

# THE CURE CHRONICLES

December 2022 ISSUE

*Enabling affordable and accessible advanced medicines*

Happy New Year! In our final issue of 2022, we have the pleasure to feature Lynda Dee, who has been a leader in advocacy from the earliest days of the HIV epidemic, and a great inspiration to us all. Caring Cross was busy these last 2 months! We were invited to present our vision for place-of-care therapy for sickle cell disease at the USA-Africa Leaders' Summit in Washington D.C., and also pleased to receive a notice of award for co-developing a clinical candidate for treating leukemia with tri-specific CAR-T cells, in a CIRM funded award to Dr. William Murphy of UC-Davis. We look forward to working with Dr. Murphy and the team at UC-Davis to create a new place-of-care CAR-T therapy that will make this potentially curative approach for leukemia and lymphoma both less costly and more broadly available in the US, as well as with international partners (article from UC-Davis describing the award: <https://health.ucdavis.edu/news/headlines/uc-davis-partners-with-caring-cross-and-cirm-to-develop-immunotherapy-for-cancer-patients/2022/12> ).

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## News

**Here is the latest on what we are excited about:**

→ The clinical trial for Lovo-Cel (BlueBird Bio's lovotibeglogene autotemcel, formerly LentiGlobin), a lentiviral gene vector approach for sickle cell disease, has been released from partial clinical hold by the FDA. This was due to the ability to ascribe a treatment associated anemia to the presence of a mutation in the alpha-globin gene in an adolescent patient enrolled in the trial. The field remains indebted to the patients who enroll in these trials, nothing would be possible without them. And thanks also to the scientists at BlueBird who continue to carry-out and share their detailed

investigations in real time. See an excellent general article on this topic by Margarida Maia in Sickle Cell Disease News: [https://sicklecellanemianews.com/news/testing-scd-gene-therapy-lovo-cel-resumes-after-holdup/?utm\\_source=SIC&utm\\_campaign=39b797c4bf-SIC\\_ENL\\_3.0\\_US&utm\\_medium=email&utm\\_term=0\\_b01e3fbae8-39b797c4bf-74539466](https://sicklecellanemianews.com/news/testing-scd-gene-therapy-lovo-cel-resumes-after-holdup/?utm_source=SIC&utm_campaign=39b797c4bf-SIC_ENL_3.0_US&utm_medium=email&utm_term=0_b01e3fbae8-39b797c4bf-74539466)

➔ The British Pharmacopoeia has issued guidance on the “Characterization of the particle population in AAV products.” This document will serve as an important reference for all groups interested in AAV-based gene therapy. Linked here: <https://www.pharmacopoeia.com/file/Consultation-document---Characterisation-of-the-particle-population-in-AAV-products.pdf>

➔ Post-transplant lymphoproliferative disease (PTLD) is a deadly leukemia-like process driven by Epstein-Barr virus in immunosuppressed patients. Although the activity of T cells against this disease has been known for some time, and the ability to use allogeneic (partially tissue matched) T cells has also been known, creating an approved product has been a challenge. After years of diligent work, Atara Biotherapeutics teamed up with Pierre Fabre to win European approval of Ebvallo™ (tabelecleucel) an adoptive immunotherapy approach to PTLT. See the press release here: <https://investors.atarabio.com/news-events/press-releases/detail/301/atara-biotherapeutics-ebvallo-tabelecleucel>

➔ Pharma Giants Moderna and Merck have united to carry-out a high impact clinical study in which a patient’s own tumor (in this case melanoma) is sequenced for genetic mutations, and then these mutations used as a source for a designer mRNA-based vaccine. When this designer vaccine (the Moderna part of the approach) is teamed with anti-PD1 checkpoint antibodies (Merck), a significant improvement in outcome was seen when compared to anti-PD1 therapy alone. This tells us that personalized sequence information can be rapidly translated into an effective therapeutic. Diseases like lung cancer and melanoma have astronomically high mutation rates, and are often responsive to anti-PD1 on their own. These “hot” or immune-infiltrated tumors are prime candidates for this approach, see a general article on this advance here: <https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-merck-vaccine-combo-cut-melanoma-recurrence-by-44-study-2022-12-13/>

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## Community Advocate Spotlight

### Lynda Dee, JD, DARE

Executive Director of AIDS Action Baltimore



#### **Tell us about your background and how you came to be in your current position.**

I am an HIV/AIDS treatment activist who co-founded AIDS Action Baltimore in 1987 after the death of my husband and two-thirds of my friends because of AIDS complications. These severe losses motivated me to become a fierce AIDS activist. I have worked for 35 years with academia, industry, and government to expedite ethical drug development to provide access to life-saving medications before approval and to ensure reasonable drug prices and increases. I work in the HIV cure research arena and was co-chair of Martin Delaney Collaboratory (MDC) CARE CAB, co-chair of the MDC DARE CAB, co-chair of the amfAR Cure Institute CAB and is now the DARE MDC Community Engagement Coordinator.

I have served on many national and local community and government advisory boards and have been a member of various FDA Antiviral Drugs Advisory approval panels and many NIH Advisory Boards, including, the Office of AIDS Research Advisory Committee, NCI, NIMH, NIDS, NIDA and NIAID, serving on the ACTG Executive Committee and what was their Community Constituency Group. I have also served on various industry HIV and HCV CABs and national and international CABs advisory boards, including the AIDS Treatment Activist Coalition, and am also a former chair and current member of the Fair Pricing Coalition. I have been a

member of the Executive Committee the Forum for Collaborative HIV Research, a community member of the CROI Planning Committee and a member of the International AIDS Society's HIV Industry Collaboration Group.

**Tell us what the focus of your efforts at the present time is and what motivates you.**

My current international focus is on HIV cure-related research. I am particularly interested in gene therapy research as I believe it provides great promise as an HIV cure intervention. Locally, I concentrate on HIV prevention for African American members of the LGBTQ+ community.

I am extremely motivated to end the HIV/AIDS epidemic with both cure-related and prevention strategies. After 35 years of work in the field, I am still driven to bring about the beginning of the end of this worldwide scourge.

**What is your vision for the future and how would you overcome any challenges?**

My vision for the future is the development of national and international HIV/AIDS cure interventions and prevention strategies that are safe, simple, affordable, scalable, and durable. Caring Cross' efforts to develop point of care manufacturing of gene therapy products is aimed directly at affordability and scalability.

One of the largest challenges to my vision of the future is meaningful community involvement across the globe, from scientific input and community engagement strategies to government funding, research, healthcare, policy, and regulatory input as well as structured interactions and collaborations with academia, industry, and a wide variety of national and international community organizations.

Community involvement in the early days of HIV/AIDS revolutionized all the above. Continuing these efforts with more funding from various sources for community education and advocacy would ensure that community-driven advocacy will continue to drive progress and innovation in the future.

**If there is one thing that would make a difference to your efforts, what would it be?**

Political will to support funding and policy considerations for community education and advocacy such that it would filter down to all the entities listed above.

## What is a fun fact about yourself that you would like to share?

I love David Bowie and his philosophy of live and let live, follow your own drummer no matter what that might be and always go beyond your comfort zone to discover new and daring possibilities.

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## Whitepapers

Interested in learning more? Read our latest whitepapers on the Caring Cross website. Click below to access them.

- [Distributive Manufacturing of CD19 CAR-T Cells Using CliniMACS Prodigy: Feasibility and Real-World Experience from India](#)
  - [Global Access to Human Gene Therapy: Lessons Learned from HIV](#)
  - [Centralized vs Decentralized Manufacturing of Personalized Cell Therapies: How to Implement Local Manufacturing of CAR T-Cells](#)
  - [Regulatory Considerations for Decentralized Manufacturing of Personalized Cell Therapies: A Path Forward for Commercialization of Decentralized Manufacturing of CAR-T Cell Therapies](#)
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## Upcoming Events

Caring Cross presents a Technology Education seminar series on the first Friday of every month. Having just completed a series on how to manufacture CAR-T cells and other gene therapy products in a place-of-care setting, in 2023 we will present a new series created by cell and gene industry expert Dr. Kevin Curran, starting Feb. 3. The first presentation will be called: ***Introduction to Cell and Gene Therapy.***

On the third Friday of every month, we feature an international expert in cell and gene therapy. This January please register to hear Karine Dubé, DrPH present,

### ***HIV Cure Research: Scaling Up Participant-Centered Approaches, Strategic Socio-Behavioral Sciences and Ethics Research***

[!\[\]\(5eb1325dfdc3f1cad8426726c0db51cd\_img.jpg\) \*\*Register for the event\*\*](#)

Date: Jan 20, 2023

Time: 3:00pm EST / 12:00pm PT

Location: Zoom (link provided upon registration)

This event will last approximately 30-40 minutes and will consist of a presentation and Q&A session following.

All our events are on Fridays at 3pm EST and require registration to access the live webinar. A recorded replay will be available to Caring Cross Community members only (**Membership is free**).

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## **Recent Events**

If you missed these recent events, click on the links below to view them.

[!\[\]\(d5d7044e5caf6907399af2dced8d6ff8\_img.jpg\) \*\*Learn and apply: Harnessing features of effective antiviral T cell responses to enhance adoptive T cell therapies for HIV\*\*](#)

[!\[\]\(35dc653d59570f8f891c312eeece91a2\_img.jpg\) \*\*Place-of-care manufacturing of CAR-T cells, a practical guide: an interview featuring Jane Reese-Koc, MBA, and Dr. Marcos de Lima\*\*](#)

[!\[\]\(ab4e2b3fc7e7887b7a72f548aa6f5e60\_img.jpg\) \*\*Accelerating Progress towards an HIV Cure for Africa\*\*](#)

[!\[\]\(104fbf564e2e5a8fbd84f31656d114c7\_img.jpg\) \*\*Place-of-Care Manufacturing of CAR-T Cells – Practical Application \(Part 4\)\*\*](#)

[!\[\]\(aab88c0d099e5d18d6533a97b13ec28d\_img.jpg\) \*\*HIV cure research: implementation challenges and participant engagement in cutting-edge therapeutic studies\*\*](#)

If you are not a member, you can [become a member](#) and view all our past events.

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## Caring Cross Community



Caring Cross was honored to present during the “Science at the USA-Africa Summit” sessions, hosted by the Tanzanian Embassy in Washington D.C. this December. The program was titled: ***Global Partnerships for Sickle Cell Disease (SCD): Advancing Science and Technology in Health in Africa***. In addition to key academic and political leaders from Tanzania such as Prof. Appolinary Kamuhabwa (MUHAS), Prof. Julie Makani (MUHAS), Grace Moshi (KK Women’s and Children’s Hospital, Singapore), Prof. Emmanuel Balandya (MUHAS), Prof. Funmi Olopade (Sickle in Africa), and Prof. Paschal Rugajo (MOH Tanzania), we also heard presentations from Prof. Cissy Kityo (JCRC), Dr. Jonathan Spector (NIBR), Dr. Francis Collins (NIH), Dr. Peter Kilmarx and Dr. George Mensah (NIH Fogarty Center), Dr. Lewis Hsu (CMO, SCD Assoc., USA), Dr. Gene Buckman (NCDI Poverty Commission), and Dr. Matt Porteus (Stanford)

NIH speakers reviewed 3 initiatives of the Sickle in Africa Consortium they help support: SPARCo (Dr. Makani, MUHAS, Sickle Pan-African Research Consortium), SADaCC (in South Africa, Sickle Africa Data Coordinating Center), and SPAN (networking center, Sickle Cell Pan Africa Network). Together they work to assess disease burden, risk factors and modifiers, and to examine the impact of initiatives on health outcomes. Dr. Collins stressed that the time is ripe to move from

donorship to ownership of data and resources, such as those generated through the H3 Africa (Human Heredity and Health) initiative and the African Genomes Centers of Excellence (GENCO). The presentation from Caring Cross focused on place-of-care cell and gene therapy approaches for sickle cell disease. Specifically, how we could take the current high-cost approach taken by commercial pioneers BlueBird Bio, and create a more effective gene vector, that can be used to deliver curative gene therapy in Africa.

Please follow the link below to be enrolled for an in-depth seminar series designed to educate our community about cell and gene therapy. This series was designed by patient advocates, with a general audience in mind. Don't miss this unique opportunity to hear from international leaders in the field, designed just for you.

***the DARE Community Cell and Gene Therapy webinar series***

➡ **Register:** <https://bit.ly/3kapavg>

**We are creating a membership community to connect** healthcare professionals, scientists and engineers, community advocates and business leaders that are on a mission to develop new advanced medicinal cures - and help make them affordable to all who need them.

**Join us to collaborate in a group, learn from seminars and training, and gain access to job opportunities or internships.**

➡ **[Become a member](#)**

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***What else would you like to hear about in this newsletter?***

Reply to let us know.

Thank you for being here, look out for another update every other month!

- Caring Cross

P.S. Are you following along with us on social media? Be the first to know about our



progress and share in the conversation!

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