



# BioPreservation Today®

Volume 3 - Issue 1 | Spring 2011



**17TH ANNUAL ISCT MEETING  
ROTTERDAM!**



**FEATURE ARTICLE**  
**HYPOTHERMOSOL® AND CRYOSTOR®:**  
**EXCIPIENT REAGENTS IN REGENERATIVE MEDICINE**



Rotterdam, host city for the 17th Annual ISCT Meeting

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## WEB RESOURCES

[www.aabb.org](http://www.aabb.org) | American Association of Blood Banks

[www.celltherapy.org](http://www.celltherapy.org) | International Society for Cellular Therapy

[www.asbmt.org](http://www.asbmt.org) | American Society for Blood and Marrow Transplantation

[www.ishrs.org](http://www.ishrs.org) | International Society of Hair Restoration Surgery

[www.alliancerm.org](http://www.alliancerm.org) | Alliance for Regenerative Medicine

[www.bestcollaborative.org](http://www.bestcollaborative.org) | BEST Collaborative

[www.regenerativemedicinefoundation.org](http://www.regenerativemedicinefoundation.org) | Regenerative Medicine Foundation

[www.phacilitate.co.uk/pages/cgtherapy/index.html](http://www.phacilitate.co.uk/pages/cgtherapy/index.html) | Phacilitate

## UPCOMING EVENTS

**17th Annual  
ISCT Meeting**  
Rotterdam, NL  
May 18-21, 2011

**North American  
Veterinary Regenerative  
Medicine Association  
Annual Meeting**  
Lexington, KY  
June 2-4, 2011

**ISSCR  
9th Annual Meeting**  
Toronto, Canada  
June 15-18, 2011

**9th Annual Int'l  
Cord Blood  
Transplantation  
Symposium**  
San Francisco, CA  
June 23-25, 2011





## EDITOR'S CORNER

Mike Rice, Chairman & CEO, BioLife Solutions, Inc.

Greetings from Rotterdam and the 17th Annual ISCT Meeting,

The regenerative medicine space has made significant strides since we met for ISCT in Philadelphia last year. I'm happy to report that as a provider of clinical grade biopreservation reagents for cellular therapies and tissue-engineered products, BioLife Solutions has also made consistent progress in seeing our HypoThermosol® and CryoStor® products incorporated into additional clinical applications. I have much more to say about this in the feature article of this Spring 2011 issue of BioPreservation Today®.

In this feature article, we share partial lists of hospital-based and commercial company development stage regenerative medicine programs that have our products incorporated into the manufacturing, storage, and delivery processes. Accompanying the feature article, we also included brief profiles of Athersys, City of Hope, DCPrime, and Intercytex, all of whom graciously agreed to allow us to share their experiences in evaluating and qualifying the use of our products to improve their biopreservation outcomes.

At the 17th Annual ISCT Meeting, Aby J. Mathew, Ph.D., our Senior Vice President and Chief Technology Officer, will present expanded information on customer adoption of our products and the science behind HypoThermosol and CryoStor in a corporate tutorial titled ***Biopreservation and Stability Considerations for Cellular Therapies – Clinical Applications of HypoThermosol® and CryoStor® as Ancillary or Excipient Reagents***. This is scheduled for Thursday, May 19th, from 12:30pm – 1:30pm in the Fortis Bank Zaal hall.

Finally in this issue, Mark Sandifer, our Vice President of Quality, provides a brief overview and discussion on supplier quality audits, from a supplier perspective.

For those readers attending ISCT this year, please stop by our corporate exhibit in booths 28 & 29. Also, feel free to visit our newly updated website at [www.biolifesolutions.com](http://www.biolifesolutions.com). Thank you for your interest in our products.

Best Regards,

Mike



# GETTING THE MOST OUT OF SUPPLIER QUALITY AUDITS

by Mark Sandifer, Vice President of Quality – BioLife Solutions, Inc.

## Introduction

The purpose of a supplier quality audit by a prospective or current customer is straightforward – to ensure that the supplier meets a minimum set of performance requirements. Supplier quality audits are mutually beneficially, since both the supplier and customer are presented with an opportunity to improve their respective quality environments.

To get the most out of an audit, it is important that the supplier prepare well ahead of the audit date, convey a positive attitude, listen critically, have documentation and personnel at the ready, effectively manage information transfer, and respond effectively and expeditiously to recommendations for improvement.

## Preparing for an audit

Ahead of an audit, the customer quality auditor typically sends the supplier an agenda describing the requested systems to be inspected and a summary of the flow of the audit. Auditors always appreciate any documentation the supplier can send ahead of the audit so that the audit can flow more smoothly. Some types of documentation include: a List of Standard Operating Procedures, Quality Manual, Quality Policy, Certifications of the Quality Management System (e.g. ISO 9001, ISO 13485), and an organizational chart.

The exact content of the audit agenda will vary depending upon the areas that are being assessed. Some examples are: Product design process, manufacturing batch records including release criteria testing results, health/environment/safety systems, the supplier's own supplier management system, human resource practices, information technology management, training methods, and financial management systems.

## The opening meeting

When the auditor arrives, the importance of making the auditor feel welcome cannot be overstated; it sets the tone for a cooperative and open dialog throughout the audit. It is also important to have key staff present at the opening meeting to underscore management commitment to the audit process. At a minimum, a senior management representative, a quality representative, a manufacturing manager, and whoever is directly involved in meeting performance requirements should attend the opening meeting. Early on at BioLife, we decided to take a very proactive view toward customer audits, and consider every audit a consulting session and an opportunity to improve our quality environment.

Auditors visiting for the first time always appreciate an overview of the company and the quality management system. A brief presentation of 15 to 20 minutes is usually adequate to give the auditor a framework to build from. Always have electronic and hard copies of the presentation prepared for the auditor to place in the audit file.

## Support during the audit

Whenever possible, have documentation and personnel at the ready during an audit. This may require adjustments to production schedules and extra work ahead of the audit; however, having immediate access to resources needed during the audit demonstrates a commitment to quality that will impress any auditor.

It is also important to immediately and politely answer any question the auditor may have. If you can't immediately answer a question that the auditor asks, explain that you will need to gather more information and let auditor know when

you will be able to provide an answer. Always take careful notes of questions and answers during the audit to avoid any misunderstanding.

## Balancing information transfer

Some information, such as trade secrets, cannot be shared during an audit, even if you have executed a confidentiality agreement with the auditor's company. To balance this against the auditor's need to know, redactions of some documentation and decisions regarding which documents may be copied should be made ahead of the audit.

## The closeout session

At the end of the audit, usually the same team is present as the one at the opening meeting. The auditor generally presents any findings, observations, and comments on opportunities for improvement, which are later summarized in a written report. Discussion of findings is best left until the formal report is received. Countering an auditor's findings at the closeout meeting is generally not conducive to conveying commitment to continuous quality improvement. It's best to simply take notes and acknowledge that you understand the auditor's findings without making other comments or immediate commitments to implement any proposed improvement.

Before the auditor departs, be sure to thank the auditor for the visit and the opportunity it provides for improvement. Always respond to the auditor's report within the time period requested. In your response, be specific regarding any corrective and preventive actions, noting who is responsible for performing each action, and when completion is expected.



# HYPOTHERMOSOL®



## MULTISTEM™ - EXTENDING FINAL DOSE STABILITY WITH HYPOTHERMOSOL®

by Robert Perry, Senior Director, Manufacturing

*Athersys is developing MultiStem, a proprietary adult stem cell product currently being used in multiple clinical trials including Phase I and II trials in indications of Acute Myocardial Infarction, transplant support (Graft Versus Host Disease prophylaxis), Ulcerative Colitis and Stroke. MultiStem is a cell therapy product that is derived from the bone marrow of a healthy donor.*

Unlike other adherent cell types, after isolation from a qualified donor, MultiStem can be expanded on a large scale for future clinical use and stored frozen until needed using a banking system (Master and Working cell banks). These Master and Working cell banks allow for the MultiStem cells to be expanded to numbers such that a single donor will be sufficient to treat hundreds of thousands of patients. These banks are extensively characterized to ensure product consistency and safety including testing for viral contamination and genetic stability.

As MultiStem has progressed through clinical development, different final product configurations have been utilized to supply the MultiStem product to the clinical site for administration. The end user has been taken into consideration when looking at how the final product will be delivered. Initially, clinical trials in this space were performed at institutional stem cell processing labs, but progression into larger later stage trials has incorporated many physician centers not associated with academic stem cell processing laboratories. We have developed configurations where cells have been supplied to the clinical sites in syringes and transfer bags where the personnel at the clinical sites have little or no manipulation to perform and can receive and deliver the product to the patient. In one trial, the demands of the final product were such that we needed to process the MultiStem sample and ship the product to the clinical site, overnight, to be delivered to the patient the next morning. This required that cells remain viable over a period of

24 hours with no processing occurring at the clinical site. After evaluating the stability profile and bedside logistics of several alternative formulations, qualification runs were performed to incorporate HypoThermosol as a dual shipping media and excipient solution for MultiStem. HypoThermosol can be cross-referenced to a US FDA Master File. Our qualification steps for HypoThermosol included an on-site supplier quality audit, in-vitro cell characterization assays and a series of in vivo safety studies in rodents and primates to demonstrate the safety of the HypoThermosol as an excipient solution for the MultiStem cell therapy product. These studies were performed over several months with regular consultations with personnel from Biolife Solutions.

The HypoThermosol formulation eliminates any thawing and washing steps at the clinical site and can be delivered immediately to the patient with no processing once received. We found that HypoThermosol enables an improved stability profile that supports expanded distribution over longer distances and shipping intervals and minimizes the need for cell therapy processing labs to be located at clinical sites.

**WWW.ATHERSYS.COM**





# CLINICAL ADOPTION OF HYPOTHERMOSOL® AND CRYOSTOR® OPTIMIZED BIOPRESERVATION MEDIA FOR REGENERATIVE MEDICINE APPLICATIONS

by Mike Rice, Chairman and CEO, BioLife Solutions, Inc.

The foundation of regenerative medicine is the use of living cells or tissues to replace or rebuild organs and systems in the body that are lost or damaged due to acute and chronic diseases, congenital defects, injuries, and degenerative disorders. Source material in the form of blood, other tissues, and fluids in the body are extracted, transported to a processing facility where specific cells of interest are isolated, transfected, or otherwise manipulated and cultured to produce a final therapeutic dose, for subsequent transportation back to the clinic and patient infusion or injection.

The regenerative medicine field continues to draw the attention of pharmaceutical companies, venture investors, clinical investigators, physicians, nurses, patients, and the media. The potential for tissue-engineered products and cell-based therapies to significantly improve patient outcomes from the leading causes of death and numerous debilitating disorders has created a competitive environment that drug and device manufacturers, regulatory agencies, government funding agencies, and the general public are all watching closely and participating in at various levels. From an industry that started with blood, then bone marrow stem cell transfusions, a vibrant landscape now exists with more than five hundred hospital centers and commercial companies currently administering regenerative medicine therapies or conducting clinical trials on perhaps one thousand or more development stage cell and tissue based products.

or final dose can be exposed to a processing or transportation time interval and still provide acceptable levels of cell isolation efficiency, cell viability and recovery, and potency after clinical administration. Of all the variables that effect overall stability (packaging, temperature, time, media, etc), biopreservation media efficacy has shown to greatly impact overall system performance. Traditional biopreservation media formulation development has followed a perhaps not surprising "Betty Crocker" approach to component selection and concentrations. Today, cell and tissue biopreservation media formulations can be broadly separated into traditional non-optimized culture media-based 'home-brew' and commercial products, and a newer class of tuned or optimized pre-formulated products that carry a robust quality footprint and despite a lack of formal direct regulatory oversight, could be considered to be of a clinical grade. Table 1 highlights key component differences between these classes of biopreservation media products. The optimization of traditional cell and tissue biopreservation media formulations and organ storage solutions into a new class of broadly applicable, highly effective products has been the focus of BioLife Solutions for the last several years. The results of this research are the commercial HypoThermosol® and CryoStor® products which have now been adopted and incorporated into the clinical development and manufacturing processes of dozens of novel regenerative medicine products and therapies.

Comparison of Biopreservation Media Formulations			
Component	Function	Traditional	Optimized
Na, K, Ca, other ions	Electrolytes	Balanced for 37C	Balanced for hypothermic temperatures
Low temp pH buffer	Maintain buffering capacity throughout preservation temperature range	Typically none	Selected for effectiveness during hypothermic temperatures
Antioxidants	Scavenge free radicals generated by preservation-induced stress	Typically none	One or more
Energy substrate	Available for generation of ATP following preservation	Typically none or glucose	One or more
Impermeant compounds	Reduce cell shrinking and swelling	Typically none	One or more
Serum	Variable and undefined benefits/consequences	May be included	None
Albumin	Serum macromolecule	Human Serum Albumin	None
Cryoprotectant	Manage cellular dehydration, ice crystallization, and transition to vitrified state	10% (v/v) DMSO	Cell specific; as low as 2% (v/v) DMSO

Table 1. Comparison of Biopreservation Media Formulations

As commercial clinical researchers and developers initially mimicked hospital-based collection and processing methods, a critical logistical limitation became apparent that prevented wider geographic distribution; poor stability (shelf-life) of source material and the final packaged dose. Stability can simply be thought of as the maximum time the source material

Biopreservation media selection for regenerative medicine products is often based on the grandfathering in of the use of traditional, non-optimized formulations. Our experience over the last five years has shown that the organizations that employ best practices considered stability constraints around the acquisition of source material, in-process hold steps, and shipment of

the final dose to the clinic early on and throughout the design of the manufacturing and biologistics processes. This approach often meets great resistance, as a default position tends to focus resources on cell characterization and mechanism of action before determining if stability limitations might in fact prevent potential commercialization. No doubt a balance is called for in the use of scarce resources and limited capital. However, an informed ranking of biopreservation media selection criteria would have component and manufacturing quality most important, followed by preservation efficacy, followed by supplier stability and customer service.

Table 2 highlights selected development stage clinical regenerative medicine applications where HypoThermosol is incorporated as either an ancillary reagent used in the manufacturing process and removed from the cells, or most often, as an excipient reagent with dual utility of storage/transport media and also as the infusion/injection carrier solution for non-frozen cell products. For specific detailed examples, please read the customer profiles of Athersys and Intercytex in the adjacent pages of this issue.

Another subgroup of customers has validated the use of CryoStor as an optimized freezing medium for cells intended for clinical

Clinical Indication	Therapy Delivery	Reagent Status	Pre-Clinical	Phase I	Phase II	Phase III	Approved
Urinary stress incontinence	N/A	Ancillary					
Myocardial infarction	IM - ventricular	Excipient					
Multiple Sclerosis	Subcutaneous	Excipient					
Ulcerative Colitis	Intravenous	Excipient					
Wound healing	Subcutaneous	Excipient					
Dilated Cardiomyopathy	Intraventricular	Excipient					
Critical Limb Ischemia	Intramuscular	Excipient					
Stroke	Intracranial	Excipient					

*Table 2. Selected clinical applications incorporating HypoThermosol®*

Over the last five years, we have taken significant steps to characterize the performance of our biopreservation media products through internal research, a small animal safety study, numerous collaborations with academic, clinical, and commercial customers, and the maintenance of updated Masters Files with the FDA. We also built and maintain a hybrid device/drug quality system that adheres to the most applicable and stringent guidance regarding aseptic media formulation, fill, and finish processes. Our quality system and manufacturing environment are certified to ISO 13485:2003.

A typical engagement with a new regenerative medicine prospect involves an initial discussion of the client’s current and desired biopreservation outcomes. Again, the most commonly identified system risks are poor preservation efficacy (stability, post-preservation viability), issues with in-house media formulation, and/or a desire for protein-free, serum-free biopreservation media. Our approach is highly consultative and supportive throughout the evaluation and validation processes. Since the formulations of HypoThermosol and CryoStor are proprietary, we tend view the dialog from the client’s perspective, and provide resources and support to de-risk the decisions to consider and use our products in clinical applications. Fortunately for prospective customers of BioLife, a significant ‘early adopter’ user group exists.

administration. The serum-free, protein-free profile of CryoStor meets an initial quality test for regenerative medicine applications. Also, a growing body of external customer data has shown CryoStor to be broadly effective in providing improved post-thaw cell viability and recovery, as compared to traditional home-brew and non-optimized freeze media formulations. Since the submission of Master Files for HypoThermosol and CryoStor, the adoption rate of our products within clinical applications has increased significantly. Table 3 provides a similar highlight of selected clinical applications where CryoStor is used as an ancillary or excipient reagent. The Beckman Research Institute of City of Hope, and DCPrime B.V. are two clinical organizations that have adopted CryoStor as a clinical grade freeze media. You will find profiles of their experiences elsewhere in this issue.



Clinical Indication	Delivery Mode	Reagent Status	Pre-Clinical	Phase I	Phase II	Phase III	Approved
Joint repair	Combination Device - Biologic	Ancillary					
Stroke	Intracranial	Ancillary					
Lymphoma	Intravenous	Ancillary					
Myeloma	Intravenous	Ancillary					
Wound repair	Intravenous	Ancillary					
Urinary stress incontinence	Intramuscular	Excipient					
Multiple Sclerosis	Subcutaneous	Excipient					
Amyotrophic Lateral Sclerosis	Intrathecal	Excipient					
Hematologic malignancies	Intravenous	Excipient					
Hematologic malignancies	Intravenous	Excipient					
AMD	Sub-retinal	Excipient					
Various cancers	Intravenous	Excipient					
Various cancers	Intravenous	Excipient					
Hematologic malignancies	Intravenous	Excipient					
Melanoma	Intratumoral	Excipient					
CHF	Intraventricular	Excipient					
Degenerative Joint Disease	Intra-articular	Excipient					
AML	Intradermal	Excipient					

**Table 3.** Selected clinical applications incorporating CryoStor®

In summary, the field of regenerative medicine holds great promise to vastly improve quality of life and survival for patients suffering from the leading causes of death and disability. Hospital transplant centers and commercial companies should look to produce the highest quality cell or tissue based therapy,

taking into consideration the critical impact that optimized biopreservation media products can have on logistics, regulatory approval, system performance, and ultimately, clinical outcomes.



# HYPOTHERMOSOL®



## EVALUATION OF VAVELTA® IN BURNS, WOUND SCARRING, AND A GENETIC SKIN DISORDER

by Paul Kemp, PhD - Chief Executive Officer & Chief Scientific Officer

*Intercytex is funded in part by a series of grants from the North West Development Agency, the UK Government's Technology Strategy Board, the European Union and by an agreement with the US Department of Defense as well as private investment. Intercytex Ltd is focused on developing and marketing VAVELTA® to ensure its potential and benefits can be realized.*

VAVELTA® (ICX-RHY) is a proprietary suspension of human dermal fibroblasts (naturally derived skin cells) in HypoThermosol® cell storage medium, for injection into the skin. VAVELTA is thought to repair the extracellular matrix to improve skin structure and function.

VAVELTA is designated as one of the first Advanced Therapy Medicinal Products (ATMP) by the European Medical Agency and has already been used in clinical trials and compassionate use programs in over 100 patients in a variety of indications.

Burns account for approximately 10% of all combat casualties caused by Improvised Explosive Devices (IEDs), an increasingly common feature of today's conflicts. IED injuries are associated with extensive traumatic skin loss. As a result, burn and trauma scar contractures (where

skin around the wound contracts, thickens and becomes inelastic) are a significant and growing problem for injured war heroes.

VAVELTA has already been used in a small number of patients suffering from scar contractures and the outcome of these treatments has led to a Phase II trial in military personnel with burn scars. The work is funded by a significant agreement from the US Department of Defense

*"VAVELTA®...HAS ALREADY BEEN USED IN CLINICAL TRIALS AND COMPASSIONATE USE PROGRAMS IN OVER 100 PATIENTS..."*

and the clinical trial is underway at the University of Pittsburgh Medical Center in partnership with the McGowan Institute for Regenerative Medicine.

Also, a phase II trial of VAVELTA is underway at King's College London to treat skin erosions in patients suffering from the severe genetic skin disorder Recessive Dystrophic Epidermolysis Bullosa (RDEB). In such patients the skin blisters at the slightest knock or rub, causing painful, open wounds which result in scarring and fusion of fingers.

Early in the development of VAVELTA, we completed a thorough evaluation of several commercial and generic hypothermic storage and preservation media products. HypoThermosol clearly outperformed all competing alternatives and meets our quality and regulatory requirements.



**WWW.INTERCYTEX.COM**



# ADOPTION OF CRYOSTOR® IN MANUFACTURING OF A DENDRITIC CELL VACCINE PLATFORM

by Prof. Dr. Ada Kruisbeek, CEO & CSO

*DCPrime B.V. (DCPrime) is a Dutch biotechnology company which develops a novel approach for making cancer vaccines. DCPrime holds a unique platform technology based upon a sustainable dendritic progenitor cell line (DCOne™). Upon loading with cancer antigens, this generates off-the-shelf DC-based therapeutic products that stimulate a cancer patient's immune system to recognize and destroy cancer antigens. DCOne™ combines the power of DC-based vaccines with the advantages of allogeneic immune stimulation, with simpler off-the-shelf clinical logistics. With this powerful platform, DCPrime is developing the next generation of cancer vaccines.*

Its founder and CEO & CSO, Prof. Dr. Ada Kruisbeek, says: "DCPrime is the first to test an allogeneic (non-patient-derived, standardized product) dendritic cell (DC)-based immunotherapy. This is based on the DCOne cell line, and the processes to produce DC from this line. Such a standardized product is much more attractive from a production, operational and clinical perspective. Moreover, it concerns a technology platform that allows for different products to be made, each tailored to a specific kind of cancer."

In April 2011, DCPrime initiated a phase I clinical trial, with a goal to investigate the safety and tolerability of DCPrime's first therapeutic cancer vaccine in patients with acute myeloid leukemia (AML). The candidate vaccine will be administered to twelve AML patients whose immune responses will be closely monitored. The study will be performed at the medical center of the Vrije Universiteit, Amsterdam (VUmc), under supervision of hematology specialists Prof. Dr. Gert Ossenkoppele and Dr. Arjan van de Loosdrecht.

Finding a clinical grade freeze media for DCPrime's final vaccine dose was a high priority. Ada Kruisbeek reports: "We considered the cost and quality aspects of

formulating a freeze media in-house against selecting a pre-formulated GMP manufactured commercial product, and completed a series of comparative experiments. BioLife's CryoStor clearly outperformed all other formulations in preservation efficacy, and it's serum-free, protein-free formulation supported our quality requirements. Our validation process for CryoStor was supported by several discussions with BioLife's scientific team members.

We know our DCOne cell line is stable, with a long shelf life. Our stock cells have been frozen for three years now. When thawed and processed, they are identical to the starter cells. Therefore, with our stock of vaccines, we won't have the variability that occurs naturally in autologous vaccines".

**WWW.DCPRIME.COM**



**CRYOSTOR®**City of  
Hope™

## OPTIMIZING MANUFACTURING OF HOSPITAL-BASED CELLULAR THERAPIES TO SUPPORT CLINICAL TRIALS

by David L. DiGiusto, Ph.D., Research Professor in Virology - Director, Laboratory for Cellular Medicine

*City of Hope is recognized worldwide for its compassionate patient care, innovative science and translational research, which rapidly turns laboratory breakthroughs into promising new therapies.*

We are one of only 40 National Cancer Institute-designated Comprehensive Cancer Centers nationwide and a founding member of the National Comprehensive Cancer Network. An independent biomedical research, treatment and education institution, we are a leader in the fight to conquer cancer, diabetes, HIV/AIDS and other life-threatening diseases.

The Laboratory for Cellular Medicine supports numerous pre-clinical studies and FDA approved clinical trials with process development expertise, in vitro and in vivo analysis of cell characterization, mechanism of action, and

engraftment, and GMP manufacturing of final packaged doses. Effective preservation of source material, whether peripheral blood or other tissues, is a critical determinant of overall processing success and yield of the final manufactured clinical dose. Cryopreservation of selected cells from source material and the final dose enables efficient clinical trial logistics, since a patient's condition may change dynamically from one day to the next.

To maximize the quality of our manufactured cells for clinical trials, we selected CryoStor for its post-thaw viability and recovery of several cell types. The product's serum-free, protein-free formulation, supported by a US FDA Master File, helped support our validation and adoption of CryoStor within our clinical production processes.

**[WWW.CITYOFHOPE.ORG](http://WWW.CITYOFHOPE.ORG)**



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# Condition of Cells: **DEAD ON ARRIVAL**

Cause of Death:  
**PREVENTABLE  
HYPOTHERMIC SHOCK**

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POWERING THE PRESERVATION SCIENCES

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BioLife Solutions develops and markets patented hypothermic storage/transport and cryopreservation media products for cells, tissues, and organs. BioLife's proprietary HypoThermosol®, CryoStor®, and BloodStor® platform of biopreservation media products are marketed to academic research institutions, hospitals, and commercial companies involved in cell therapy, tissue engineering, cord blood banking, drug discovery, and toxicology testing. BioLife products are serum-free and protein-free, fully defined, and formulated to reduce preservation-induced, delayed-onset cell damage and death. BioLife's enabling technology provides research and clinical organizations significant improvement in post-preservation cell and tissue viability and function.