

Universally Implantable Regenerative Human Tissue



Disclaimer



These slides and the accompanying oral presentation contain forward-looking statements. All statements, other than statements of historical fact, included in these slides and the accompanying oral presentation are forward-looking statements reflecting management's current beliefs and expectations. In some cases, you can identify forward-looking statements by terminology such as "will," "anticipate," "expect," "believe," "intend" and "should" or the negative of these terms or other comparable terminology. Forward-looking statements in these slides and the accompanying oral presentation include, but are not limited to, statements about our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our plans, anticipated timelines and ability to obtain marketing approval from the U.S. Food and Drug Administration ("FDA") and other regulatory authorities, including the European Medicines Agency, for our bioengineered human acellular vessels ("HAVs") and other product candidates, including our Biologics License Application seeking approval of the HAV in urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated and when autologous vein use is not feasible; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials, including for our V007 Phase 3 clinical trial; the outcome of our ongoing discussions with the FDA concerning the design of our clinical trials; our anticipated growth rate and market opportunities; the potential liquidity and trading of our securities; our ability to raise additional capital in the future; our ability to use our proprietary scientific technology platform to build a pipeline of additional product candidates; the characteristics and performance of our HAVs; our plans and ability to commercialize our HAVs and other product candidates, if approved by regulatory authorities; the expected size of the target populations for our product candidates; the anticipated benefits of our HAVs relative to existing alternatives; our assessment of the competitive landscape; the degree of market acceptance of HAVs, if approved, and the availability of third-party coverage and reimbursement; our ability to manufacture HAVs and other product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; our expectations regarding our strategic partnership with Fresenius Medical Care Holdings, Inc. to sell, market and distribute our 6 millimeter HAV for certain specified indications and in specified markets; the performance of other third parties on which we rely, including our third-party manufacturers, our licensors, our suppliers and the organizations conducting our clinical trials; our ability to obtain and maintain intellectual property protection for our product candidates as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others; our ability to maintain the confidentiality of our trade secrets, particularly with respect to our manufacturing process; our compliance with applicable laws and regulatory requirements, including FDA regulations, healthcare laws and regulations, and anti-corruption laws; our ability to attract, retain and motivate qualified personnel and to manage our growth effectively; our future financial performance and capital requirements; our ability to implement and maintain effective internal controls; and the impact of the overall global economy and increasing interest rates and inflation on our business. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. The potential risks and uncertainties that could cause actual results to differ from the results predicted include, among others, those risks and uncertainties included under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 10-K filed with the Securities and Exchange Commission on March 24, 2023 and subsequent annual reports, quarterly reports and other filings made with the Securities and Exchange Commission from time to time. Any forward-looking statements contained herein are based on assumptions that we believe to be reasonable as of the date hereof. Except as required by law, we assume no obligation to update these forward-looking statements, even if new information becomes available in the future. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of our securities, in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the reregistration or qualification under the securities laws of any such state or other jurisdiction.

Humacyte is a Leader the Field of Regenerative Medicine: Investigational Bioengineered Tissues & Organs





Category-Defining Innovation that Creates New Tissues

Universally Implantable Regenerative Human Tissue





Potential First-in-Class Technology & Manufacturing Platform

Large addressable markets

(trauma, dialysis, peripheral artery disease, diabetes, coronary bypass)



Nearing Potential Market Launch

BLA granted Priority Review by FDA

in February 2024 for HAV in vascular trauma with August 10, 2024 PDUFA date

Commercial-Scale Manufacturing

Commercial-scale manufacturing in place with annual capacity of up to 40,000 HAVs in existing facility

Validated through Multiple Partnerships





Humacyte Leadership & Board



Leadership Team



Laura E. Niklason, MD, **PhD** Founder, President, **Chief Executive Officer**



Dale Sander Chief Corporate Development Officer



Chief Financial Officer, Heather Prichard, PhD **Chief Operating Officer**



Shamik Parikh, MD Chief Medical Officer



Cindy Cao Chief Regulatory Officer



BJ Scheessele Chief Commercial Officer



Sabrina Osborne **Executive Vice** President. **Business Strategy & People**



William Tente, MS **Executive Regulatory Fellow**



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Prior Experience















Heath and Human











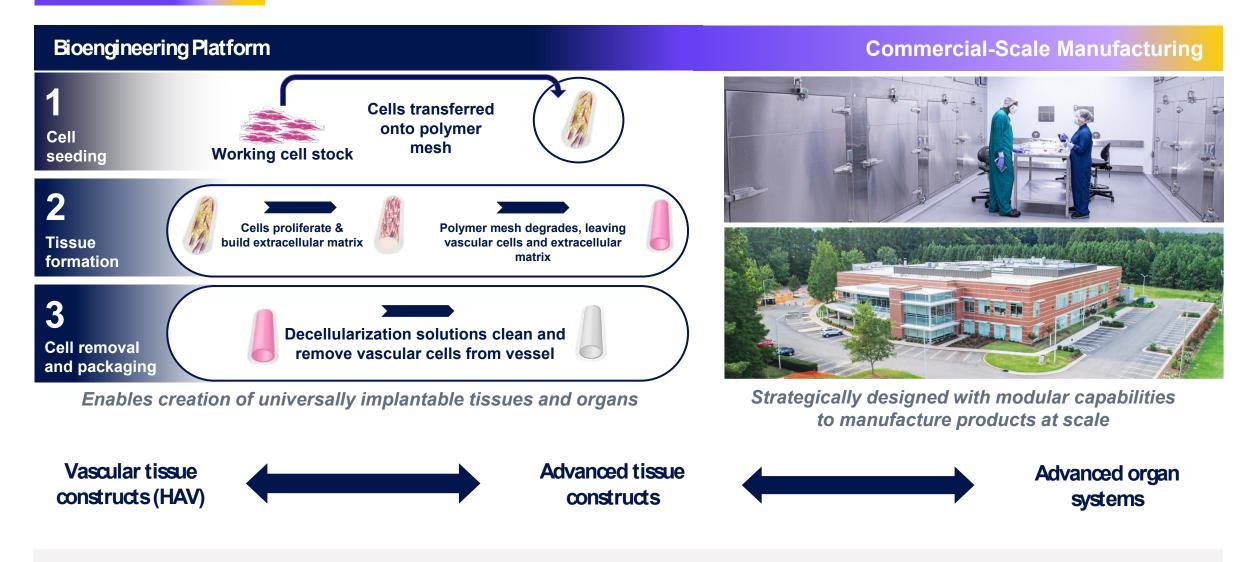






Platform & Manufacturing: Enable Broad Pipeline of Regenerative Medicine Products





Our platform technology enables development of a broad range of product candidates

Pipeline with Multiple Potential Commercial Launches



	Preclinical	Phase 1/2	Phase 3
Vascular Tissue Constructs (HAV)			
Trauma			
Dialysis (AV Access)			
PAD			
Pediatric Heart Disease			
CABG			
Complex Tissue Constructs			
Urinary Conduit			
Tracheal Replacement			
Esophageal Replacement			
Complex Organ Systems			
BioVascular Pancreas (T1D)			
Lung			

HAV Observed to Repopulate with Patient's Own Cells Potentially Enabling Infection Resistance & Self-Healing



HAV Overview



Host cells observed to repopulate the HAV¹

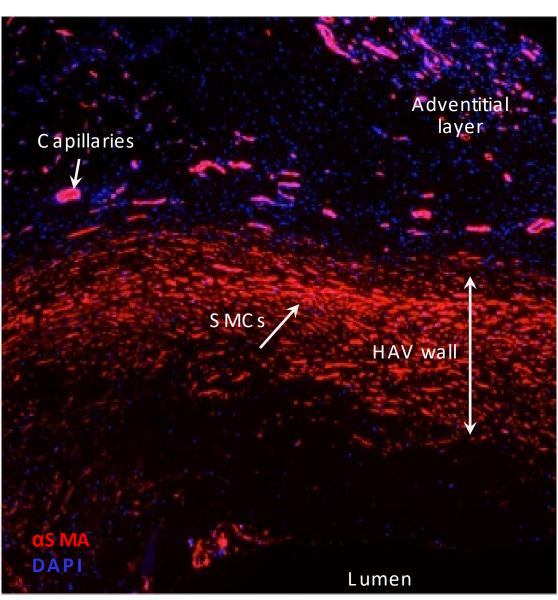


HAV observed to have low rates of infection



HAV may have the ability to self-heal after host cell repopulation

More than 500 patients across multiple indications



Benefits of HAV



Off-the-shelf, immediately available with 18-month shelf life



Long-term durability



Resistant to infection even in contaminated wound bed



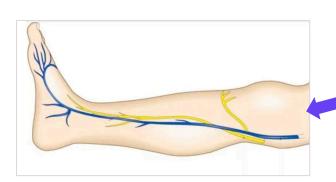
No evidence of immunogenicity



Vascular Injuries - Value Proposition for the HAV



- Common causes of vascular injuries include workplace injuries, car accidents, gunshots and stabbings, and sports injuries
- Currently available treatment options have significant drawbacks:



 Vein is the standard of care, but causes injury from harvest and takes valuable time, delaying revascularization

Shotgun Wound



 Synthetics are quick, but have infection risk and high rates of amputation

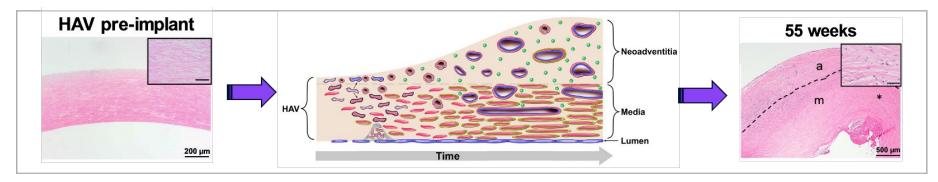
3. Amputation



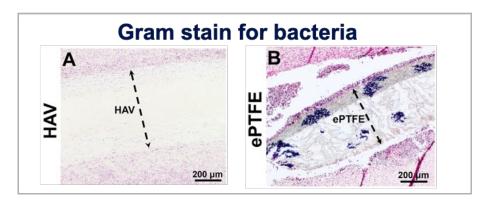
Why HAV for Traumatic Vascular Injury?



- HAV is off the shelf and immediately available for implant
 - In contrast to harvesting vein from the patient which can take an hour ¹
- HAV repopulates with the patient's cells, becoming a living tissue ²



• HAV is resistant to infection, compared to synthetic grafts ³



CLN-PRO-V005 Phase 2/3 Pivotal Trial

Human Acellular Vessel (HAV) in Vascular Trauma (NCT03005418)

Single-arm, open label trial
Level 1 trauma centers in US and Israel
Arterial injury repair

Primary endpoint 30-day patency in patients with extremity injuries

69 total patients enrolled as of data cut off
51 patients with extremity injuries — focus for BLA filing

- ALL patients had NO VEIN for repair, as assessed by treating surgeons
- Hence, patients would have received synthetic grafts, ligation of the bleeding vessel and/or amputation, had they not gotten the HAV.
- Extremity Injuries at high risk of contamination/infection¹

- > Historical Benchmarks
 - Systematic literature review of synthetics in vascular trauma
- > Primary Comparison
 - > 30-day endpoint of patency
- > Secondary Comparisons
 - Infection rate
 - > Amputation rate

Success Criteria

- Comparable (or higher) Patency
- Infection rate comparable or lower than Synthetic Grafts
- > Amputation rate comparable or lower than Synthetic Grafts
- > No unexpected safety signals



Example Vascular Injuries Treated in CLN-PRO-V005 Trial





Gunshot Wound



Industrial Accident



Knee Dislocation

V005 Trial: HAV vs Synthetic Graft Benchmarks

Endpoint	HAV Extremity (V005) %	Synthetic Graft Benchmark %
Secondary Patency	90.2%	78.9%
Conduit Infections	2.0%	8.4%
Amputations	9.8%	24.3%

V005 Trial was a Success and Met All Objectives

Observations from V005 trial:

Secondary Patency

 HAV performed better than historic benchmark

Conduit Infections

 HAV point estimate lower than historic benchmark

Amputations

 HAV performed better than historic benchmark



Ukraine Real World Experience of HAV Use in Vascular Repair



- 19 patients received a HAV
- 17 consented for data collection and study participation
- 16 patients had extremity trauma repair; one patient required HAV for latrogenic Trauma Repair
- Ukraine Humanitarian Experience presented at MHSRS¹ 2023 Annual meeting on August 14th 2023

Measure	V017 Trial Ukraine Extremity Patients (n=16)	
30-day Patency	93.8%	
Amputation	0.0%	
Limb Salvage	100.0%	
Conduit Infection	0.0%	



Ukraine Patient Blast Injury



Pre-op CT Scan



HAV repair of Femoral artery



Walking once again (Day 113)

HAV Combined Results from V005 and V017 Trials

The FDA advised Humacyte to include in its BLA submission patient outcomes from V017 (the humanitarian program conducted in Ukraine)

Endpoint	HAV Extremity (V005 + V017 Meta Analysis) %	Synthetic Graft Benchmark %
Secondary Patency	91.5%	78.9%
Conduit Infections	0.9%	8.4%
Amputations	4.5%	24.3%

Combined V005 + V017 Results Further Supports HAV Performance Versus Synthetic Graft Benchmarks

Observations from combined V005 and V017 trials:

Secondary Patency

 HAV performed better than historic benchmark

Conduit Infections

 HAV performed better than historic benchmark

Amputations

 HAV performed better than historic benchmark



Priority Review of BLA and Planned Market Launch



- BLA submitted to FDA in December 2023
- Priority Review granted by FDA in February 2024
- PDUFA date of August 10, 2024
- Factors supporting Priority Review:
 - In May 2023 the FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation for use of the HAV in urgent arterial repair following extremity vascular trauma
 - The HAV was assigned a priority designation by the Secretary of Defense under Public Law 115-92, enacted to expedite the FDA's review of products that are intended to diagnose, treat or prevent serious or life-threatening conditions facing American military personnel
- Planned market launch in 2nd Half 2024 if approved



AV Access for Hemodialysis Has Substantial Limitations



Estimates of Access (U.S.)

~60% AV fistulas

Primary/AV Fistula (Autogenous)

Market targeted by ongoing V007 Phase 3 Trial



~20% Catheters

Venous / Temporary Catheter

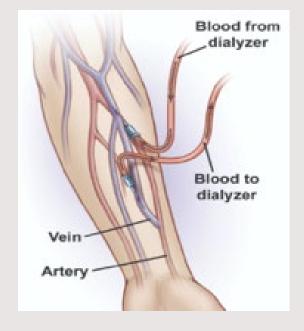


~20% Grafts

Secondary / Graft



Limitations of AV Fistulas (Current Standard of Care)





- ~40% of fistulas fail to mature
- Even the fistulas that do mature take 3-6 months to become usable for dialysis
- While fistulas are unusable, patients are required to use catheters:
 - Catheter infection rates are up to 200% per patient-year

HAV is Designed to Address Failures in AV Access



Expected Improved Patient Outcome

- HAV usable for dialysis after only four weeks
- HAV reduces catheter contact time, thereby reducing risk of catheter infection
- >90% of HAVs functional for dialysis at 6 months
- HAV infection rate is <1% per patient year



HAV Expected Economic Benefits

 Expected reduction in catheter contact time, infection, and failure rate have potential to reduce costs, including the following:

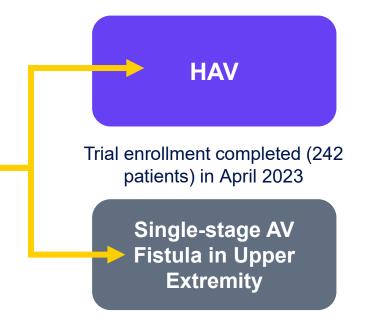
Reduce Costs from Infection

Reduce Costs of Additional
Access Procedures

Enrolled Phase 3 Trial in Dialysis: HAV vs. Fistula

V007 Phase 3 Trial Design: Compare the Efficacy and Safety of Humacyte's Human Acellular Vessel with that of an Autologous Arteriovenous Fistula in Subjects with End-Stage Renal Disease

- Subjects with end-stage renal disease in need of dialysis and suitable for single-stage arteriovenous fistula
- Target 240 total subjects



> Endpoints

- Efficacy: Useability for dialysis and patency during the first year
- > Safety: interventions, infections, etc.

> Duration

 Subjects followed for 24 months after implantation

> Stes

> 30 centers in the U.S.

> Timelines

 Top-line readout expected in 2024 (12-month followup from last subject enrolled)



Useable for dialysis (%)

Supportive Data From Completed Phase 2 & Phase 3 Studies of HAV





Completed studies of HAV as a conduit for hemodialysis compare well to published results for AV Fistula.

The V006 trial of HAV was conducted versus ePTFE. It did not meet its primary endpoint, which was secondary patency compared to ePTFE at 18 months. The secondary patency of the HAV was greater than that of ePTFE at 6 and 12 months, but lower at 18 and 24 months.

^{1.} Woodside, Kenneth J., et. Al, American Journal of Kidney Diseases, Volume 71, Issue 6, 2018, Pages 793-801

Allon, M., et al. American J Kidney Disease 2018; 71: 677-689

^{3.} Arhuidese, et al, 2018; JVS

^{4.} Lok, et al; 2013 CJAS N



Peripheral Artery Disease (PAD)

Critical Limb Threatening Ischemia

Treatment Requires Restoration of Blood Flow

Can progress to multiple leg arteries, further reducing circulation

- Tissue does not receive enough blood flow to survive
- If untreated, leads to tissue loss, gangrene, and ultimately amputation
- Non-surgical, catheter-based intervention
 - Surgical bypass







For the 40% of PAD patients who do not have an ipsilateral saphenous vein for arterial bypass, HAV may represent a promising means of revascularization and limb salvage



Current Clinical Experience with HAV in Peripheral Arterial Disease

Phase 2
Trials

- V002 20 patients (EU)
- V004 15 patients (US)

EA

Over 20 U.S. patients with critical limb ischemia treated under FDA Expanded Access program

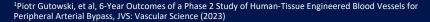
Mayo IND Investigator-sponsored IND

- Up to 35 patients with severe PAD at risk of limb loss
- Results to be presented 2024

 Six-year results from V002 published in Journal of Vascular Surgery – Vascular Science¹

 Publication of First Eight Expanded Access Cases in Annals of Vascular Surgery²

 Preliminary results presented at Midwestern Vascular Surgical Society Meeting in September 2023 showing 86% limb salvage rate





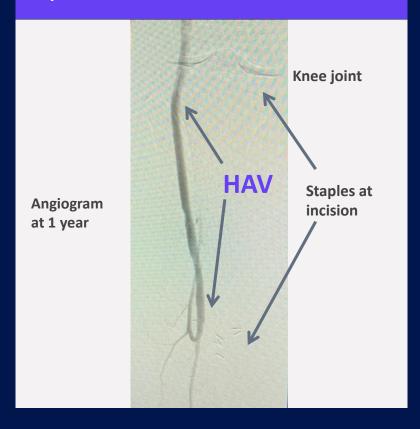
Expanded Access Case Study: Restoring Mobility with HAV

- The HAV was used under compassionate use program in 70-year-old patient with severe vascular disease
- No vein was available to perform a bypass, as the vein was previously harvested for a CABG
- A right distal superficial femoral artery-to-peroneal artery bypass was performed using an HAV
- The patient's postoperative course was unremarkable
- At 1-year follow-up the angiography showed a patent HAV without significant stenosis at the distal anastomosis
- Four years after HAV implantation, the patient continues to do well and is walking.

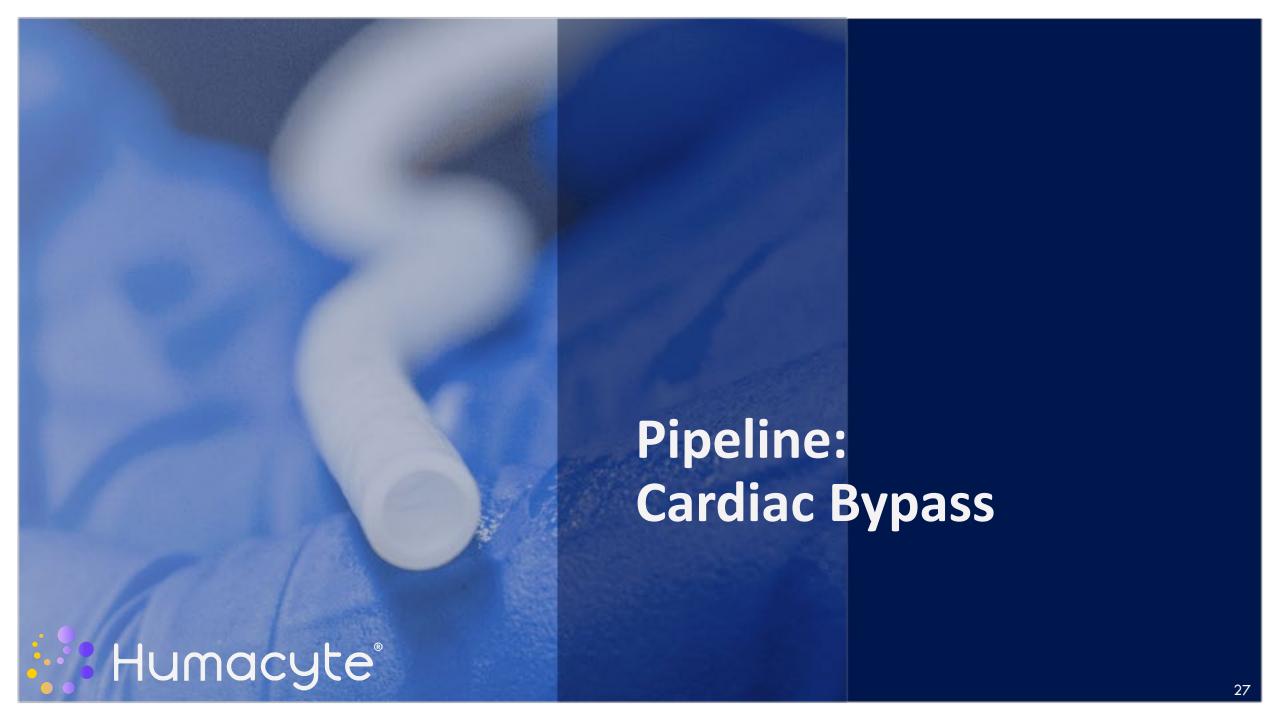


This case was included in HAV results in critical limb ischemia presented at VESS meeting in January 2022

Bypass performed using the HAV in patient with severe vascular disease







Potentially Transforming CABG Care: Greater Durability, Less Morbidity





- Saphenous Vein Graft (SVG)
 - Harvesting SVG from the patient is painful and complicated:
 - 41% have persistent numbness
 - 32% develop infection
 - 23% have persistent swelling; worse in obese and diabetic patients; 2x worse in women
 - SVGs do not last long enough: ~33% of patients will require one or more regrafting procedures during their lifetimes

Humacyte's HAV

- Does not require tissue harvest from the patient
- Immediately available and avoids morbidity of vein harvest
- Particularly important to avoid vein harvest in diabetics, women, and the overweight
- Durable and highly uniform in diameter and quality





Surgeons know what they are getting each time



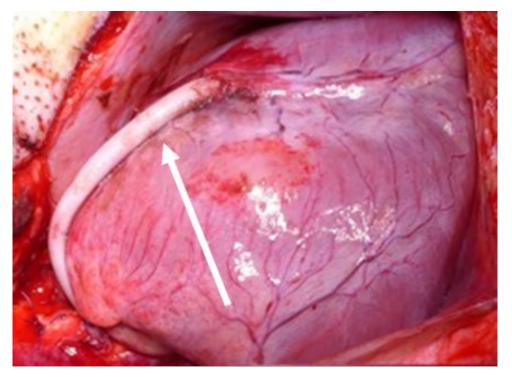
CABG Preclinical Results



Next Steps in CABG Development

Proceeding to IND enabling nonclinical studies to support first-inhuman clinical trials

- Testing of HAV in baboon model has transitioned to right coronary artery (RCA) as distal target
- Results showing HAV maintained patency and exhibited host-cell remodeling through six months



Humacyte HAV in Baboon



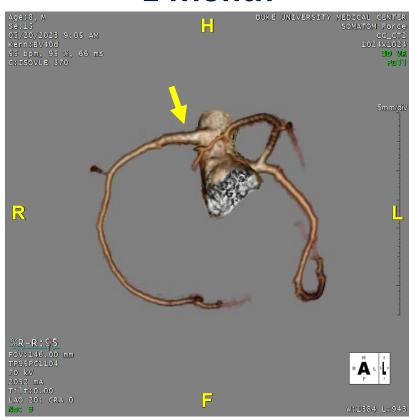
Primate – CABG Angiography – Adaptive Remodeling:

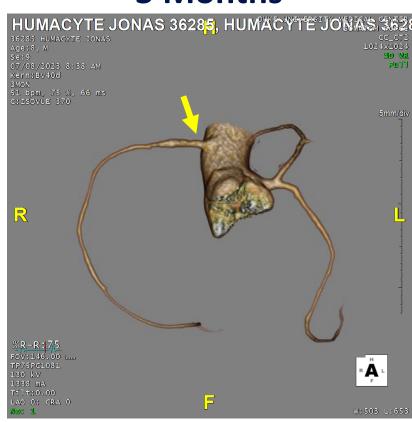


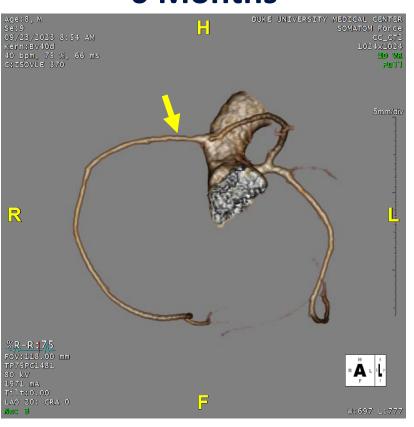
1 Month

3 Months

6 Months







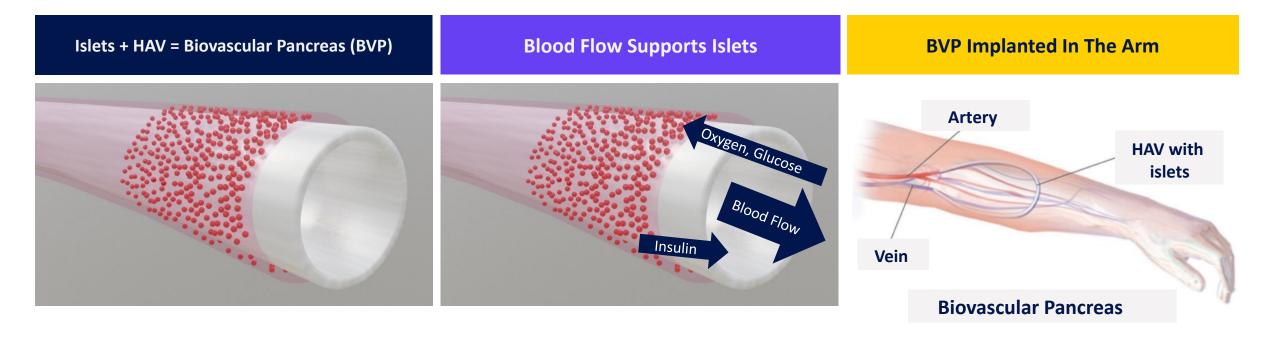
Jonas – Left Ventricular Function (%)

Pre-Op	1-Month	3-Month	6-Month
70%	73%	74%	73%



Biovascular Pancreas May Deliver Curative Islets to Diabetics



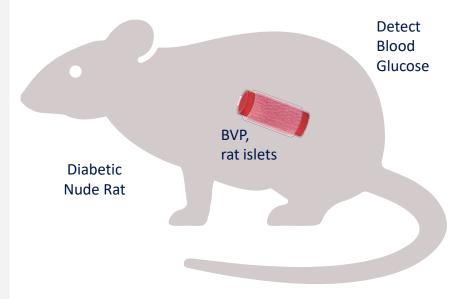


- Islets die after injection into the liver, due to lack of oxygen and nutrients
- Humacyte's HAV is being developed as a means to provide oxygen and nutrients to islets that are coated on the outside: "Biovascular Pancreas" (BVP)
- Once implanted in the vasculature, blood flow supplies oxygen and nutrients to islets
- One 42-cm HAV is expected to accommodate all the islets in an entire human pancreas

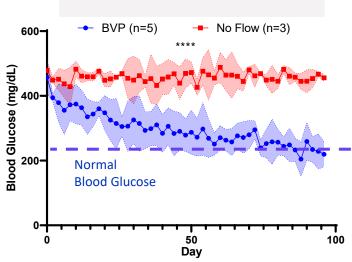
Biovascular Pancreas Normalized Glucose in Diabetic Animals

- Diabetic rodents implanted with BVPs
- All treated animals normalized glucose over time. All shamtreated animals ("No Flow") remained diabetic

Transplant BVP into Vasculature



Blood Glucose Levels







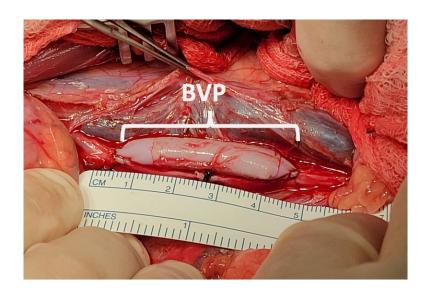


Han EX, Wang J, Kural M, et al. Journal of Tissue Engineering; 12: 1-18

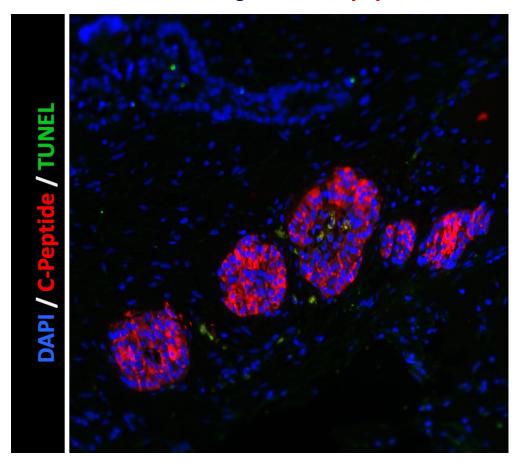
Primate BVP – Islets Survive, and Produce Insulin



- In this model, the BVP is produced by harvesting islets from one animal, and creating a BVP comprising human HAV and primate islets
- Animal receives the primate-islet BVP into the aorta
 - 25,600 islet equivalents
 - Corresponds to a potentially curative number of islets in a human



Islets survive for weeks after implantation, continue making insulin (c-peptide).



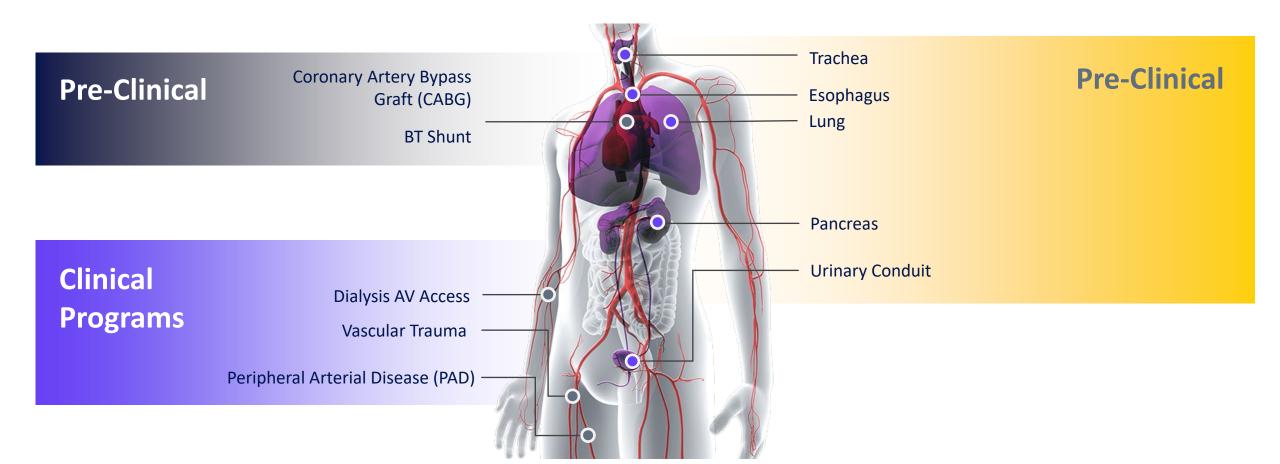


Our Technology Addresses Compelling Unmet Needs in Attractive Markets



Vascular Tissue Constructs

Complex Tissue Constructs and Organ Systems



Preparing for Strong Commercial Launch



Vascular Trauma is a Concentrated Market



- Majority of trauma vascular repair performed at Level 1 centers
- Approximately 200 level 1 trauma centers in U.S.
- Clear call point as majority of cases performed by vascular surgeons
- Humacyte expects DoD to stockpile for deployment to sites of conflicts

Compelling Health
Economic Value
Proposition for HAV

- Budget Impact Model expected to support economic benefit of HAV
- Costs associated with complications in vascular trauma potentially avoided with HAV:

Amputation Infection Harvest Site Infection

Opportunity for incremental CMS and private pay NTAP payment

Experienced Hospital /
Surgical Sales
Professionals

- Estimate we can reach market with fewer than 20 sales representatives
- Direct force expected to secure hospital approvals through VACs and also drive adoption by vascular surgeons



Strategic Collaboration

- Large shareholder with \$175 million invested in Humacyte
- Global collaboration for HAV in trauma, dialysis and PAD
- Largest provider of renal care services in the U.S.

Commercial Manufacturing Scale – LUNA200 System

Bioreactor bag

Each bioreactor bag contains a single polymer mesh scaffold, seeded with banked human cells



Growth drawer

10 bioreactor bags per growth drawer; tubing connects to shared nutritive media



LUNA200 System

Each LUNA200 can produce 200 HAVs per batch (or ~1,000 HAVs annually) ¹



Commercial 83,000 sq ft Bioprocessing Facility

- Currently operating 8 LUNA200 systems
- Annual Capacity expected to exceed 40,000 HAVs
- Functionally closed system with state-of-the-art process automation





Anticipated 2024 Milestones



Completed in 2023

- Vascular Trauma (HAV):
- Completion and positive results from V005 Phase 2/3 trial



 Positive Ukraine humanitarian trauma results



BLA submission



Completion of enrollment of Phase 3 HAV dialysis trial



Positive Phase 2 results from PAD trial conducted by Mayo Clinic



Preclinical BVP results showing survival and function of islets



Anticipated for 2024

Vascular Trauma (HAV):





U.S. commercial launch

Top-line results V007 HAV dialysis (AV Access) Phase 3 trial

Publication of Mayo Clinic HAV Phase 2 trial results in severe PAD BioVascular Pancreas (BVP) for type-1 diabetes:

 Results from preclinical studies showing survival and function of islets cells in large animals and diabetes models

Results from large animal studies of small-diameter HAV in Cardiac Bypass Surgery (CABG)

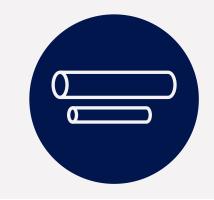
Publications & Presentations

(Multiple other clinical and preclinical publications and presentations expected for 2024)

The Promise of Regenerative Medicine

Bioengineering Platform

Broad platform of universally implantable off-the-shelf bioengineered human tissues and organs



Extensive Markets

Platform targets extensive markets across multiple indications



Commercial Scale Manufacturing

Existing facilities expected to support anticipated commercial launch with room for modular expansion







