Corline biomedical

October 2020

Solutions for life

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Advancing regenerative medicine through CHC™ coating technology

Proprietary CHC™ technology	• Proprietary heparin conjugate technology that reduces bleeding risks associated with systemic administration of heparin • Reduces coagulation, complement cascade activation and inflammation • Used for surface modification of medical devices, cells and vasculature of solid organs
Renaparin® for kidney transplantation	• Preventing ischemia/reperfusion injury through ex vivo treatment for improved kidney transplantation outcomes • Protection from innate immune response and improved immediate kidney function, demonstrated through proof of concept studies in animals • Phase I trial presented favourable safety and tolerability profile • Phase II trial currently being planned
Opportunities for expansion	• Renaparin® – further uses within lung and liver transplantation being explored • CHS™ – validated potential in medical device coating with two pivotal customer contracts signed H2 2020 • CHC™ technology has potential to become a surface modification platform within regenerative medicine (e.g. stem cell transplantation and soft tissue repair)

corline biomedical

Leadership team

Management

Henrik Nittmar, *PhD*
CEO

Gunnar Tufveson, *Prof, MD*
Chief Medical Officer

Jessica Magnusson, *MSc*
Regulatory & Quality Assurance Manager

Fredrik Carlsson, *PhD*
Research Manager

Patrizia Caldirola, *PhD*
Project Manager *Renaparin®*

Mats Reslow, *PhD*
Consultant Head of CMC

Board

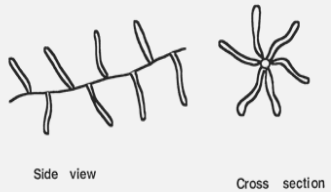
Adam Dahlberg
Chairman

Lars Sunnanväder
Board Member

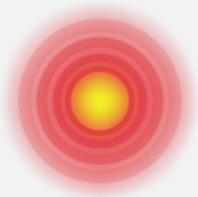
Gunilla Ekström
Board Member

Henrik Krook
Board Member

CHC™ – proprietary heparin conjugate technology



- **Corline Heparin Conjugate (CHC™)** is a proteoglycan-like conjugate of covalently bound heparin
- Heparin is a naturally occurring biomolecule routinely used in surgery as a systemic anticoagulant
- CHC™ is used to locally increase concentration of heparin without the bleeding risks associated with systemic administration



- **CHC™** modification makes surfaces blood compatible, mimicking the inner lining of a blood vessel
- Effectively CHC™ reduces coagulation, complement cascade activation and inflammation, thus **attenuating immune thrombosis**

- **CHC™** technology can be used to modify surfaces of medical devices, cells and vasculature of solid organs

Renaparin®

> Improving the outcome of kidney transplantation

CHS™ Medical Devices

Opportunities & validation

Ischemia/reperfusion injury – no drug approved for prevention

Explantation → **Preservation** → **Transplantation**

Ischemia

Lack of natural blood flow and consequently insufficient oxygen supply

Causes blood vessel damage manifested as endothelial activation and shedding

Reperfusion injury

Immune thrombotic reaction when kidney is connected to the recipient's blood flow, causing damage to the underlying kidney tissue resulting in reduced function

Ischemia/reperfusion injury (IRI) reduces clinical efficacy of kidney transplantation

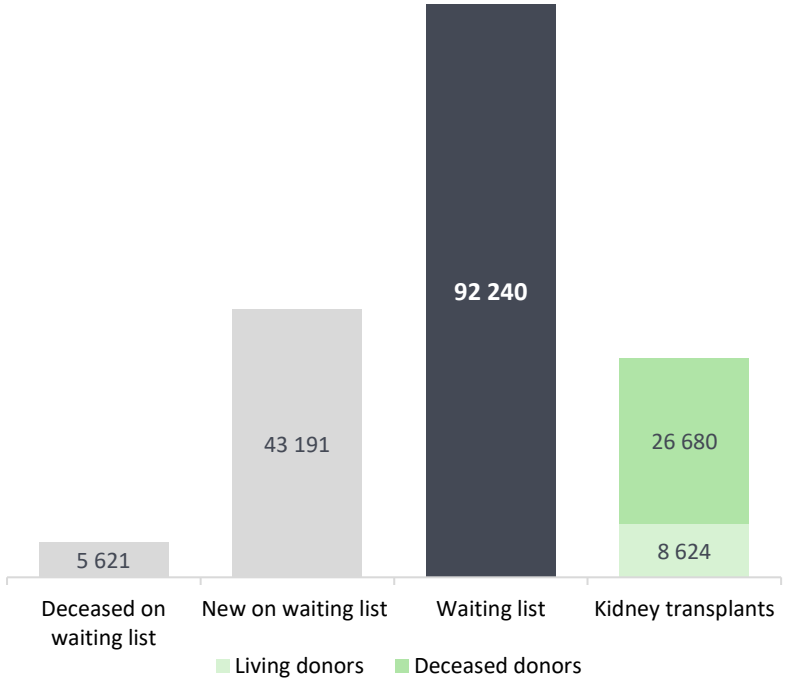
- → IRI leads to delayed graft function
- → IRI is associated with decreased graft function and survival
- → No drug approved for prevention of IRI

40%	+10-14 days	USD 100k	USD 2.5k/day
transplants affected	added to ICU stay	transplant cost	ICU cost

Organ shortage – a multi-faceted challenge for kidney transplantation

Significant organ shortage gap remains…

US & EU5 Kidney transplants[1] (2017)



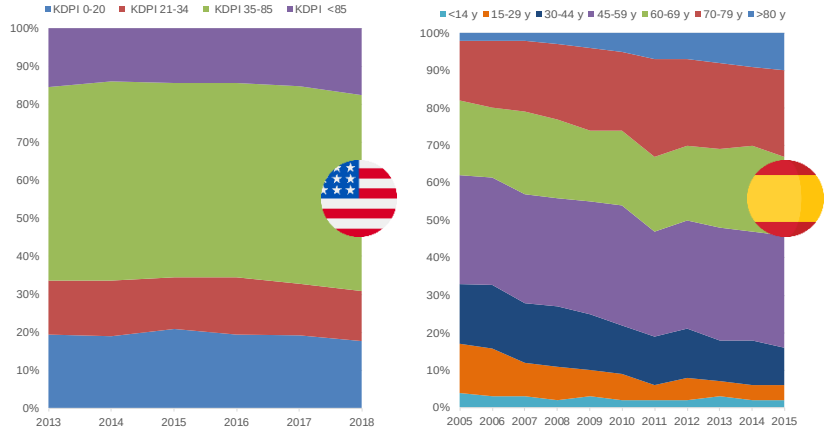
…driving acceptance of marginal donors

Deceased donor kidney transplants CAGR 2012-17[2]

4.9% US

3.1% EU5

Increase in high KDPI and ECD donors[3]



> Marginal donors are more susceptible to IRI/DGF

Source: (1) Transplant Newsletter 2018; GroupH high-level estimate; (2) EDQM Transplant Newsletter Years 2006 - 2018; (3) US - OPTN database; Spain - Matesanz et al. 2017

Renaparin® – reducing risk of marginal donor kidney transplantation

Explantation → **Renaparin® + Preservation** → **Transplantation**

Ex vivo Renaparin® treatment + **Standard preservation**

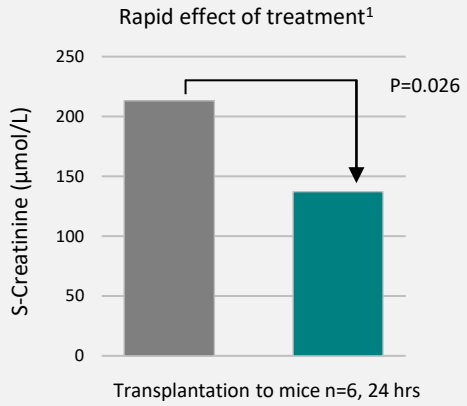
Renaparin® helps avoid delayed graft function -> reduced need for dialysis, duration of hospital stay and improved kidney function/survival

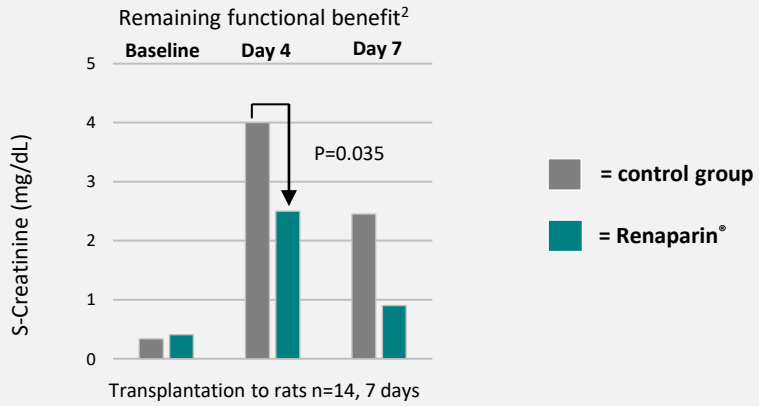
- ✓ Restores/repairs vessels in the kidney (endothelial repair), emulating a coherent vascular glycocalyx
- ✓ Prevents Ischemia/Reperfusion injury in kidney transplantation by presenting a repaired endothelium and attenuating the reperfusion injuries
- ✓ Compatible with all standard perfusion solutions, cold storage and machine perfusion

Phase I Completed	Phase II Design Underway	Orphan Drug Designation
With a good safety profile	Primary end-point is eGFR at 3 months	Obtained for both US and EU

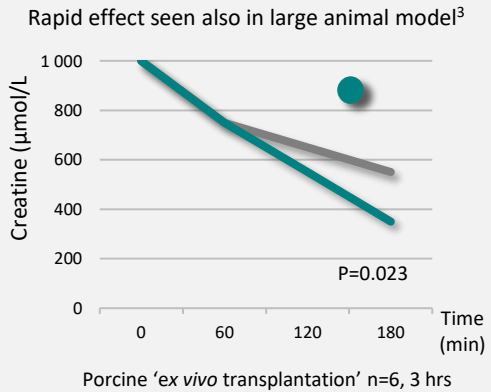
Promising results from proof-of-concept studies in small and large animals

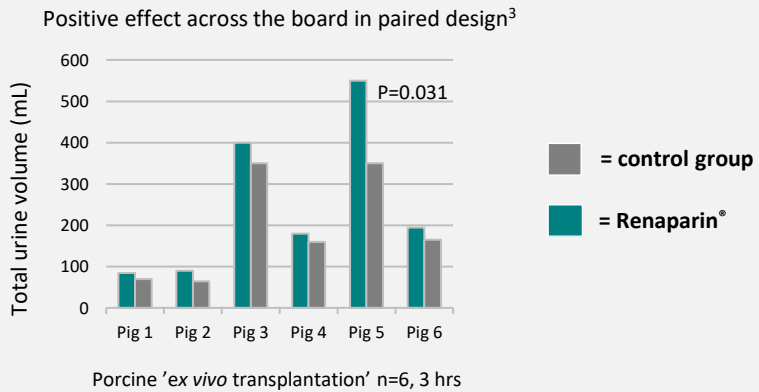
Small animals





Large animals





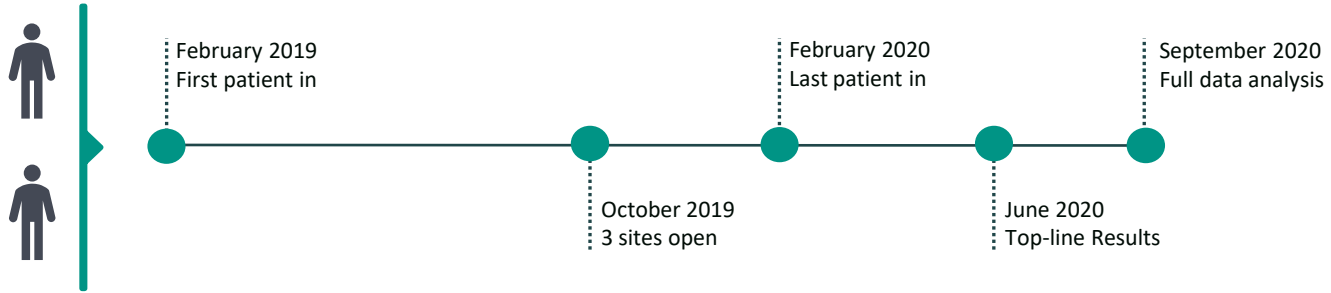
Source: (1) Nordling, et al 2018., (2) Corline proprietary non-published data., (3) Sedigh et al, 2018.

Clinical safety and tolerability demonstrated in recent Phase I study

Description	• Phase I interventional, double-blind, randomized, controlled study of kidney transplantation after ex vivo treatment with Renaparin® of kidneys from deceased donors • Multi-center in Sweden, at 3 sites: Uppsala, Stockholm and Gothenburg
Endpoints	• Number and severity grade of Serious Adverse Events and Adverse Events including description of their associated MedDRA terms during the first 30 days after transplantation
Conclusions	• **Primary and secondary safety endpoints were successfully evaluated – it was concluded that Renaparin® administration is safe and tolerable for this indication and dose**

8 patients
Renaparin®
30 days follow-up

8 patients
Placebo
30 days follow-up



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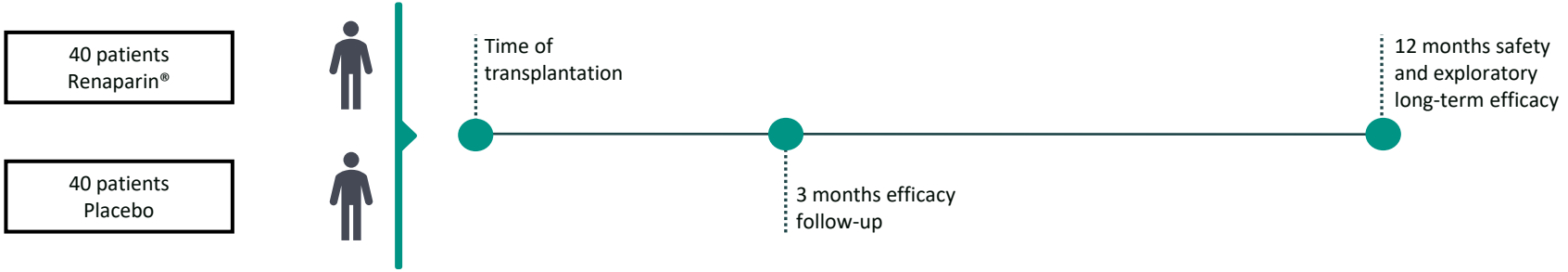
Preliminary Phase II study design

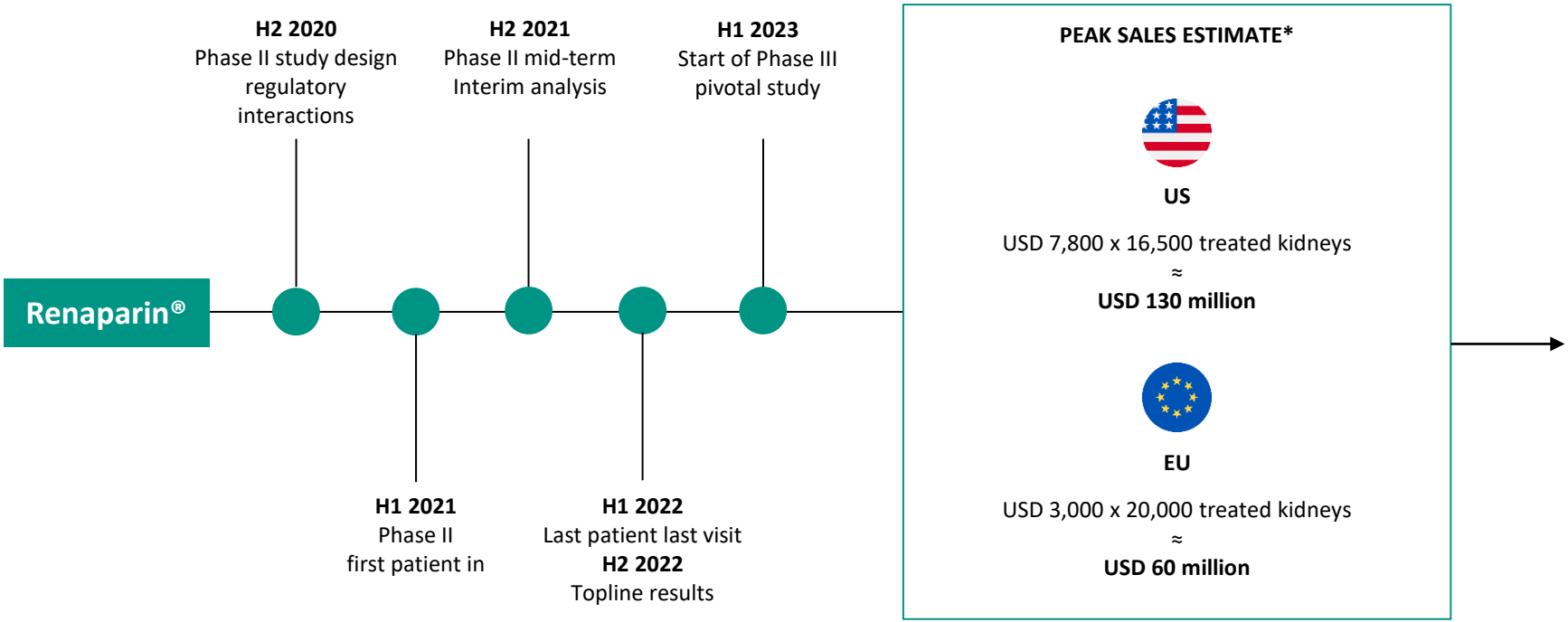
Description	• Phase II interventional, single-blind, randomized, controlled study of kidney transplantation after ex vivo treatment with Renaparin® of kidneys from deceased donors • Multi-center in EU, at 3-4 sites in 2 countries
Objectives	• Primary objective: assess efficacy of donor kidney pre-treatment with Renaparin® in renal transplant patients with a high risk of IRI/DGF • Secondary objectives: assess incidence of DGF, DGF severity, rejection and safety evaluation
Endpoints	• Primary end-point: eGFR (MDRD7) at 3 months • Secondary endpoints: creatinine, incidence and severity of DGF, BPAR proven rejection and assessment of AE/SAEs
Target Population	• Deceased donor kidney recipients at increased risk of developing IRI/DGF (ECD-DBD, DCD)



Renaparin® – primary prevention as a differentiating factor

Company	Product description	Stage	Characteristics
Corline biomedical	• Ex-vivo administration into transplant organ • Repairs and protects organ vessel system	Phase II	+ Protects kidneys from innate immunity + Avoids bleeding risks of systemic heparin administration
Angion Biomedica corp	• HGF mimetic that activates repair pathways • IV twice after transplantation	Phase III	+ Promising Phase II data + Targets treatment of actual cases - Market opportunity reduced as it targets only known cases - Systemic administration
Quark Pharmaceuticals	• TP53 gene inhibitor- temporarily reduces cell apoptosis • IV injected once at transplantation	Phase III	+ Novartis partnership + Good safety profile - Did not meet Phase II endpoints - IV injected
CSL Behring	• Complement inhibitor (C1INH), • IV injected at transplantation	Phase II	+ Data shows an increased eGFR at 12 months + Approved for another indication - Plasma derived product with very limited supply - Too expensive for DGF prophylaxis - Phase II: no effect on DGF - Systemic administration
HEMARINA	• Oxygen carrier from sea worms • *Ex vivo* administration into preservation fluid	Medical Device Phase I/II	+ Medical device. + Promising early efficacy signals in Phase I/II - No controlled source (sea worm) makes CMC a challenge

Development timeline to market



Source: (*) GroupH market access study; assumption is high penetration in high risk cases and low to no penetration in low risk / standard criteria donors

Renaparin®

> Improving the outcome of kidney transplantation

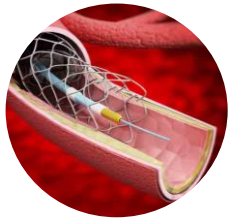
CHS™ Medical Devices

> Anti-thrombotic coating for vascular devices

Opportunities & validation

CHC™ for medical devices – prospects of a high-margin business model

Thrombosis in relation to medical device use



→ Artificial surfaces can cause thrombotic reactions upon contact with blood

→ Vascular stents, dialysis catheters, etc. all initiate immune thrombosis

Thrombosis may increase patient risks – clot formation, infection, endothelial and damage – compromising device function

Coating with CHS™

→ Corline Heparin Surface (CHS™) coating system can be used on any type of medical device, e.g. coronary stents and dialysis catheters

→ CHS™ renders high concentration of surface-bound heparin locally on the device, without any systemic heparin exposure for the patient

→ Coagulation and infection risk is reduced at the source, and the risk of bleeding associated with IV-heparin treatments is mitigated

Competitive landscape & profitability benchmark

→ **In head-to-head comparisons:** CHS™ functionality is on par or better than industry gold standard CBAS® (Carmeda/Gore Medical)

→ **Business model advantage:** CHS™ can easily be outsourced to customers – simple CHC based design

→ CBAS® cannot be easily outsourced to customers

→ Medical device coating business has **prospects of high-margins**

Competitor EBITDA-margin (%)

2016	2017	2018	2019
69%	**64%**	**74%**	**66%**

Establishing a track-record within device coating

Use case examples

- ✓ CHS™ surface technology applied on bare metal **stents**, **stent grafts** and **vascular grafts** can minimise the risk for blood clotting
- ✓ CHS™ coating reduces the risk of thrombosis during the **ablation catheter** procedure, which can lead to acute stroke or even death

Current status

>100,000

patients in EU have received coronary stents coated with CHS™

Imperative CARE

SEK 35m

expected annual income on full roll-out of CHS™ treated stroke care product – more in pipe-line

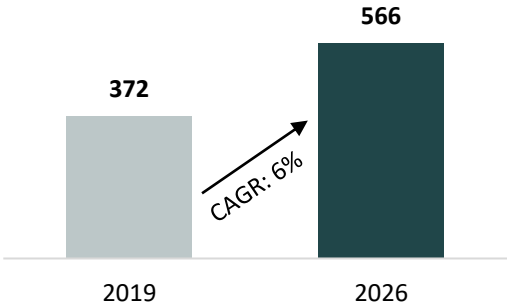
Kardium

SEK 50m

expected annual income on full roll-out of CHS™ treated ablation catheters

Future potential

Global medical device coatings market[1] (USDm)



Anti-thrombotic coatings are estimated to represent **USD 50-100m**[2] of the 2019 medical device coatings market

Source: (1) Global Medical Coatings Sales Market Report 2020, MarketResearch.com; (2) Company estimate based on aforementioned market report and competitor sales

Renaparin®

> Improving the outcome of kidney transplantation

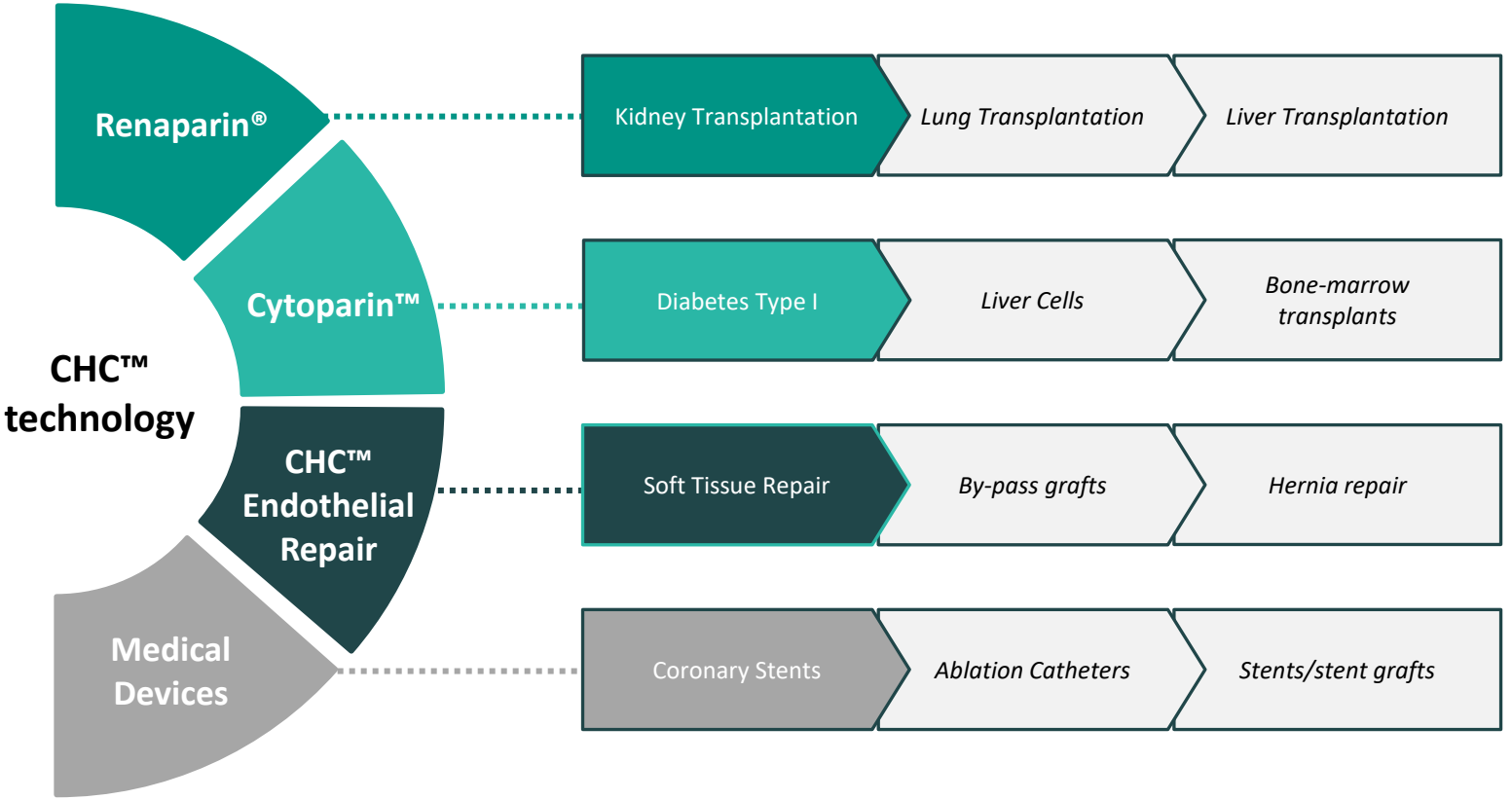
CHS™ Medical Devices

> Anti-thrombotic coating for vascular devices

Opportunities & validation

> CHC™ – potential to become a surface coating platform

Opportunities for expansion based on CHC™



CHC™ – validated by over 80 scientific publications

CHC™ – robust scientific validation…

- → **20+** articles on regenerative medicine
- → **25+** articles on medical device coating
- → **40+** articles on R&D use

Validated by our KOLs

Rutger J. Ploeg
Professor of Transplant Biology
University of Oxford

Robert Gaston
Senior Director, Regulatory & Scientific Affairs and Senior Medical Director
Clinical Trial & Consulting (CTI)

…with publications in reputable journals

STEM CELLS
TRANSLATIONAL AND CLINICAL RESEARCH

Are Therapeutic Human Mesenchymal Stromal Cells Compatible with Human Blood?

Gesine Moll,[a] Ida Rasmusson-Duprez,[b] Lena von Bahr,[a,c] Anne-Marie Connolly-Andersen,[d,e] Graciela Elgue,[b] Lillemor Funke,[b] Olaima A. Hamad,[b] Helena Lidmark,[a] Petra U. Magnusson,[b] Javier Sanchez,[b] Yuji Terakura,[a] Kristina Nilsson-Ekdahl,[b] Olle Ringdén,[a] Olle Korsgren,[b] Bo Nilsson,[b] Katarina Le Blanc[a,c]

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Key Words. Mesenchymal stromal cell • Endothelial cell • Cellular therapy • Thrombosis

ABSTRACT

Multipotent mesenchymal stromal cells (MSCs) are tested in numerous clinical trials. Questions have been raised concerning fate and function of these therapeutic cells after systemic infusion. We therefore asked whether culture-expanded human MSCs elicit an innate immune attack, termed instant blood-mediated inflammatory reaction (IBMIR), which has previously been shown to compromise the survival and function of systemically infused islet cells and hepatocytes. We found that MSCs expressed hemostatic regulators similar to those produced by endothelial cells but displayed higher amounts of prothrombotic tissue-stromal factors on their surface, which triggered the IBMIR after blood exposure, as characterized by formation of blood activation markers. This process was dependent on the cell dose, the choice of MSC donor, and particularly the cell-passage number. Short-term expanded MSCs triggered only weak blood responses in vitro, whereas extended culture and coculture with activated lymphocytes increased their prothrombotic properties. After systemic infusion to patients, we found increased formation of blood activation markers, but no formation of hyperfibrinolysis marker D-dimer or acute-phase reactants with the currently applied dose of 1.0–3.0 × 10⁶ cells per kilogram. Culture-expanded MSCs trigger the IBMIR in vitro and in vivo. Induction of IBMIR is dose-dependent and increases after prolonged ex vivo expansion. Currently applied doses of low-passage clinical-grade MSCs elicit only minor systemic effects, but higher cell doses and particularly higher passage cells should be handled with care. This deleterious reaction can compromise the survival, engraftment, and function of these therapeutic cells. STEM CELLS 2012;30:1565–1574

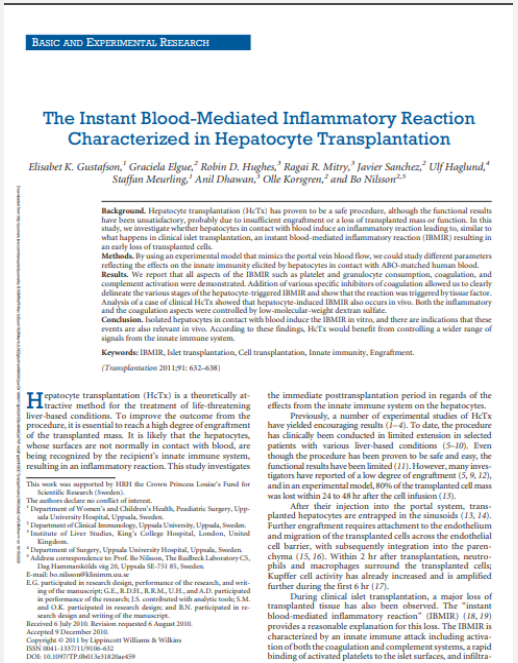
Disclosure of potential conflicts of interest is found at the end of this article.

INTRODUCTION

Based on their immunomodulatory and tissue reparative properties, multipotent mesenchymal stromal cells (MSCs) have been thought to offer a novel therapeutic approach for treatment of various inflammatory diseases [1–3]. At present, MSCs are being evaluated in clinical trials in cartilage repair, stroke, spinal cord injury, graft-versus-host disease (GvHD), heart disease, Crohn's disease, and several other diseases [4]. Intravenous infusion of MSCs appears safe, [3] and no acute toxicity has been reported, at the currently applied cell dose. However, many basic questions concerning the hemocompatibility of MSCs [5] and their fate after systemic infusion remain unanswered [4, 6].

Early investigation into the biodistribution of MSCs after systemic delivery indicated that MSCs are rapidly cleared from the circulation in humans [7]. MSCs infused intravenously into rodents are rapidly entrapped in the lung [8–14] and then cleared from the circulation [15]. The microemboli that form in the pulmonary circulation are potentially lethal to the animals if sufficient numbers of cells are infused [11, 12]. Similarly, MSCs injected on the arterial side arrest at the precapillary level [15]. Studies in large animals have corroborated the formation of arterial microinfarcts as well as lung entrapment after infusion on the venous side [16, 17]. Rapid trapping in the lung has been attributed to the combination of high concentrations of strongly adhesive MSCs entering lung capillaries of a low diameter during the first passage [6]. However, the fraction of MSCs trapped in the lung is not

Author contributions: G.M., I.R.D., K.N.E., O.K., and K.L.B.: designed the study and wrote the manuscript; O.K. and K.L.B.: led the clinical study; G.M., I.R.D., L.v.B., A.M.C.A., and J.S.: performed the research and analyzed the data; P.M., O.E., L.F., L.L., O.H., and Y.T.: assisted various experiments.



BASIC AND EXPERIMENTAL RESEARCH

The Instant Blood-Mediated Inflammatory Reaction Characterized in Hepatocyte Transplantation

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Background. Hepatocyte transplantation (HcTx) has proven to be a safe procedure, although the functional results have been unsatisfactory, probably due to insufficient engraftment or a loss of transplanted mass or function. In this study, we investigate whether hepatocytes in contact with blood induce an inflammatory reaction leading to, similar to what happens in clinical islet transplantation, an instant blood-mediated inflammatory reaction (IBMIR) resulting in an early loss of transplanted cells.
Methods. By using an experimental model that mimics the portal vein blood flow, we could study different parameters reflecting the effects on the innate immunity elicited by hepatocytes in contact with ABO-matched human blood.
Results. We report that all aspects of the IBMIR such as platelet and granulocyte consumption, coagulation, and complement activation were demonstrated. Addition of various specific inhibitors of coagulation allowed us to clearly delineate the various stages of the hepatocyte-triggered IBMIR and show that the reaction was triggered by tissue factor. Analysis of a case of clinical HcTx showed that hepatocyte-induced IBMIR also occurs in vivo. Both the inflammatory and the coagulation aspects were controlled by low-molecular-weight dextran sulfate.
Conclusion. Isolated hepatocytes in contact with blood induce the IBMIR in vitro, and there are indications that these events are also relevant in vivo. According to these findings, HcTx would benefit from controlling a wider range of signals from the innate immune system.

Keywords: IBMIR, Islet transplantation, Cell transplantation, Innate immunity, Engraftment.

(*Transplantation* 2011;91: 632–638)

Hepatocyte transplantation (HcTx) is a theoretically attractive method for the treatment of life-threatening liver-based conditions. To improve the outcome from the procedure, it is essential to reach a high degree of engraftment of the transplanted mass. It is likely that the hepatocytes, whose surfaces are not normally in contact with blood, are being recognized by the recipient's innate immune system, resulting in an inflammatory reaction. This study investigates the immediate posttransplantation period in regards of the effects from the innate immune system on the hepatocytes.

Previously, a number of experimental studies of HcTx have yielded encouraging results (*1–4*). To date, the procedure has clinically been conducted in limited extension in selected patients with various liver-based conditions (*5–10*). Even though the procedure has been proven to be safe and easy, the functional results have been limited (*11*). However, many investigators have reported of a low degree of engraftment (*5, 9, 12*), and in an experimental model, 80% of the transplanted cell mass was lost within 24 to 48 hr after the cell infusion (*13*).

After their injection into the portal system, transplanted hepatocytes are entrapped in the sinusoids (*13, 14*). Further engraftment requires attachment to the endothelium and migration of the transplanted cells across the endothelial cell barrier, with subsequently integration into the parenchyma (*15, 16*). Within 2 hr after transplantation, neutrophils and macrophages surround the transplanted cells; Kupffer cell activity has already increased and is amplified further during the first 6 hr (*17*).

During clinical islet transplantation, a major loss of transplanted tissue has also been observed. The "instant blood-mediated inflammatory reaction" (IBMIR) (*18, 19*) provides a reasonable explanation for this loss. The IBMIR is characterized by an innate immune attack including activation of both the coagulation and complement systems, a rapid binding of activated platelets to the islet surfaces, and infiltra-

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The authors declare no conflict of interest.
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Advancing regenerative medicine through CHC™ coating technology

Proprietary CHC™ technology	• Proprietary heparin conjugate technology that reduces bleeding risks associated with systemic administration of heparin • Reduces coagulation, complement cascade activation and inflammation • Used for surface modification of medical devices, cells and vasculature of solid organs
Renaparin® for kidney transplantation	• Preventing ischemia/reperfusion injury through ex vivo treatment for improved kidney transplantation outcomes • Protection from innate immune response and improved immediate kidney function, demonstrated through proof of concept studies in animals • Phase I trial presented favourable safety and tolerability profile • Phase II trial currently being planned
Opportunities for expansion	• Renaparin® – further uses within lung and liver transplantation being explored • CHS™ – validated potential in medical device coating with two pivotal customer contracts signed H2 2020 • CHC™ technology has potential to become a surface modification platform within regenerative medicine (e.g. stem cell transplantation and soft tissue repair)

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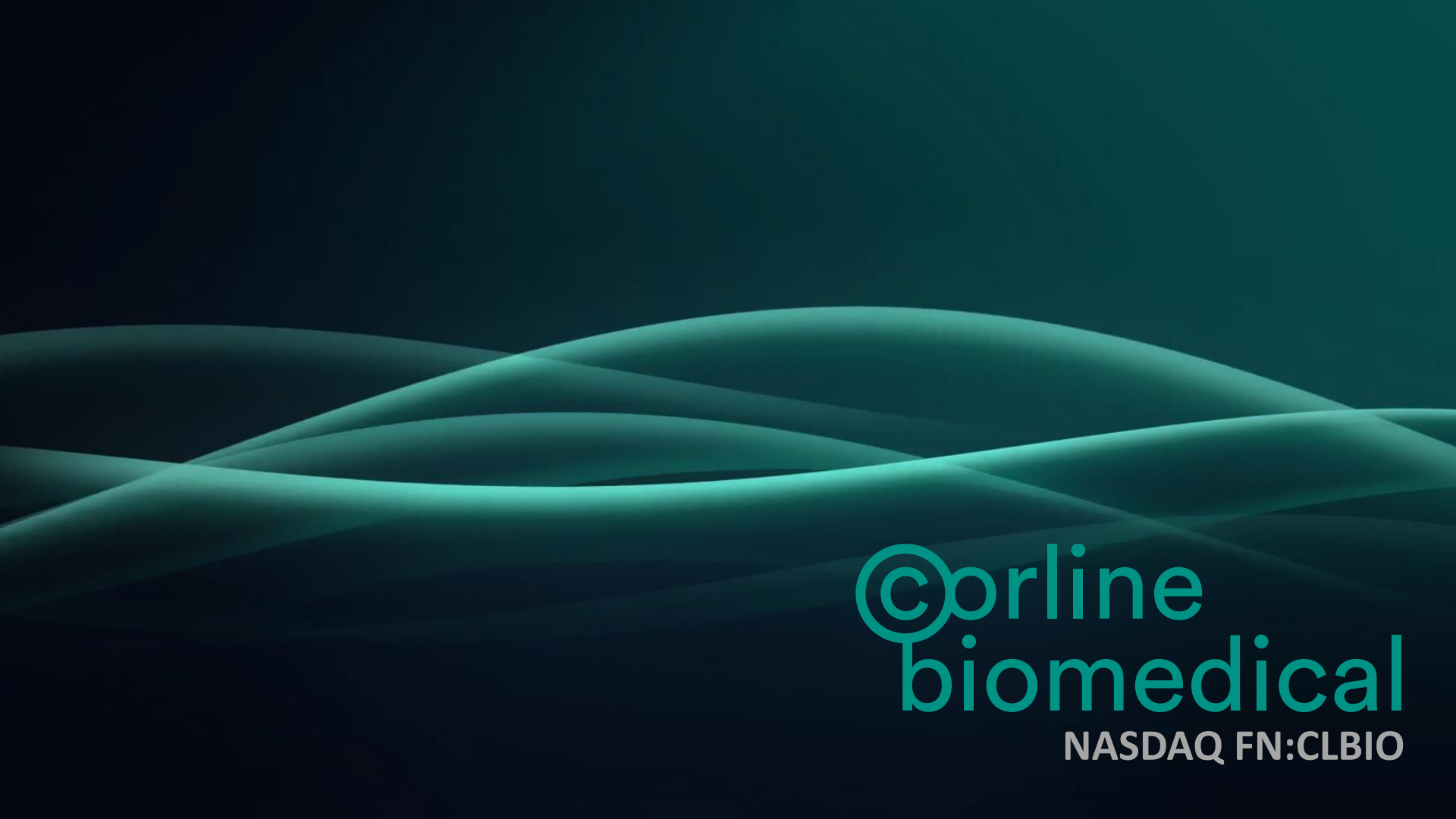
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