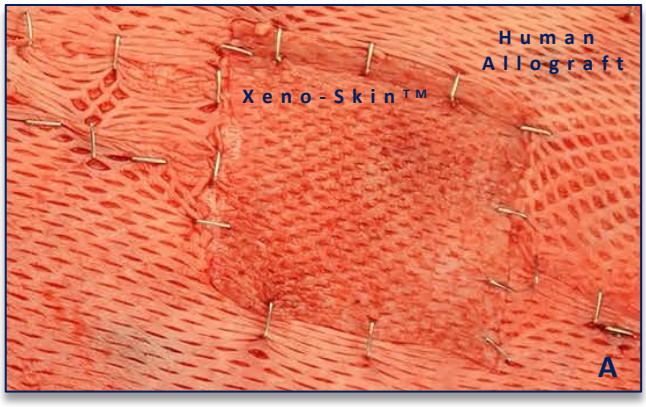
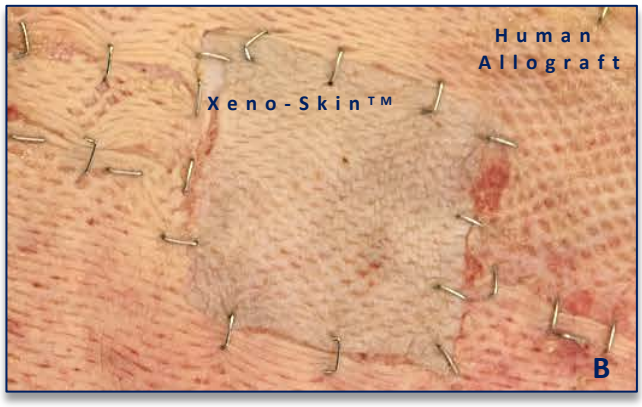
From Pig to Patient: First US Clinical Trial Successful

XENO-001: An Open-label Phase I Study to Evaluate the Safety and Tolerability of Xeno-Skin™ for Temporary Coverage of Severe and Full Thickness Burn Wounds





A) Patient with severe, extensive burn wounds from mixed depth flame burn to the lower back. Xeno-Skin™ was applied to preserve viable dermis at the time of debridement, excision, and allograft placement. B) Allograft and Xeno-Skin™ appeared indistinguishable. **No adverse events have been observed or reported, to date.**

Evidence of Safety and Efficacy Allows for Accelerated Patient Enrollment

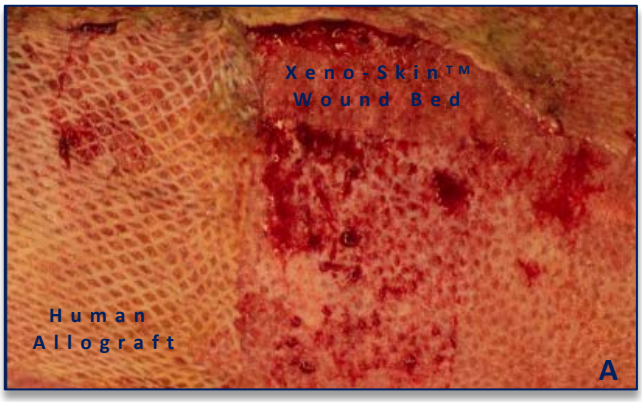
XenoTherapeutics, a clinical-stage cell therapy company engineering immune-compatible cells, tissues, and organs, has completed the first of two patient cohorts in the company's Phase I clinical trial of Xeno-Skin™, a first-in-human, live-cell xenotransplant for the treatment of severe and extensive burn wounds.

As a result, the U.S. Food and Drug Administration (FDA) has agreed to permit accelerated patient enrollment; patients may now enroll in the trial's second cohort simultaneously. This first-in-human trial, conducted in partnership with the Massachusetts General Hospital, is expected to be completed by the end of 2020. More information is available at clinicaltrials.gov.

New data will be announced from its Phase I trial in a virtual correlative presentation at the American Burn Association 53rd Annual Meeting from April 7-9th, 2021.

Clearance of this pivotal clinical trial was based on a comprehensive body of evidence gathered from a series of XenoTherapeutics' preclinical studies performed under independently audited, GLP-compliant conditions (Journal of Xenotransplantation: Immune Response; Journal of Burn Care and Research: Clinical Efficacy; Journal of Burn Care and Research: Cryopreservation), which confirmed findings from prior academic, peer-reviewed research.

Surgeries to implant Xeno-Skin™ were performed under the care of Dr. Jeremy Goverman (Principal Investigator) and Dr. John Schulz at the Massachusetts General Hospital (MGH) Sumner Redstone Burn Center. All patients who



A) Xeno-Skin™ was fully adherent and indistinguishable from the allograft comparator at the time of autograft.

participated in the trial received surgical transplants of both live skin from a clinical-grade, genetically engineered porcine donor and skin from a human deceased donor, today's current clinical standard of care, in a side-by-side comparison.

No adverse events or safety issues have been observed or reported to date, following careful evaluation of all patient data by the trial's independent Safety Review Committee. Visible signs of efficacy were also promising; in all patients, Xeno-Skin™ and the human skin comparator were indistinguishable at the time of autografting.

"This trial demonstrates a novel way to treat complicated burns and we are encouraged by the results thus far"

"The field of burn care requires a multidisciplinary approach to treat the most complex injuries, and we are constantly seeking new options to improve patient recovery time," said Jeremy Goverman, MD (Principal Investigator). "This trial demonstrates a novel way to treat complicated burns, and we are encouraged by the results thus far; additionally, this trial represents a step forward for the field of xenotransplantation."

Especially notable, post-operative RT-PCR evaluation of all patient samples showed no evidence of detection of the porcine endogenous retrovirus. Historically, this concern has posed a significant hurdle to the widespread clinical use of porcine cells, tissues, or organs in human recipients. The data from this trial align with decades of evidence that zoonotic disease poses a low risk of infection to human patients, a view further supported by numerous other experts in the field.

The US-FDA in 2018 cleared XenoTherapeutics to conduct this first-in-human, investigational clinical trial to evaluate the safety and tolerability of a novel, live-cell xenotransplant sourced from a clinical-grade, genetically optimized porcine donor. This "is a great step forward for the xenotransplantation community and hopefully paves the way for smoother regulatory processes for future xenotransplantation products," said Professor Linda Scobie of Glasgow Caledonian University, who also serves as an Associate Editor of the Journal of Xenotransplantation.

For this work, XenoTherapeutics received the American Burn Association's 2019 Burke/Yannas Bioengineering Award, named in honor of Dr. John F. Burke and Dr. Ioannis V. Yannas, the pioneers of Integra, a widely used artificial skin in the clinic today. Recently, the U.S. Patent and Trademark Office (USPTO) awarded XenoTherapeutics Patent No. 10,799,614, granting the company an exclusive methods patent related to essential regulatory criteria necessary to procure clinical-grade cells, tissues, and organs for transplantation from non-human donor animals.

"This small step has significant implications for patient care, for our field, and where we're headed," said XenoTherapeutics CEO Paul Holzer. "This affirms my enthusiasm for where our discoveries will go from here – very big things are coming soon."

XENO-001: STUDY SYNOPSIS

Protocol number: XENO-001	**Drug:** Xeno-Skin™
Title of the Study: An Open-label Phase 1 Study to Evaluate the Safety and Tolerability of Xeno-Skin™ for Temporary Coverage of Severe and Extensive, Deep Partial and Full Thickness Burn Wounds	
Number of Subjects: Approximately 6 subjects will be enrolled equally into 1 of 2 cohorts in a dose escalation study	
Site(s): Single center	
Status: Actively enrolling	**Clinical Phase:** 1
Primary Objective: To assess the safety and tolerability of Xeno-Skin™ after 28 days when applied as temporary coverage to severe and extensive, deep partial or full thickness burn wounds prior to autograft placement	
Preclinical Research: Preclinical studies determining the safety of Xeno-Skin™ for this Phase I first-in-human trial were performed at contract research organization, Biomere	

Preclinical Research performed by Biomere

A) Patient with severe, extensive burn wounds, Xeno-Skin™ was applied to preserve viable dermis at the time of debridement, excision, and allograft placement. B) Allograft and Xeno-Skin™ appeared indistinguishable. **No adverse events were observed or reported.**

XenoTherapeutics is a 501(c)(3) Massachusetts private scientific research and development foundation founded to further advance the science of xenotransplantation through education, research, development, and clinical testing towards an eventual practical therapeutic use for the public benefit. Xeno-Skin™ is derived from gal-safe porcine donors through a licensing agreement with Columbia Technology Ventures, a technology transfer office for Columbia University which enables promising technologies to accelerate out of academia and to market as quickly and successfully as possible.