New HIV Eradication Study in Progress

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Cytheris has announced the launch and recruitment of a new Phase II study of the company's interleukin-7 (IL-7) drug—combined with the entry inhibitor Selzentry (maraviroc) and the integrase inhibitor Isentress (raltegravir)—with the goal of eradicating HIV.

Current antiretroviral (ARV) therapy is quite potent. When it works well, it completely shuts down HIV reproduction. Unfortunately, a small reservoir of infected cells remains in the body, and when people stop taking their HIV medication, the virus quickly resumes replication.

Traditional ARVs can't target HIV genetic material (HIV DNA) inside this reservoir of infected cells. This is because the cells are inactive; most ARVs only work in cells that are actively reproducing. Researchers are now exploring drugs that either wake up these resting cells or help purge their HIV DNA and, ultimately, make the virus vulnerable to HIV drugs. These strategies are one of several being explored with the goal of eradicating HIV from the human body (see "From Mice to Men" in the October/November issue of POZ).

One hopeful new therapy is IL-7. This naturally occurring cellular messenger (cytokine) helps different types of T-cells develop, mature and reproduce. IL-7 can also cause resting CD4 cells to "wake up." It is this latter quality that researchers are exploring in the study now under way.

The study (ERAMUNE 01)—which is being conducted by a nonprofit French institute called the Objectif Recherche VAccin Sida (ORVACS) and headed by Christine Katlama, MD, from the Hopital Pitie-Salpetriere in Paris—is enrolling people with HIV who are on a fully suppressive ARV regimen and who are judged to have a very small reservoir of infected cells based on a measurement of HIV DNA in the blood. The study will enroll 28 people living with HIV in Paris, Milian, Barcelona and London.

Katlama and her colleagues will add Isentress and Selzentry to everyone's regimen, an approach known as treatment intensification, to help maximize control of HIV replication. Eight weeks after people add Isentress and Selzentry, the research team will give them two cycles of IL-7 injections. The primary aim is to simply decrease the size of the HIV reservoir. Secondary goals include establishing the safety of this approach and, potentially, eradicating HIV.

"The unique hypothesis tested in this study is that with [IL-7 inducing CD4 cell activation and Isentress and Selzentry containing infection of CD4s] eventually [this will contribute] to viral reservoir reduction and potential eradication," said Thérèse Croughs, MD, the chief medical officer

of Cytheris.

A similar 28-patient study, ERAMUNE 02, is being conducted in the United States—in Chicago, San Francisco and New York—and is exploring Isentress or Selzentry treatment intensification in combination with an HIV-recombinant Ad5-based vaccine to boost the immune system's response to HIV DNA.

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