


corline
biomedical

The background features several overlapping, wavy, horizontal bands in shades of teal and green, creating a sense of motion and depth.

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)

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 Sunnaväder
Board Member

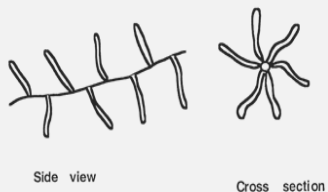


Gunilla Ekström
Board Member

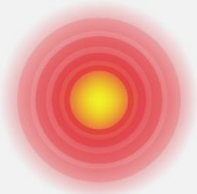


Henrik Krook
Board Member

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

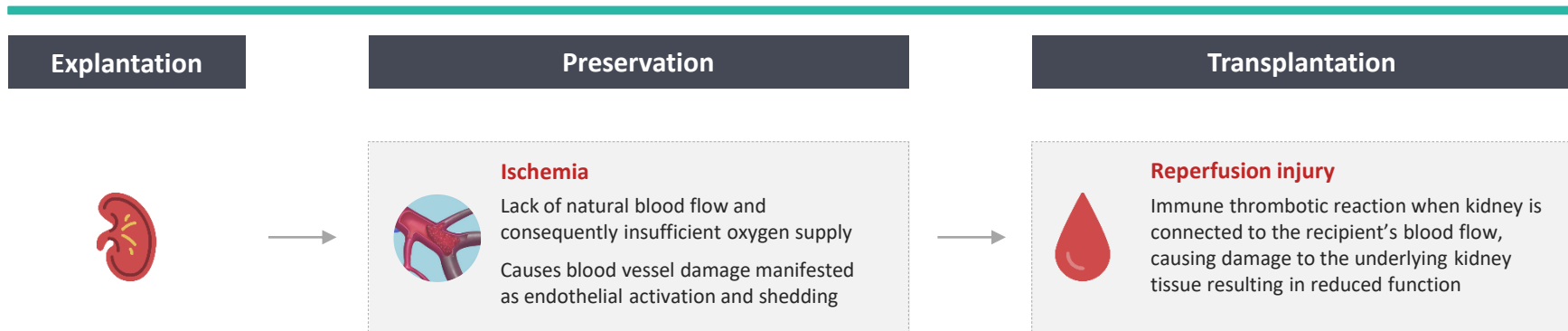
Renaparin®

> Improving the outcome of kidney transplantation

CHS™ Medical Devices

Opportunities & validation

Ischemia/reperfusion injury – no drug approved for prevention



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%
transplants affected

+10-14 days
added to ICU stay

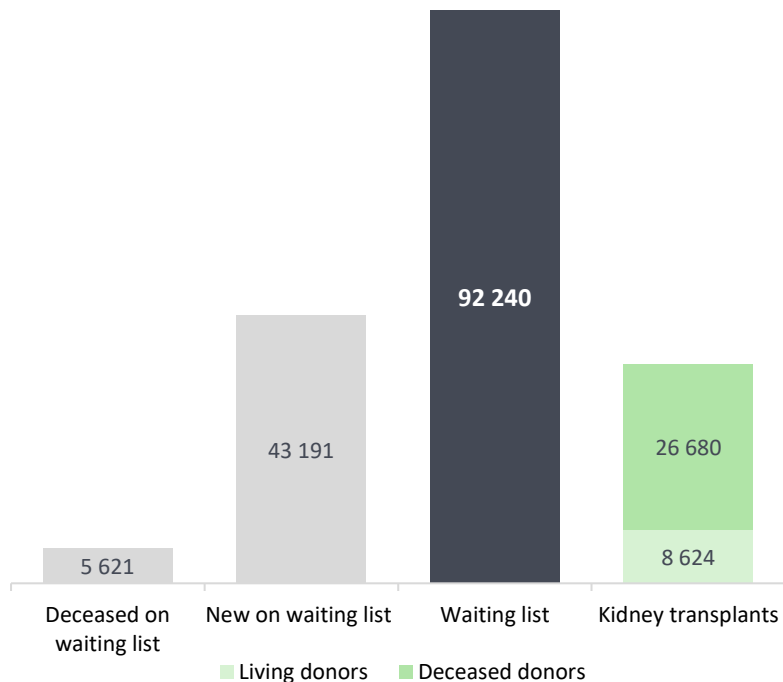
USD 100k
transplant cost

USD 2.5k/day
ICU cost

Organ shortage – a multi-faceted challenge for kidney transplantation

Significant organ shortage gap remains...

US & EU5 Kidney transplants¹ (2017)



...driving acceptance of marginal donors

Deceased donor kidney transplants CAGR 2012-17²

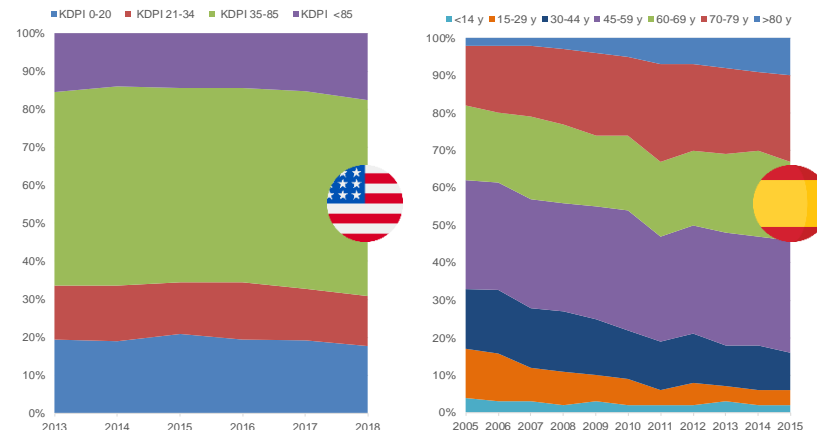
4.9%

US

3.1%

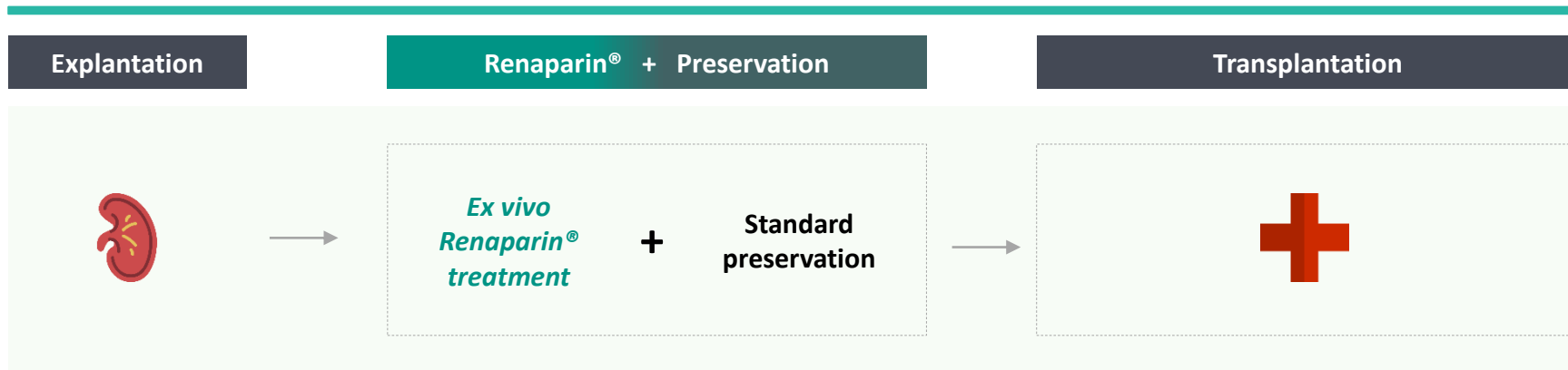
EU5

Increase in high KDPI and ECD donors³



> Marginal donors are more susceptible to IRI/DGF

Renaparin® – reducing risk of marginal donor kidney transplantation



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**

With a good
safety profile

**Phase II Design
Underway**

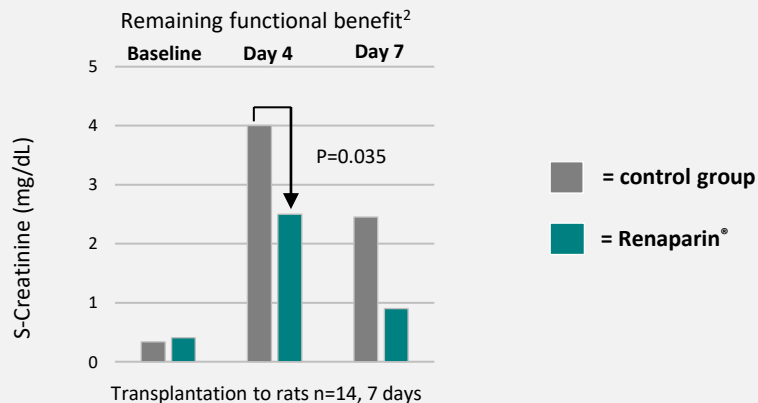
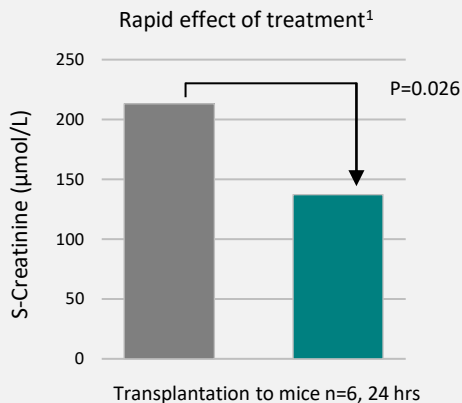
Primary end-point is
eGFR at 3 months

**Orphan Drug
Designation**

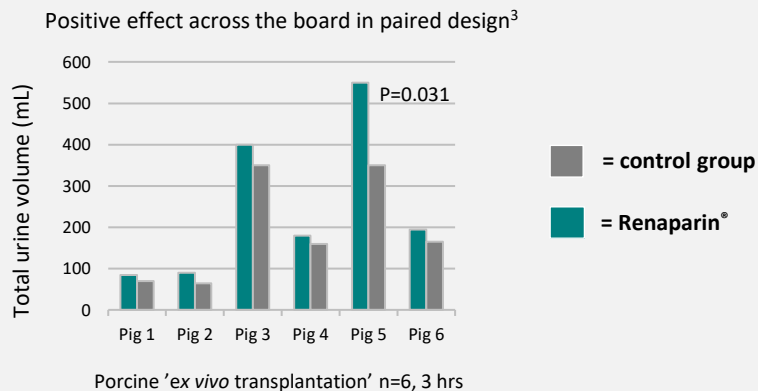
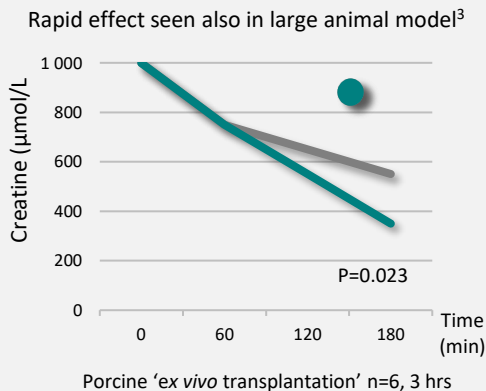
Obtained for both
US and EU

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

Small animals



Large animals



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

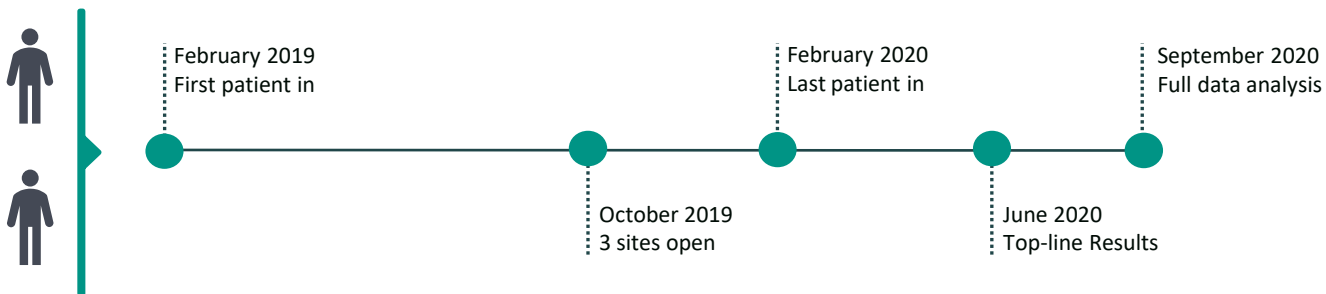
- Number and severity grade of Serious Adverse Events and Adverse Events including description of their associated MedDRA terms during the first 30 days after transplantation

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



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

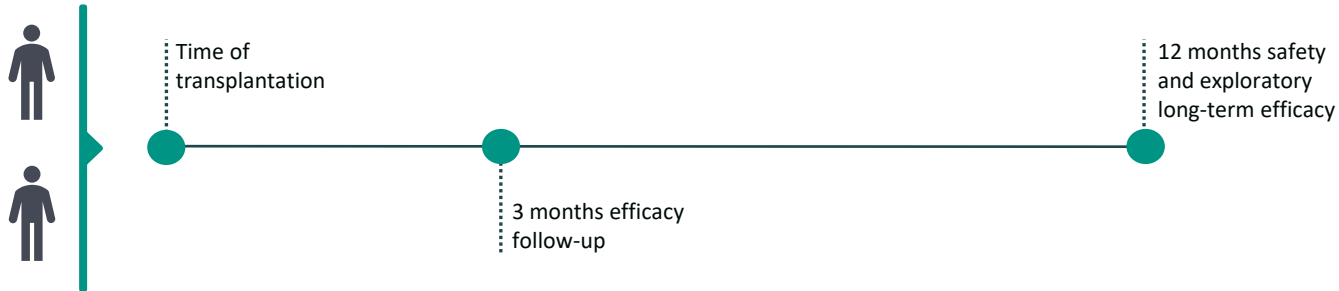
- Primary end-point: eGFR (MDRD7) at 3 months
- Secondary endpoints: creatinine, incidence and severity of DGF, BPAR proven rejection and assessment of AE/SAEs

Target Population






- Deceased donor kidney recipients at increased risk of developing IRI/DGF (ECD-DBD, DCD)

40 patients
Renaparin®

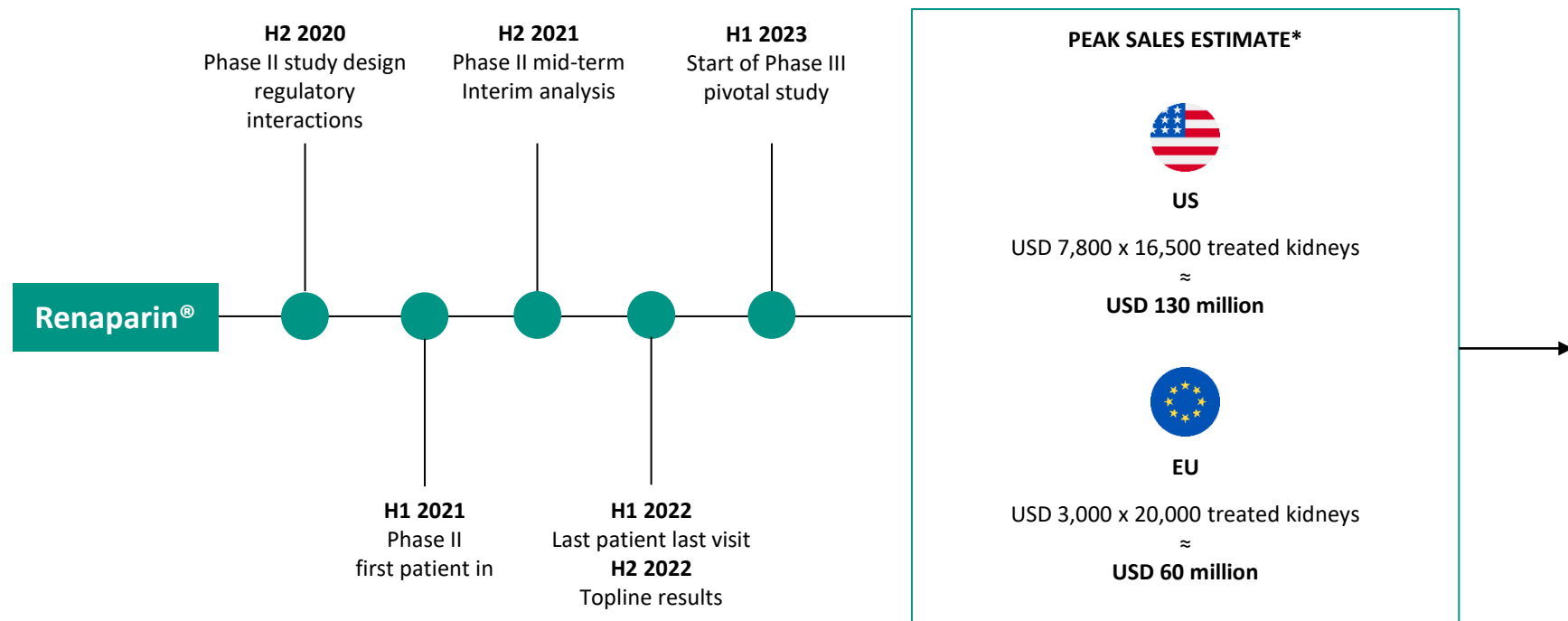
40 patients
Placebo



Renaparin® – primary prevention as a differentiating factor

Company	Product description	Stage	Characteristics
	<ul style="list-style-type: none"> Ex-vivo administration into transplant organ Repairs and protects organ vessel system 	Phase II	<ul style="list-style-type: none"> + Protects kidneys from innate immunity + Avoids bleeding risks of systemic heparin administration
	<ul style="list-style-type: none"> HGF mimetic that activates repair pathways IV twice after transplantation 	Phase III	<ul style="list-style-type: none"> + Promising Phase II data + Targets treatment of actual cases - Market opportunity reduced as it targets only known cases - Systemic administration
	<ul style="list-style-type: none"> TP53 gene inhibitor- temporarily reduces cell apoptosis IV injected once at transplantation 	Phase III	<ul style="list-style-type: none"> + Novartis partnership + Good safety profile - Did not meet Phase II endpoints - IV injected
	<ul style="list-style-type: none"> Complement inhibitor (C1INH), IV injected at transplantation 	Phase II	<ul style="list-style-type: none"> + 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
	<ul style="list-style-type: none"> Oxygen carrier from sea worms Ex vivo administration into preservation fluid 	Medical Device Phase I/II	<ul style="list-style-type: none"> + Medical device. + Promising early efficacy signals in Phase I/II - No controlled source (sea worm) makes CMC a challenge

Development timeline to market



Renaparin®

> Improving the outcome of kidney transplantation

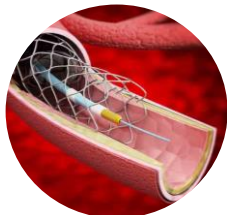
CHS™ Medical Devices

> 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™



SEK 35m

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

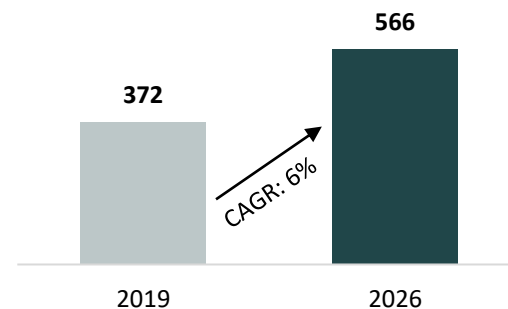


SEK 50m

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

Future potential

Global medical device coatings market¹ (USDm)



Anti-thrombotic coatings are estimated to represent **USD 50-100m²** of the 2019 medical device coatings market

Renaparin®

> Improving the outcome of kidney transplantation

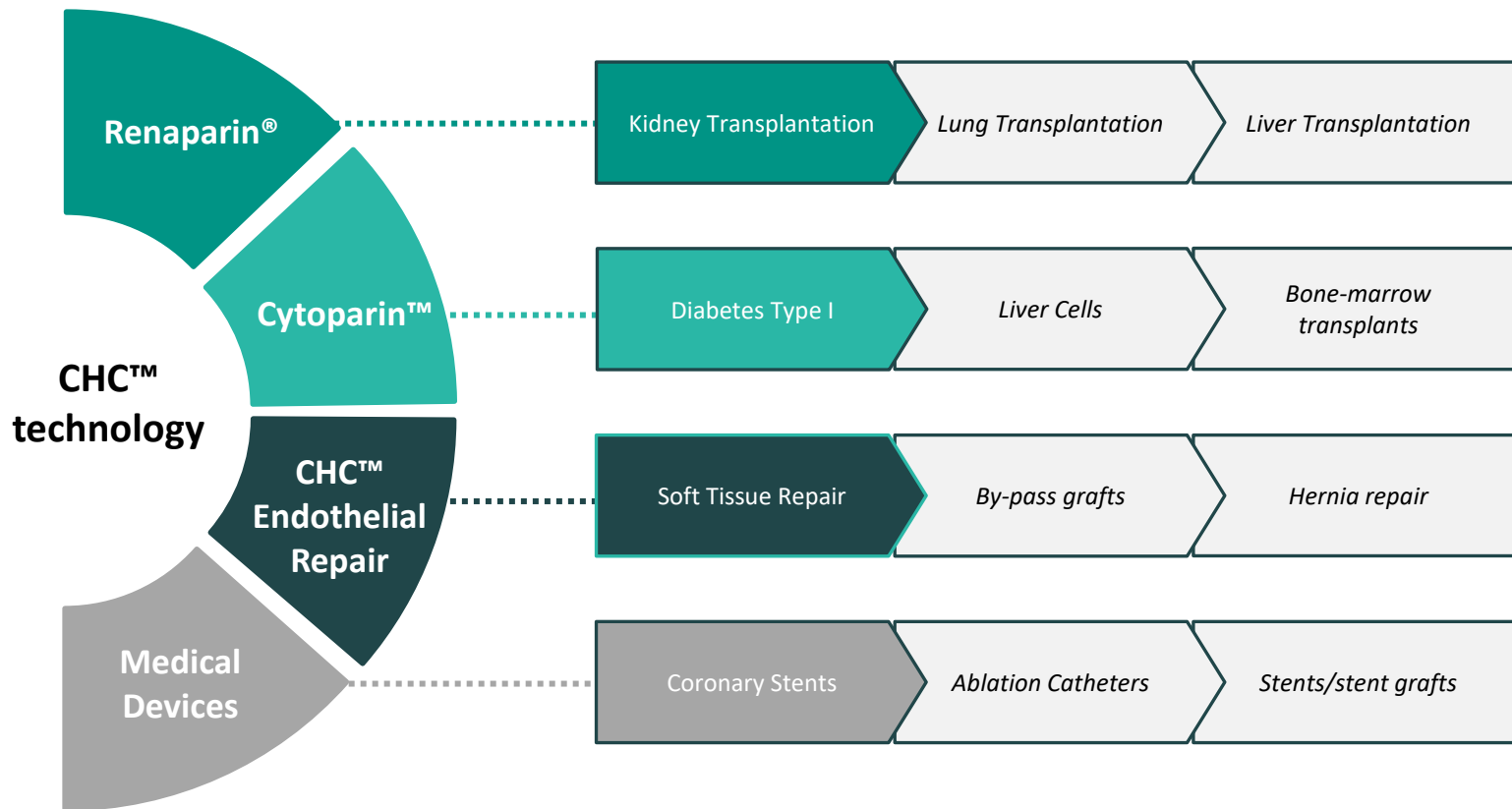
CHS™ Medical Devices

> 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?

Giuseppe Mele,^{1,2} Iga Roszkowska-Dobrow,² Lena von Barth,^{2,3} Anna-Maria Conzales-Sanchez,^{4,5*} Gabriela Erazo,² Leilanianna Fong,² Olaya A. Hidalgo,² Helena Lindvall,² Perera L. Muthunayagam,² Javier Sanchez,² Yajit Teranishi,² Karolina Nandamoorath,² Olay Rosales,² Olek Kowalski,² Björn Nilsson,² Karolina Le Blang.^{2,3*}

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Key Words: Mesenchymal stromal cell; Translational cell; Cellular therapy; Translational

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 immunostimulatory 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 hyperfibrinolytic marker. Endine 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;30:1548–1554

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 cardiac, stroke, spinal cord injury, graft-versus-host disease (GVHD), liver disease, Crohn's disease, and several other diseases [4]. Intravenous infusion of MSCs appears safe [5] and its 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].

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

BASIC AND EXPERIMENTAL RESEARCH

The Instant Blood-Mediated Inflammatory Reaction Characterized in Hepatocyte Transplantation

Elisabet K. Gustafson,¹ Graciela Elgort,² Robin D. Hughes,³ Ragui R. Mitry,³ Javier Sanchez,² Ulf Haglund,⁴ Staffan Meurling,⁵ Anil Dhawan,⁶ Ole Krogvgen,⁷ and Björn Nilsson^{1*}

Background. Hepatocyte transplantation (HcTx) has proven to be a safe procedure, although the functional results have been unsatisfactory, probably due to 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 innate factors. 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 this procedure, it is essential to reach a high degree of engraftment of the transplanted cells. 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

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The authors declare no conflict of interest.

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EG participated in research design, performance of the research, and writing of the manuscript; G.E., R.D.H., R.M.M., U.H., and A.D. participated in performance of the research; J.S. contributed with analytic tools; S.M. and O.K. participated in research design and R.D.H. participated in research design and writing of the manuscript.

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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 conditions in selected patients whose surfaces are not normally in contact with blood. Even though the procedure has been proven to be safe and easy, the functional results have been limited (1). However, many investigators have reported of a low degree of engraftment (5, 8, 12), and in an experimental model, 80% of the transplanted cell mass was lost within 24 to 48 hr after the cell induction (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 subsequent 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 cell 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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