

Embargoed for release until 8am PDT, Wednesday June 25th, 2014

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## **Calimmune Approved to Treat Second Group in HIV Stem Cell Gene Modification Study**

June 25, 2014

San Diego, CA – Calimmune today announced encouraging safety data from its innovative gene-based stem cell therapy, Cal-1-being developed to help cure individuals infected with HIV. The company can now begin treating the second group of patients in the trial, which is being funded in part by a grant from the California Institute for Regenerative Medicine (CIRM).

The company was given the green light to move ahead following a review of safety data by the Data Safety Monitoring Board (DSMB). The DSMB found none of the participants experienced any serious adverse events or dangerous side effects from the therapy.

“We are very excited and encouraged by this development,” says Louis Breton, Chief Executive Officer of Calimmune. “This recommendation from the DSMB is an important step in bringing this potential one-time therapy to the patients, and takes us closer to our ultimate goal of eradicating AIDS.”

Breton continued: “We are proud of our ongoing partnership with CIRM and are most appreciative of their continued financial support of this critical effort.”

The Phase I/II clinical trial focuses on a protein called CCR5 that plays a key role in enabling HIV to infect cells. Blocking CCR5 may provide the cells a protective shield against HIV, which in turn would help retain immune system functionality.

“The mission of CIRM is to efficiently accelerate the development of stem cell treatments for patients suffering from unmet medical conditions,” says C. Randal Mills, Ph.D., President and CEO of CIRM. “While still early in clinical development, this announcement demonstrates real progress towards this mission. The accomplishment of Calimmune’s team is a great example of how CIRM partnerships are working to impact patient’s lives today.”

In the first phase of this study 4 HIV-positive participants were infused with their own blood stem cells as well as mature T cells that had been modified to carry a gene that blocks production of CCR5. The hope is that those stem cells will then create a new blood system that is resistant to HIV.

The participants had all previously been on anti-retroviral drugs but had discontinued taking them because of side effects or treatment fatigue, where the body stops responding to the medications as effectively as in the past.

The second group of 3-4 participants will not only get Cal-1 but will also receive a preconditioning regimen, aimed to make the therapy more effective.

The goal of the trial – which is being conducted in San Francisco and Los Angeles - is to assess the safety of the therapy, to determine the ease of use and feasibility of the approach for HIV/AIDS patients and to evaluate what, if any, side effects there may be.

“With more than one million Americans living with HIV/AIDS there is clearly an urgent need for treatments that do more than just hold the virus at bay,” says Jonathan Thomas, Ph.D., J.D., and Chair of the stem cell agency’s governing Board. “Current medications are often effective, but come with a big cost both in terms of dollars and side effects. Our goal with this project is to help find an approach that effectively cures people with HIV/AIDS.”

### **About CIRM**

CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for Stem cell research, research facilities, and other vital research.

**About Calimmune**

Calimmune is a clinical-stage HIV gene medicine company focused on developing innovative cell-based therapies for HIV. The company's stem cell technology was discovered in the labs of Nobel Laureate, Dr. David Baltimore (Caltech) and Dr. Irvin Chen (UCLA AIDS Institute). Calimmune is also developing a rich product candidate pipeline to address the needs of different types of individuals at different states of HIV infection and with different levels of treatment experience.