

# Hemoglobin Oxygen Therapeutics LLC

**The world leader in life preserving oxygen  
carrying solutions**

March 2021

Investor Presentation

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# Mission Statement

To develop and commercialize the first and best in class technology platform for oxygen-carrying solutions addressing critical unmet medical needs in human and veterinary indications.

# Company at a Glance

Delaware registered in 2014, technology is going back to 1990s with \$1 billion invested  
\$20 million in equity financing to date

Acquired and developed the intellectual property for two Hemoglobin-Based Oxygen Carrier (HBOC) products :

- Hemopure (HBOC-201) for human use
- Oxyglobin (HBOC-301) for veterinary use

Existing collaborations in veterinary and human markets

Groundbreaking HBOC organ perfusion technology

Currently 12 employees

Production facility in Souderton, Pennsylvania

# Highly experienced team

## Zaf Zafirelis

Co-Founder & CEO



30 years of Biotech, Pharma, and Medical Device industries  
More than 20 years CEO experience  
Raised more than \$100 million with successful exits

## Igor Serov

Co-Founder & CFO



Over 20 years of investment banking experience

## Joseph Rappold, MD

Chief Medical Officer



30 years of active service (US Navy) with 6 combat deployments commanding a variety of medical facilities. Professor of Surgery at Tufts University. Chief of Acute Care Surgery and Trauma Medical Director at Maine Medical Center.

## Brian Dawson

Senior Director, Process Development



25 years experience in development & commercialization of HbO<sub>2</sub>'s products from pre-clinical research to product approval & marketing.

## Greg Dube, PhD

VP, Research & Development



30 years experience in drug R&D in large pharma and biotech firms.

## Arkadiy Pitman

Senior Director, Statistics & Data Management



20 years of pharmaceutical & healthcare US experience with strong background in mathematics, statistics & logistics.

## Melissa Zafirelis

Director, Regulatory & Clinical Operations



Over 22 years multinational regulatory & clinical operations experience.

## Fantao Meng








Director of Research and Development



Hemoglobin specialist with 20 years of research experience in developing hemoglobin-based oxygen carriers (HBOCs)

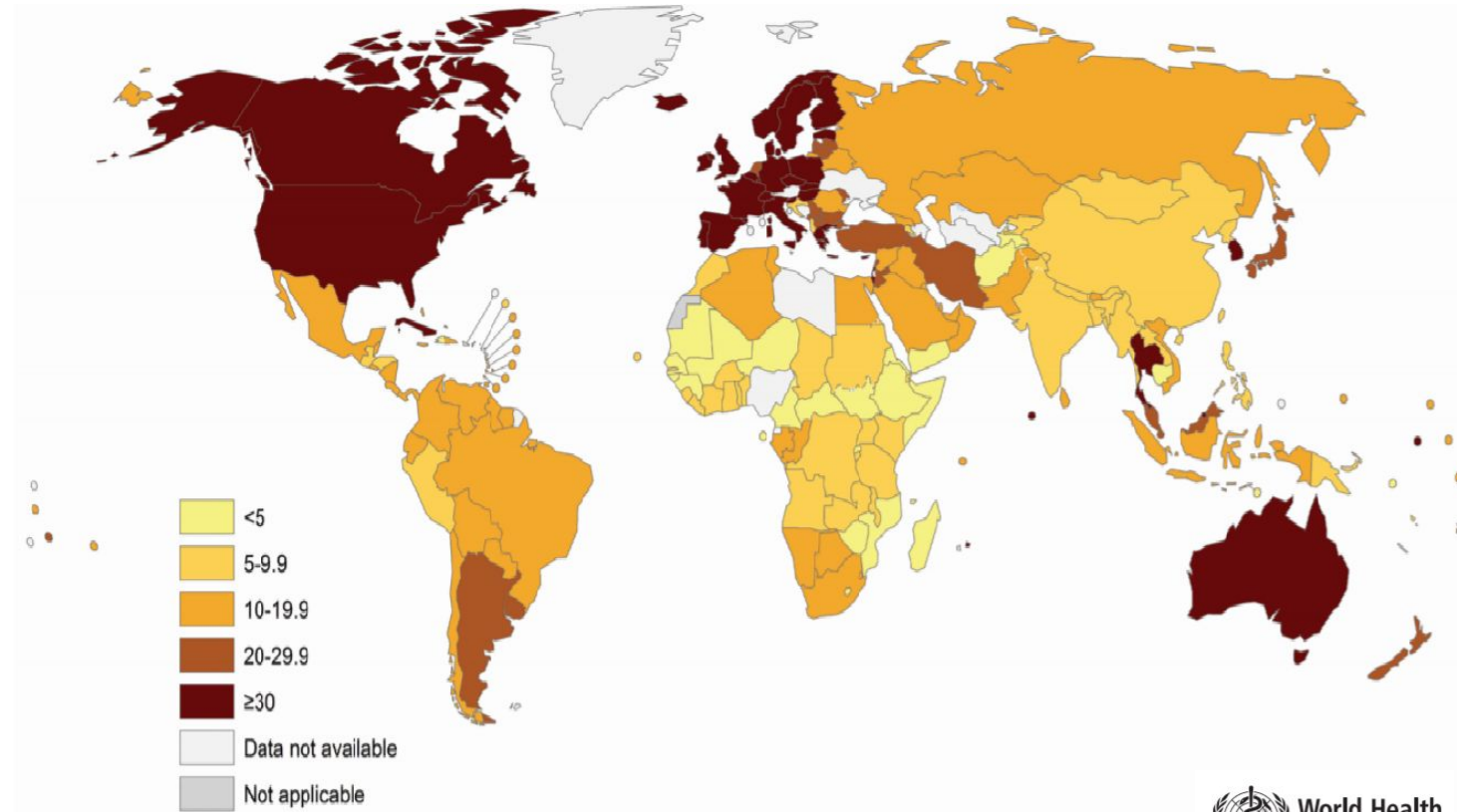
# Hemopure and Oxyglobin

HBOCs with unique efficacy and safety profiles...

		Packed Red Blood Cells	Hemopure/Oxyglobin
	<b>STORAGE</b>	Refrigerated	Room temperature (2-30°)
	<b>PREPARATION</b>	Testing, typing, cross matching	Ready to use - no reconstitution
	<b>COMPATIBILITY</b>	Type specific	Universal
	<b>SHELF-LIFE</b>	42 days	36 months
	<b>PURITY</b>	Tested and screened for known infectious agents	Sterile pharmaceutical product
	<b>RAW MATERIAL</b>	Blood, limited availability	Bovine hemoglobine : abundant, controlled source
	<b>EFFECTIVENESS</b>	Dependant on storage length	Immediate oxygen delivery Same hemoglobin concentration as whole blood (13 g/dl)

# Worldwide blood shortage

- Shortages of blood donations, not reaching the critical threshold of 30 per 1000 population in many countries
- COVID-19 pandemic highlights the need for a product that can successfully substitute blood's oxygen carrying capacity in time of need
- Hemopure has received marketing authorizations for acute anemia in South Africa & Russia



Global Status Report on Blood Safety and Availability 2016



**Russia and South Africa alone cumulate a 3 millions blood units shortfall.  
Blood shortage represents a \$1 billion worldwide market per year.**

# Prehospital Trauma & Medical Readiness



- Strategic National Stockpiles



- Out-of-hospital / Ambulance services



- Remote locations / Military battlefield use



**Prehospital trauma (military & civilian) and disaster preparedness in the US markets represent \$500 million in revenue per year.**



# Blood Is Not An Option

- Blood disorders including Sickle Cell disease, Hemolytic Anemia, etc.
- Rare blood types
- Religious objectors (refuse blood transfusion).



**160,000 patients with blood disorders need transfusions per year in US and Europe, which represents \$400 million in revenue per year. Religious objectors represent another \$149 million in annual revenue in the United States alone.**



# Blood shortage, a similar issue in veterinary markets

- 2 million canine transfusions are needed annually in US and in Europe
- Veterinary product is approved in US and EU
- 30 different species has been successfully treated with Oxyglobin
- Only up to 25% of veterinary transfusion blood supplies are covered by blood banks
- 84% of US veterinarians are dissatisfied with current options



**The US and European canine markets represent \$550 million in revenue.**



# Organ Transplantation: Another Worldwide Shortage



- There is a constant demand for donated organs
- Organ eligibility criteria are extremely severe
- The ability to extend the life of organs ex-vivo and to assess their compatibility and health can dramatically improve the supply for transplantations
- The perfusion process allows doctors to assess reconditioning and viability of organs, limbs and tissues prior to transplantation both at room temperature and body temperature (37°C)

**The transplantation market amounts to \$137 million per year.**

# ➔ Additional indications include...

- Ischemia indications including
  - ✓ Minimization of infarct size (STEMI - ST-Elevation myocardial infarction)
  - ✓ Resuscitation from sudden cardiac arrest
  - ✓ Minimization of tissue loss in Limb ischemia / PAD claudication
- Antidote for carbon-monoxide and cyanide poisoning
- Oncology with solid tumors
- Burn victims and plastic surgery
- Perfusion of
  - ✓ Limbs prior to transplantation
  - ✓ Brain cells for diagnostic purposes

**The average potential US market size in each of these new indications is \$500m.**

# Robust Pipeline

Product	Indication	Pre-Clinical	Proof of Concept	Pivotal	Approval	Marketing
<b>Veterinary</b>						
Oxyglobin	Anemia - Canine	✓	✓	✓	✓	✓
Oxyglobin	Anemia - Feline, Equine	✓	✓			<b>Off-label use</b>
Oxyglobin	Anemia - Zoological Species	✓	✓			<b>Off-label use</b>
<b>Human</b>						
Hemopure	Acute Anemia (S.Africa/Russia)	✓	✓	✓	✓	<b>2022/23</b>
Hemopure	Acute Anemia - Blood not an Option	✓	✓	✓	<b>2023 EU/US</b>	
Hemopure	Acute Anemia - Pre-hospital Trauma	✓	✓	<b>on-going</b>	<b>2023/24</b>	
ZK1	Organ Perfusion for Transplantation	✓	✓	✓	<b>2022 EU</b>	
ZK1	Limb / Flap Perfusion	✓	✓	<b>2025</b>		
HBOC-201	Smoke inhalation antidote	✓	✓	<b>2022</b>		
Hemopure	FDP reconstitution	✓	✓	<b>2024/25</b>		
HBOC-201	Solid tumor treatment	✓	<b>2021</b>			
HBOC-201	Ischemia	✓	✓	<b>2026</b>		

# Strong value creating recent progress

- US Department of Defense signed and sponsored Hemopure trial for pre-hospital trauma
- Groningen liver transplantation trial finalized with 100% success
- Patent filed for HBOC/Freeze Dried Plasma combination
- Collaboration signed with Department of Defense and Teleflex on Hemopure use as a reconstitution agent for FDP
- Yale University brain perfusion study with Hemopure published in Nature
- Publication of high dose Hemopure case series
- Patent filed for smoke inhalation antidote
- Publication of an article supporting use of Hemopure in emergency preparedness including pandemics such as COVID-19

# Strong value creating milestones

- FDA submission for Hemopure Phase 3 pivotal BNO clinical trial
- Start of hand transplant study
- Submission of the IDE for the kidney perfusion trial
- Oncology collaboration for the treatment of refractory solid tumors
- Completion of production facility
- Filing of CE Mark for perfusion solution
- cGMP facility validation by US & EU regulators
- Oxyglobin market launch
- Hemopure market launch in South Africa

# Major academic & health centers collaborations





# Expanded access program hospitals



# Over 300 peer-reviewed publications

**PRETRANSPLANT SEQUENTIAL HYPOTERMIC AND NORMOTHERMIC MACHINE PERFUSION OF SUBOPTIMAL LIVERS DONATED AFTER CIRCULATORY DEATH USING A HEMOGLOBIN-BASED OXYGEN CARRIER PERFUSION SOLUTION**

Yves de Waele<sup>1,2</sup>, Aida K.M. Madder<sup>3,4</sup>, Maarten W. N. Nijsten<sup>5</sup>, Maureen J.M. Vermeir<sup>6</sup>, Aad P. van den Berg<sup>7</sup>, Marlene I. de Boer<sup>8</sup>, Carlijn A. Uije<sup>9</sup>, Marlene T. van der Wal<sup>10</sup>, Ruben J.J. de Kock<sup>11</sup>, Otto B. van Leeuwen<sup>12</sup>, Peter Meyer<sup>13</sup>, Marisa P. van der Wal<sup>14</sup>, Vincent F. de Maess<sup>15</sup>, Ruben J. Porte<sup>16</sup>

**Therapie einer extremen Anämie mit vernetztem Rinderhemoglobin**

Fallberichte mit Literaturübersicht

**Restoration of brain circulation and cellular functions hours post-mortem**

Parvathi Venkila<sup>1,2</sup>, Rishabh C. Sarin<sup>1,3,4</sup>, Javed Siddiqui<sup>5</sup>, Perumal Selvaraj<sup>1,2,6</sup>, Vijay M. Mohan<sup>1,2</sup>, Anil M.P. Das<sup>1,2</sup>, Robin P. Suresh<sup>8,9</sup>, Madhavan S. B. Chandrasekar<sup>1,2</sup>, Sridhar Reddy<sup>1,2</sup>, Suresh Kumar<sup>1,2</sup>, Theran W. Chung<sup>10</sup>, Shreshth K. Khanna<sup>11,12</sup>, Devendra Kumar<sup>1,2</sup>, Charles J. Gonsky<sup>13,14</sup>, Sachin D. Pathak<sup>15</sup>, Sushant S. Wadhwa<sup>16</sup>, Javed Khan<sup>17,18,19,20,21</sup>

**Consult QD**

**Hemopure Saves the Life of a Patient With Severe Hemorrhage**

Case highlights the utility of a blood substitute product when blood transfusions are not an option

**Abstract:** A patient with severe hemorrhage and anemia was treated with Hemopure (HBOC-201) in addition to blood transfusions. HBOC-201 was used as a bridge to definitive hemostatic therapy. The patient was successfully treated with HBOC-201 and did not require further blood transfusions. HBOC-201 is a safe and effective treatment for acute anemia in patients with severe hemorrhage who are unable to receive sufficient red blood cells from blood transfusions.

**CASE REPORT**

**Management of thymoma-associated pure red cell aplasia: A novel use of blood substitute HBOC-201 in a Jehovah's Witness**

Maria M. Beldhuis<sup>1</sup>, Cheryl Cass<sup>2</sup>, Anil T. Avasthi<sup>3</sup>, Gregory P. Bialek<sup>4</sup>, Gregory J. Kraybill<sup>5</sup>, Joel V. DeWaal<sup>6</sup>

**CASE REPORT**

**Hemoglobin-Based Oxygen Carrier Rescues Double Transplant Patient From Life-Threatening Anemia**

Michael J. Casper<sup>1</sup>, O. Akar<sup>2</sup>, D. Gendron<sup>3</sup>, M. Lynn<sup>4</sup>

**COMMENTARY**

**Addressing the unmet need of life-threatening anemia with hemoglobin-based oxygen carriers**

Randall S. Zwissler<sup>1</sup>, Amber G. Aronoff<sup>2</sup>, Joseph Muscarelli<sup>3</sup>, Nicole H. Simon<sup>4</sup>, Anthony J. Long<sup>5</sup>, Paul G. Vero<sup>6</sup>, and Cary S. Silverman<sup>7</sup>

**A case study of 10 patients administered HBOC-201 in high doses over a prolonged period: outcomes during severe anemia when transfusion is not an option**

Mark Zimberg<sup>1</sup>, Ted Griffin<sup>2</sup>, Elizabeth J. Griffla<sup>3</sup>, Gary Schwartz<sup>4</sup>, David S. Zarembo<sup>5</sup>, Stephen Wachtel<sup>6</sup>, Kim-Hwa Park<sup>7</sup>, Amanda Vercasini<sup>8</sup>, Matthew Lynn<sup>9</sup>, and Joseph Kowalski<sup>10</sup>

**Abstract:** The objective of this study was to evaluate the safety and efficacy of HBOC-201 in the treatment of severe anemia in patients who are unable to receive sufficient red blood cells from blood transfusions. Ten patients were treated with HBOC-201 in high doses over a prolonged period. All patients were successfully treated with HBOC-201 and did not require further blood transfusions. HBOC-201 is a safe and effective treatment for acute anemia in patients with severe hemorrhage who are unable to receive sufficient red blood cells from blood transfusions.

**CASE REPORT**

**Use of the blood substitute HBOC-201 in critically ill patients during stroke crisis: a three-case series**

Jonathan M. Davis<sup>1</sup>, Nura El-Haf<sup>2</sup>, Nivdih N. Shah<sup>3</sup>, Gary Schwartz<sup>4</sup>, Margarete Block<sup>5</sup>, James Walsh<sup>6</sup>, Clark T. Vanelli<sup>7</sup>, and Robert Halima<sup>8</sup>

**CASE REPORT**

**A Bridge to Bloodless Surgery: Use of Hemoglobin-Based Oxygen Carrier for Anemia Treatment and Autologous Blood Preservation During Redo Pulmonic Valve Replacement**

Henry Henderson, MD, Jonathan H. Chew, MD, Kenich A. Tanaka, MD, MSc

**blood**

40 • BASIC SCIENCE AND CLINICAL PRACTICE IN BLOOD TRANSFUSION | DECEMBER 7, 2017

**Use of a Hemoglobin Substitute (HBOC-201) to Treat Acute Anemia in a Leukemic Patient with Anti-Vel Antibodies**

N. Taghi Agajani, MD, Kenneth Saragovitz, MD, Harun Hashmi, MD, Guillermo McDaniel, MD (ASCP), Russell K. Bass, MD, PhD, Yibin Li, M.D., MSc, M.D., FRCPC, MD, PhD

**ESA PAPER**

**Transplantation of High-risk Donor Livers After Ex Situ Resuscitation and Assessment Using Combined Hypo- and Normothermic Machine Perfusion: A Prospective Clinical Trial**

Otto B. van Leeuwen, ESC<sup>1</sup>, Yves de Waele, MD<sup>2</sup>, Masato Fujimoto, MD, PhD<sup>3</sup>, Maarten W. N. Nijsten, MD, PhD<sup>4</sup>, Koen Vanhove, MD<sup>5</sup>, Geert-Jan Peetermans, PhD<sup>6</sup>, Maureen J. M. Vermeir, MD<sup>7</sup>, Koen M. B. B. Rogiers, MD<sup>8</sup>, Aad P. van den Berg, MD, PhD<sup>9</sup>, Marlene I. de Boer, MD, PhD<sup>10</sup>, Ruben J. J. de Kock, MD<sup>11</sup>, Van Leeuwen, PhD<sup>12</sup>, Vincent E. de Steyer, MD, PhD<sup>13</sup>, and Ruben J. Porte, MD, PhD<sup>14</sup>

**Abstract:** The aim of this study was to evaluate the safety and efficacy of ex situ normothermic machine perfusion (EMPF) for the resuscitation and assessment of high-risk donor livers. In this prospective clinical trial, 10 high-risk donor livers were resuscitated and assessed using EMPF before transplantation. All livers were successfully resuscitated and transplanted. EMPF is a safe and effective method for the resuscitation and assessment of high-risk donor livers.

**Original Clinical Research - Liver**

**The Use of an Acellular Oxygen Carrier in a Human Liver Model of Normothermic Machine Perfusion**

Daniela W. Leung, MD<sup>1</sup>, David H. Ehrig, PhD<sup>2</sup>, Lenora Wilson<sup>3</sup>, Van Doren, MD<sup>4</sup>, Timothy J. Hall, PhD<sup>5</sup>, Daniel A. Clark, PhD<sup>6</sup>, Timothy J. Hall, PhD<sup>7</sup>, Andrew P. Kelly, PhD<sup>8</sup>, Patrick P. Glendon, PhD<sup>9</sup>, Paul R. Hain, PhD<sup>10</sup>, James W. Yoo, PhD<sup>11</sup>, Andrew P. Kelly, PhD<sup>12</sup>, and Daniel A. Clark, PhD<sup>13</sup>

**COMMENTARY**

**Hemoglobin glutamer 250 (bovine) in South Africa: consensus usage guidelines from clinician experts who have treated patients**

Merjan Moe<sup>1</sup>, Eric Hoogwerf<sup>2</sup>, Lee White<sup>3</sup>, Barry Jacobson<sup>4</sup>, Emily Lyden<sup>5</sup>, Jacques Swinnen<sup>6</sup>, Martin A. Sussman<sup>7</sup>, Atiba Jansen<sup>8</sup>, Achraf Ben Ghalib<sup>9</sup>, Nadia Alqamri<sup>10</sup>, and Jonathan S. Fine<sup>11</sup>

**Open access - Pre-proof**

**BMJ Open Transplantation of high-risk donor livers after resuscitation and viability assessment using a combined protocol of oxygenated hypothermic, rewarming and normothermic machine perfusion: study protocol for a prospective, single-arm study (DHOPE-COR-NMP trial)**

**ORIGINAL CONTRIBUTION**

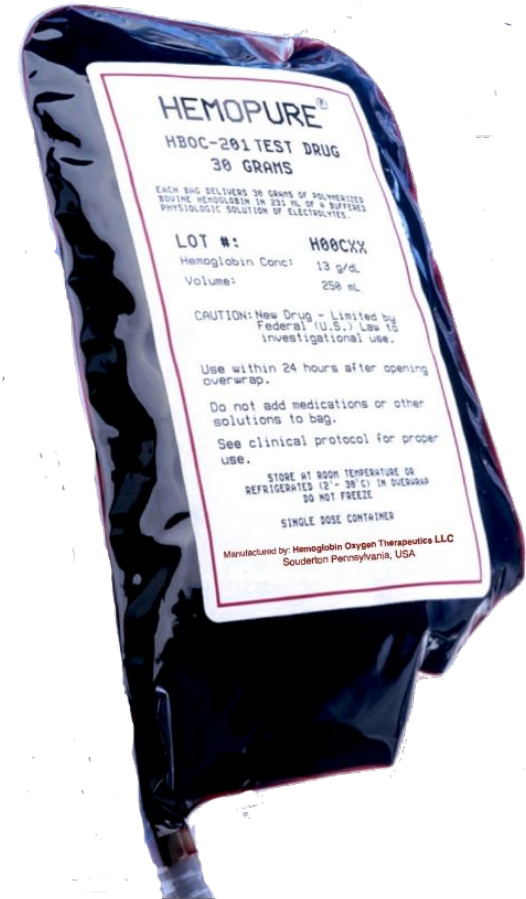
**Bloodless reperfusion with the oxygen carrier HBOC-201 in acute myocardial infarction: a novel platform for cardioprotective probes delivery**

Jero M. Govers, PhD<sup>1</sup>, Gert-Jan Peetermans, PhD<sup>2</sup>, Koen Vanhove, PhD<sup>3</sup>, James Agard<sup>4</sup>, Koen Vanhove, PhD<sup>5</sup>, An Gertjan Peetermans, PhD<sup>6</sup>, Marlene Nijsten, PhD<sup>7</sup>, Gregory P. Bialek<sup>8</sup>, Ruben J. J. de Kock<sup>9</sup>, Joelle A. Bove<sup>10</sup>, Caroline Van Dorp<sup>11</sup>, Amanda Vercasini<sup>12</sup>, Sergio Halima<sup>13</sup>

**Abstract:** The objective of this study was to evaluate the safety and efficacy of HBOC-201 in the treatment of acute myocardial infarction. In this study, HBOC-201 was used to deliver cardioprotective probes to the infarcted area of the heart. HBOC-201 is a safe and effective treatment for acute myocardial infarction.

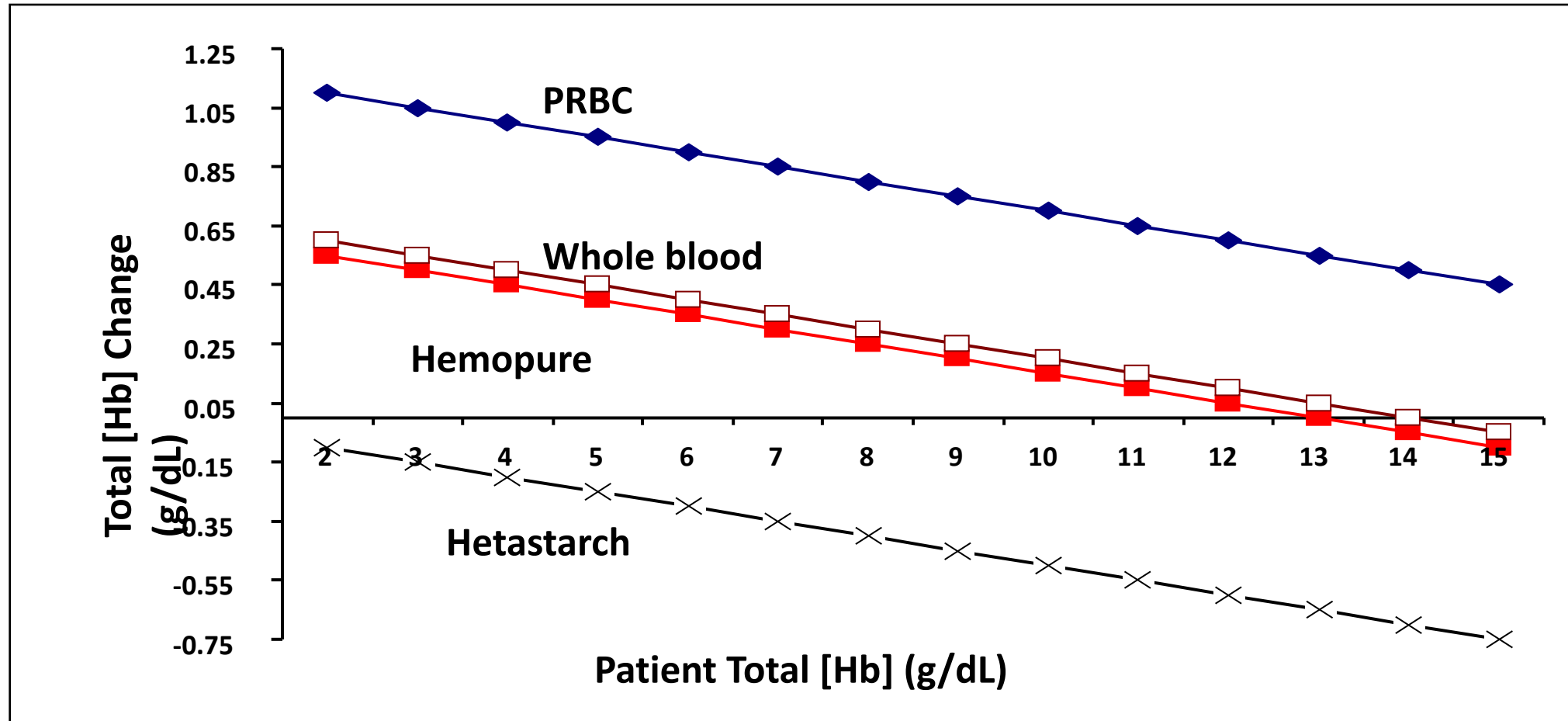
# Characteristics of Hemopure

- Hb concentration 13 g/dL
- Plasma half-life ~ 19 hours
- Size = ~ 1 million < RBC
- Stable for 3 years at 2-30 °C
- Iso-osmotic, iso-oncotic
- P50 = 40 mm Hg
- Colloid (COP ~ to 6% albumin)
- Viscosity = 2.1 cP (~4 cP for RBC)



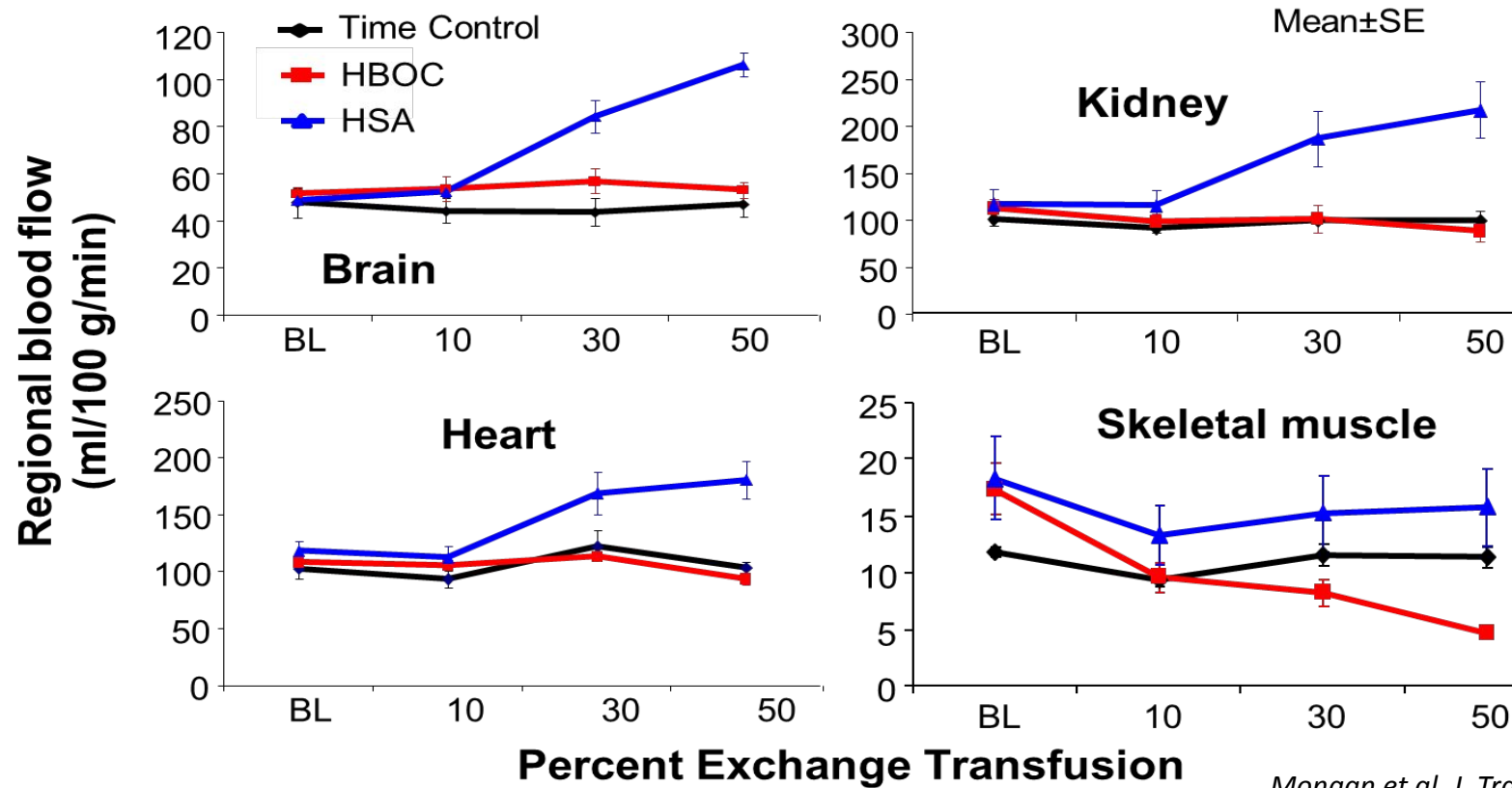
# Relative Efficacy to Increase Total Hb

Impact of 250 mL : PRBCs > whole blood, > Hemopure, > hetastarch



# Vital Organ Blood Flow

- MAP responds to Hemopure;  $\uparrow$  10 – 20 mmHg
- Vital organ blood flow maintained



Mongan et al, J. Trauma 67:51-60, 2009

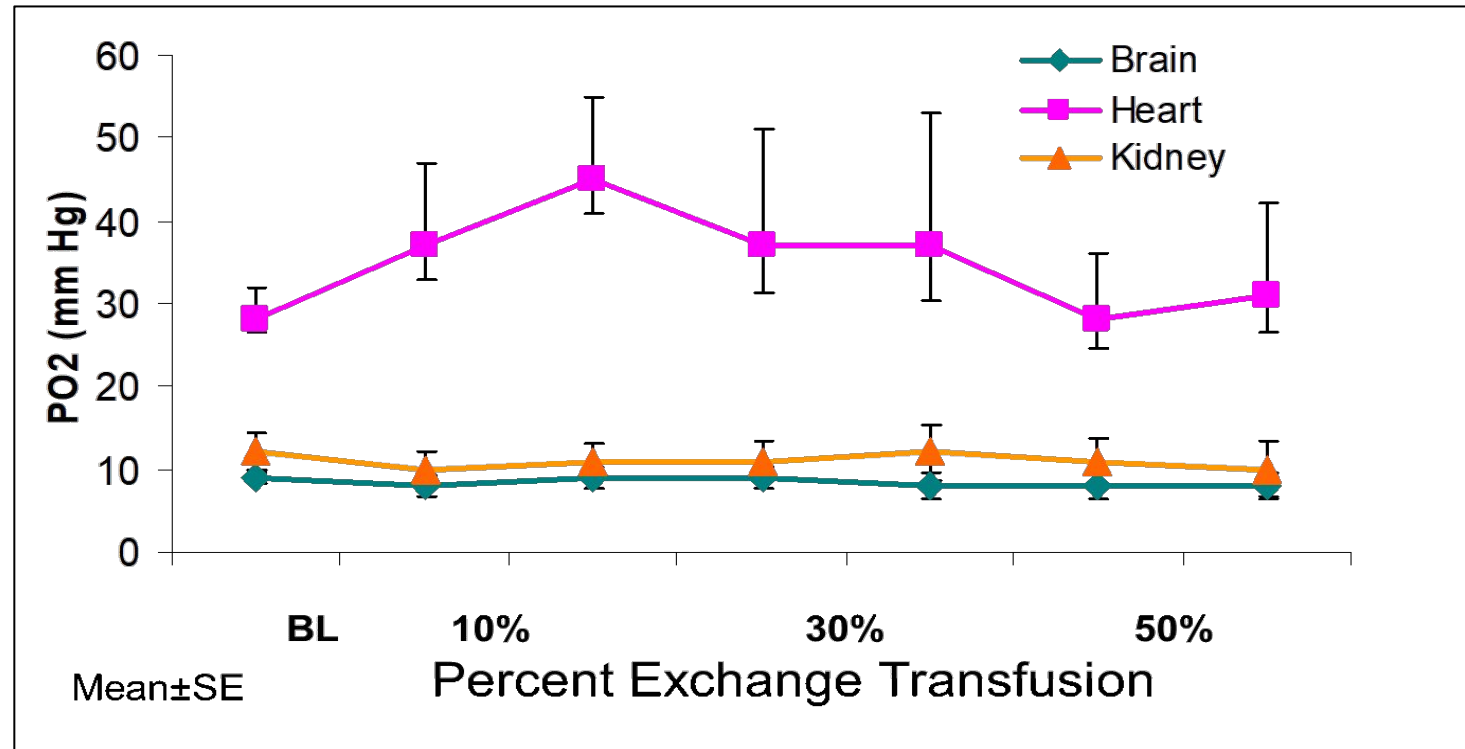
# Tissue Oxygenation

## Vital Organ Oxygenation Maintained

### Model

- Hemodilution carried out in 3 stages: 10%, 30%, 50%
- Organ-specific tissue PO<sub>2</sub> determination via EPR imaging

### Results



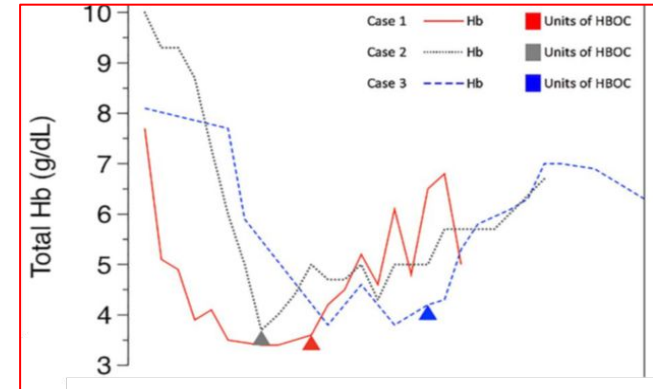
Muir et al Shock v35, 597-603, 2011

# Expanded Access Real World Clinical Experience

## Representative Cases

### Three sickle cell patients in crisis: RBCs refused/unavailable

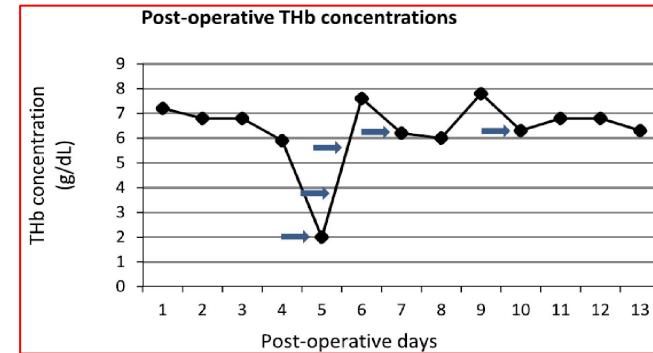
- Hb nadirs 3.5 - 4.0 g/dL
- Febrile, MOF, neurologic dysfunction.
- Hemopure administered: 6, 23, and 27 Units
- Full recoveries



Davis et al, Transfusion, v58, 132-137, 2017

### Kidney – Pancreas transplant: RBCs refused

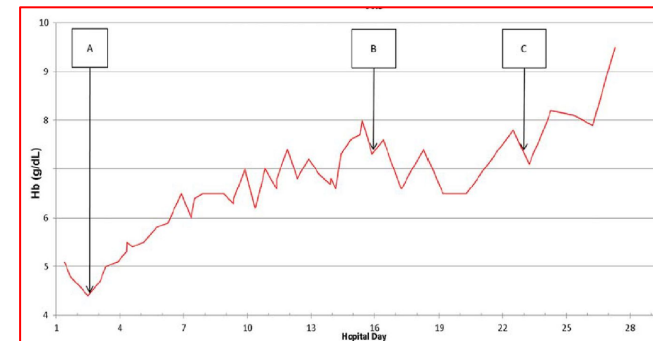
- Hb Nadir 2.0 g/dL
- Tachycardia, tachypnea.
- Hemopure administered: 12 units.
- Full recovery



Gomez et al, Am J Transplant, v17, 1941-1944, 2017

### Autoimmune Hemolytic Anemia: RBCs refused


- Hb nadir 4.6 g/dL
- Elevated lactate
- Hemopure administered: 27 units.
- Full recovery



Epperla et al, Transfusion, v56, 1801-1806, 2016

# Ex-situ Perfusion prior to Transplantation

Transplantation of high-risk donor livers after ex situ resuscitation and assessment using combined hypo- and normothermic machine perfusion: a prospective clinical trial

Declined livers (ECD = high-risk) 

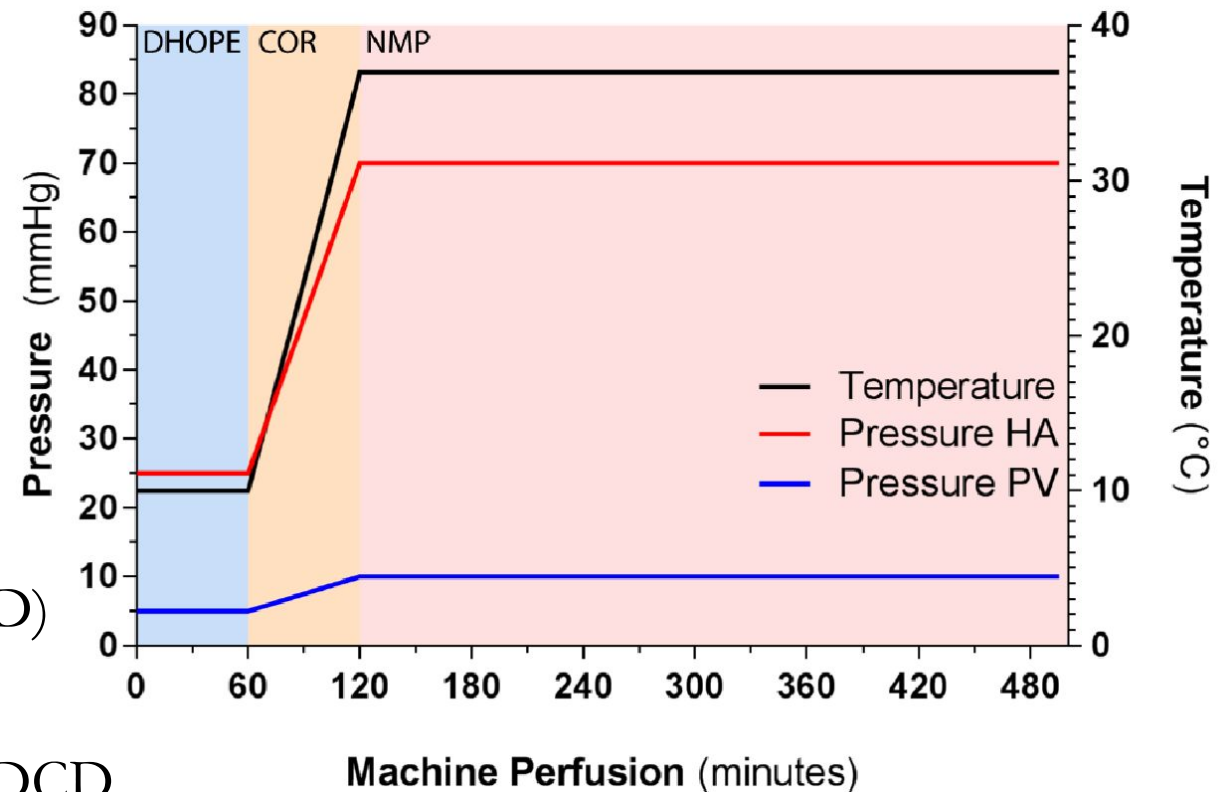
DHOPE = dual hypothermic oxygenated machine perfusion (4°C - 12°C).

COR = controlled oxygenated rewarming.

NMP = normothermic machine perfusion (37°C)

## Post-operative results

- 12-mo Graft survival: 100% ( $\geq$  std DCD & DBD)
- Peak ALT & AST:  $\ll$  std DBD & DCD
- DHOP-COR-NMP:  $\uparrow$  donor livers 20% vs. std DCD & DBD

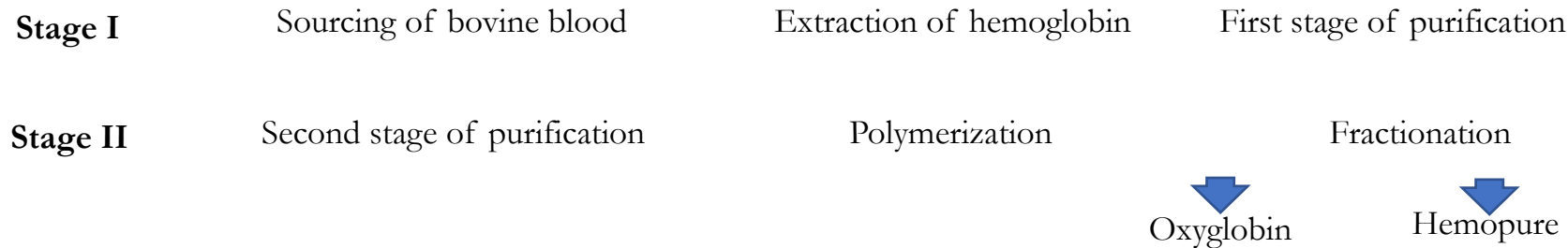


Van Leeuwen et al, Ann Surg, 2019  
de Vries Y, et al. BMJ Open 2019



# Manufacturing capacities

The manufacturing process involves two stages:



- Facility building is fully constructed
- Stage I is in place and operational (\$20m replacement value)
- Stage II – all equipment is acquired and waiting for installation (\$70m replacement value)
- Production facility fully operational in 9 months
- Expansion capacity is secured on an adjacent plot



**Certification from US and EU regulators is expected in 18 months**

# Cash positive in 2023 with \$50m investment

## \$20m commitment secured

Year	2022 \$m	2023 \$m	2024 \$m	2025 \$m	2026 \$m	2027 \$m
Total Revenues	0.8	26.9	50.9	118.4	157.5	211
EBITDA	-16.6	8.9	29.1	93.4	125.3	168.9
Free Cash-Flow	-26.9	4.8	25.0	68.8	93.5	94.2

# Why invest in HBO2 ?

## Strengths

- Innovative products with superior competitive advantages
- Highly experienced team
- Existing approvals in both animal and human markets
- Distribution agreement for veterinary market
- Near term profitability and net cash flow

## Opportunities

- Cash efficient plan to achieve market approvals and products launches
- Multi-billion dollar potential markets
- Potential additional indications
- Easy expansion into new geographical areas