

**2023**

# Newborn Stem Cell Year in Review

## Progress made. Lives changed.

### CBR® CLIENT STORIES

## Families choose newborn stem cell preservation following in utero diagnoses

Faced with an *in utero* diagnosis of hydrocephalus, two young families, separated by over a thousand miles, discovered themselves on similar paths leading both to CBR® and eventually to a cord blood infusion as part of the Duke University Expanded Access Protocol.



### JUSTICE'S STORY

Alison and Patrick learned that their son, Justice, had hydrocephalus following his 18-week prenatal scan.

They chose to store Justice's newborn stem cells with CBR. This decision was influenced by members of a Facebook group for parents of children with hydrocephalus who told them about Duke University's investigational research into the use of cord blood infusions for treating neurological damage related to hydrocephalus.<sup>1</sup>

Because his parents had the foresight to preserve both of their children's newborn stem cells, Justice was able to receive two infusions with his own cord blood and a third infusion using cord blood from his immune-matched sister.

Watch the video to see the impact that cord blood infusions had on Justice and his family.\*

### LILY'S STORY

Lily's hydrocephalus was confirmed by an MRI at 32 weeks. In the five weeks before her cesarean delivery, her mother, Whitney, immersed herself in learning all she could to help.

Like Justice's parents, Whitney found invaluable support in a Facebook group for parents of children with hydrocephalus. It was there that she learned about the CBR Newborn Possibilities Program® which provides newborn stem cell processing and 5 years of storage at no-cost for families with a qualifying medical need.

Access to Lily's cord blood was pivotal in her acceptance into Duke University's Expanded Access Protocol, which provided cord blood infusions for hydrocephalus using family-banked samples.<sup>1</sup>

At 14 months, Lily underwent a stem cell infusion at Duke using her preserved CBR cord blood sample. Her family said they noticed improvements shortly after.\*



## "The Drew Barrymore Show" sits down with CBR spokesperson, Dr. Christine Sterling, OB/GYN

As part of our ongoing awareness campaign, CBR spokesperson, Dr. Christine Sterling, made a special appearance on "The Drew Barrymore Show" to discuss the potential benefits of newborn stem cell preservation.

This short segment looked at the importance of healthcare providers educating patients about saving their baby's cord blood and cord tissue. It also featured an appearance by a CBR family whose son underwent a life-saving cord blood transplant.\*



1. Kurtzberg, Joanne, "Expanded Access Protocol: Umbilical Cord Blood Infusions for Children With Brain Injuries," ClinicalTrials.gov, 2023, Sept. 5, <https://clinicaltrials.gov/study/NCT03327467>

\*This family's personal experiences are not necessarily representative of other's experiences and cannot predict outcomes for others. CBR cannot and does not guarantee specific results. CBR compensated Justice's family for telling their story.

# 2023 Newborn Stem Cell Year in Review Progress made. Lives changed.



by CooperSurgical®

## RESEARCH



### FDA approves first expanded cord blood product for hematologic malignancy

In a landmark decision, the FDA approved the first expanded cord blood product for hematopoietic stem cell transplants.

Developed by Gamida Cell, Omisirge® is derived from cord blood that has been expanded *ex vivo* to increase the number of blood-producing stem cells, offering access for patients aged 12 and above requiring an allogeneic hematopoietic stem cell transplant for hematologic malignancy.<sup>1</sup> The FDA's approval follows a decade of research and a phase III clinical trial completion in the US.<sup>2,3</sup>

This approval is a significant milestone for the cord blood community, as it paves the way for further development of additional expanded cord blood products.



### Novel Australian study demonstrates adequate collection of cord blood in extremely preterm babies

Researchers at Monash Children's Hospital in Melbourne, Australia, achieved a significant milestone in the world's inaugural study on umbilical cord blood collection for extremely preterm infants. Supported by Cell Care™, CBR's sister company in Australia, an impressive 70% of the collections from participating patients had an adequate volume of cord blood for cryopreservation.<sup>4</sup>

Building on this research, the Monash Children's Hospital team is currently conducting an ongoing trial known as CORD-SAFE. This trial aims to evaluate the safety and feasibility of autologous umbilical cord blood infusions for babies born before 28 weeks of gestation.<sup>5</sup> The study results are anticipated to be published in the near future.



### Stem cells continue to demonstrate value as a potential therapeutic option for type 1 diabetes

Stem cells, including hematopoietic stem cells (HSCs) from cord blood and mesenchymal stem cells (MSCs) from cord tissue, have unique qualities that make them potentially valuable in treating type 1 diabetes.<sup>6</sup>

- HSCs have been researched for multiple treatment options in both transplant and regenerative medicine. Early trials indicate promise in resetting the immune system with a transplant using a person's own peripheral blood stem cells and alleviating the symptoms of type 1 diabetes.<sup>7</sup>
- MSCs also exhibit various qualities that could address type 1 diabetes complications. Clinical trials utilizing MSCs aim to target insulin-resistant tissues, protect islet  $\beta$ -cells, and lower blood sugar levels.<sup>8</sup>

As research progresses, optimizing factors like treatment timing will be key.<sup>9</sup> For families, preserving newborn stem cells with organizations like CBR offers a potential resource for future clinical trials and therapies.



Read more

## Exclusive pricing for the OB/GYN and midwife community

CBR offers you and your staff significant savings on newborn stem cell preservation. Speak to your CBR representative or call Healthcare Provider Support at **1.888.588.0258**.

1. OMISIRGE [package insert]. Gamida Cell. 2023. <http://www.gamida-cell.com/wp-content/uploads/Omisirge-final-PI.pdf>. 2. Pilot Study Evaluating Safety & Efficacy of DCBT: NiCord® & UNM CBU to Patients With Hematological Malignancies. ClinicalTrials.gov identifier: NCT01221857. Updated August 2021. <https://clinicaltrials.gov/ct2/show/NCT01221857>. 3. Horwitz ME, Stiff PJ, Cutler C, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. *Blood* 2021; 138(16):1429-1440. 4. Zhou L, McDonald CA, Yawno T, Penny T, Miller SL, Jenkin G, Malhotra A. Feasibility of cord blood collection for autologous cell therapy applications in extremely preterm infants. *Cytotherapy*. 2023 May;25(5):458-462. doi: 10.1016/j.jcyt.2023.01.001. Epub 2023 Feb 4. PMID: 36740465. 5. Malhotra et al. (2020). Autologous Umbilical Cord Blood-Derived Cell Administration in Extreme Preterm Infants: protocol for a safety and feasibility study. *Stem Cells Translational Medicine*. May 11;10(5). 6. Moreira, A., Kahlenberg, S. & Hornsby, P. Therapeutic potential of mesenchymal stem cells for diabetes. *J. Mol. Endocrinol.* 59, R109-R120 (2017). 7. Li, L. et al. Autologous hematopoietic stem cell transplantation modulates immunocompetent cells and improves cell function in Chinese patients with new onset of type 1 diabetes. *J. Clin. Endocrinol. Metab.* 97, 1729-1736 (2012). 8. Huang, Q., Huang, Y. & Liu, J. Mesenchymal Stem Cells: An Excellent Candidate for the Treatment of Diabetes Mellitus. 2021, (2021). 9. Zhu, Y. et al. Administration of mesenchymal stem cells in diabetic kidney disease: mechanisms, signaling pathways, and preclinical evidence. *Mol. Cell. Biochem.* (2022) doi:10.1007/s11010-022-04421-4.

The use of cord blood is determined by the treating physician and is influenced by many factors, including the patient's medical condition, the characteristics of the sample, and whether the cord blood should come from the patient or an appropriately matched donor. Cord blood has established uses in transplant medicine; however, its use in regenerative medicine is still being researched. There is no guarantee that potential medical applications being studied in the laboratory or clinical trials will become available.

Cord tissue use is still in early research stages, and there is no guarantee that treatments using cord tissue will be available in the future. Cord tissue is stored whole. Additional processing prior to use will be required to extract and prepare any of the multiple cell types from cryopreserved cord tissue. Cbr Systems, Inc.'s activities for New York State residents are limited to collection of umbilical cord tissue and long-term storage of umbilical cord-derived stem cells. Cbr Systems, Inc.'s possession of a New York State license for such collection and long-term storage does not indicate approval or endorsement of possible future uses or future suitability of these cells.