessels
 - High local concentration exerting an anticoagulative effect
- Size & resorption
 - Typically ≤ 2 mm
 - Fully resolved in $\leq 1-2$ days

Tafoxiparin Efficacy

- Significantly less women with protracted labor (>12h)
- The number of vacuum extractions as a cause of protracted were significantly lower
- Shorter labor time after labor induction

Tafoxiparin Safety

- Safe and well tolerated
- No placenta passage
- No increase vaginal tears or bleeding events
- No effects on vital signs
- No effect on laboratory data

Strong IP Protection

- Use patent granted on all major markets
- Exclusivity of use for all LAHs in protracted labor
 - Independent of:
 - Manufacturing process
 - Composition of matter
- Effective blocking strategy against competitors' use of LMWH on the indication

Executive Summary Tafoxiparin

- First-in-Class - novel therapeutic derived from known substance
- Promising Ph IIa clinical data
- Significant market potential
- Favorable health economics profile
- Meets major unmet medical need
- Strong IP protection in Major Markets



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