



Lupus Accelerating Breakthroughs Consortium Announces Expanded Partnership with U.S. FDA at First Anniversary Meeting

Center for Biologics Evaluation and Research Joins Consortium to Accelerate Engineered Cell Therapies for Lupus

BETHESDA, MD – [April 16] The Lupus Research Alliance (LRA), founder and administrator of the Lupus Accelerating Breakthroughs Consortium (Lupus ABC), announced today at the Consortium’s first anniversary meeting an expanded partnership with the U.S. Food and Drug Administration (FDA) with the inclusion of the Center for Biologics Evaluation and Research (CBER). The addition of CBER to Lupus ABC will enhance the Consortium’s focus on engineered cell therapies, a promising new area in lupus therapeutic development. Lupus ABC was launched in collaboration with the FDA Center for Drug Evaluation and Research (CDER) in March 2023.

Lupus ABC is a first-of-its-kind public-private partnership (PPP) uniting individuals with lupus and their advocates, industry, clinicians, researchers, and government stakeholders to collaboratively identify and pursue the most effective ways to accelerate the development of urgently needed personalized treatments for people with lupus.

The field of engineered cell therapies in lupus is an exciting and rapidly evolving area of research of significant interest to individuals living with lupus. While questions of long-term durability, safety and effectiveness continue to be examined, early clinical results with CAR-T cells in lupus offer much promise, and hope for a potentially curative treatment approach. CBER’s participation in Lupus ABC will help facilitate the creation and deployment of patient-focused tools and approaches in the development of CAR-T cell and other engineered cell therapies and ensure a focus on the most pressing questions for advancement of the field.

As keynote speaker at the Lupus ABC meeting, Peter Marks, M.D., Ph.D., director of CBER commented, “Patients with lupus experience many debilitating manifestations and require lifelong immunosuppression. CBER shares the excitement and enthusiasm around the transformative potential of emerging technologies such as CAR-T therapies to address an unmet medical need for patients with this serious, potentially life-threatening condition. We look forward to collaborating with Lupus ABC to shepherd the product development plans in a safe manner.”

“We are delighted to have the Center for Biologics Evaluation and Research join Lupus ABC at this important juncture in the development of engineered cell therapies for lupus to help us accelerate their clinical evaluation,” said Teodora Staeva, Ph.D., Vice President, and Chief Scientific Officer, LRA. “CBER’s engagement, along with that from people with lived lupus experience, industry, clinicians, and other federal partners, will provide urgently needed guidance for the field to enable improved lupus outcomes. We are grateful to both CBER and CDER for their commitment to this important effort.”

Since its establishment less than a year ago, Lupus ABC has made robust progress through building a strong community of [40 member groups](#) and launching three projects focused on different outcome measures for lupus trials— including Treatment Response Measure for SLE (TRM-SLE), Cutaneous Lupus Erythematosus Disease Area Severity Index (CLASI), and Lupus Patient-Reported Outcomes. The fourth project, centering on CAR-T cells, will include essential representation from CBER. Importantly, the voices of people living with lupus were considered in establishing each of the Lupus ABC projects and will continue to be central to the activities moving forward.

Lupus is a complex, potentially life-threatening autoimmune disorder that disproportionately impacts women and communities of color. Lupus can affect the joints, skin, brain, lungs, kidneys, and blood vessels, causing widespread inflammation and tissue damage in the affected organ. A heterogeneous disease, lupus affects each person differently and its effects can change over time, making it one of the most difficult diseases to diagnose and treat. Black/African American, Native American, Hispanic/Latino and Asian populations are two to three times more likely than white Americans to be diagnosed with lupus.

About Lupus ABC

The [Lupus Accelerating Breakthroughs Consortium \(Lupus ABC\)](#) is a public-private partnership (PPP) that includes the U.S. Food and Drug Administration (FDA) and other key lupus stakeholders, dedicated to accelerating the development of safer and more effective lupus therapies. Lupus ABC convenes regulators, other government representatives, drug developers, academics, patient advocacy groups, and professional societies to collaboratively develop and implement strategies that tackle the most pressing challenges in lupus drug development in a pre-competitive forum. The direction and priorities of the Lupus ABC are determined with input from its members. Lupus ABC is managed by the Lupus Research Alliance. For more information, visit LupusABC.org.

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Media Contact:

Caren Begun
Caren.Begun@tmstrat.com
C: 201-396-8551

Margy Meislin
mmeislin@lupusresearch.org
C: 516-426-6160