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TO: SANDY THURMAN
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FROM: Published Study Provides New
Understanding About HIV Infection
and Significance of Urine HIV-1
Testing

ATTN:

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PUBLISHED STUDY PROVIDES NEW UNDERSTANDING ABOUT HIV INFECTION AND SIGNIFICANCE OF URINE HIV-1 TESTING

Calypte Biomedical Team Led Study and Developed Peer-Reviewed Paper

ALAMEDA, CA — September 2, 1999 — Findings regarding the significance of detecting HIV-1 antibodies in the urine of individuals who test negative to HIV-1 in blood tests were reported by scientists from Calypte Biomedical Corporation (NASDAQ: CALY) in the September 1 issue of the peer-reviewed journal *Clinical Chemistry*.

The paper, titled: "Urine Antibody Tests: New Insights into the Dynamics of HIV-1 Infection," highlights two important findings about people who have discordant HIV-1 antibody testing results (those in which the serum and urine HIV-1 test results disagree). First, the study investigated a mysterious case of AIDS in which a French woman had an AIDS-like disease but consistently tested negative for antibodies to HIV-1 in her blood during the course of her illness.

A farm worker in rural France, the subject had no risk factors associated with contracting HIV-1. While the woman died without ever having blood antibodies confirmed for HIV-1, her urine contained HIV-1 antibodies evidenced in both a urine screening test and a urine supplemental (or confirmatory) test. Subsequent to her death, a variant of the HIV-1 virus was isolated. This variant is now referred to as HIV-1 Group O. In addition, the woman gave birth to a child who also died of an AIDS-like illness.

The Calypte research team used a new "mosaic analysis" approach to study the virus. The approach was first used to discover the human chromosome origin in the reshuffled genes associated with certain chronic diseases.

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The genetic analysis of the HIV-1 virus isolated from this woman, known as HIV-1vau, contained genetic segments of DNA found on fourteen different human chromosomes. Some of these segments have been implicated in several human malignancies. Interestingly, a significant piece of the monkey virus, simian immunodeficiency virus — African green monkey strain (SIVagm) — was also found in the subject's HIV viral DNA.

According to the study's lead author, Howard Urovitz, Ph.D., chief science officer of Calypte, "The findings strongly suggest that this mysterious case of AIDS in the French woman may have originated as a result of genetic reshuffling of genes. In certain individuals, AIDS may be a result of an underlying disease mechanism that somehow reshuffles normal human chromosomes, leading to AIDS-like symptoms and a drop in CD4 T cells. This would explain the hundreds of documented examples of people with AIDS who do not have any detectable HIV-1 antibodies in their blood."

The second main finding from Calypte's study was that seronegative people at risk for HIV-1 infection — intravenous drug users, partners of HIV-1 positive subjects, and subjects with sexually transmitted diseases — had a significantly increased frequency (up to 30 times greater) of a particular HIV-1 antibody in their urine, IgA, as compared to low-risk life insurance applicants.

"During the last six years, Calypte Biomedical has been aggressively researching people who demonstrate discordant HIV-1 antibody results in their blood and urine," said Bill Boeger, president and CEO of Calypte. "The *Clinical Chemistry* peer-reviewed paper highlights the significant contributions Calypte's urine test has made to HIV-1 and AIDS research. The urine test appears to provide a window into the human immune system that differs from serum. Considering the number of discordant samples there appear to be among the general population, Calypte continues to support the idea of combination testing of both urine and serum."

“We will also continue to oversee the ongoing clinical trials involving discordant individuals, particularly those who test negative with the blood HIV test, but positive with the urine HIV test,” added Boeger. “Naturally, we are very excited that the unique qualities of the urine test may contribute to our understanding of the development of HIV and AIDS.”

Calypse Biomedical Corporation is an Alameda, California-based healthcare company dedicated to the development and commercialization of urine-based diagnostic products and services for HIV-1, sexually transmitted diseases and other chronic illnesses. Calypse manufactures the only two FDA-licensed HIV-1 antibody tests that can be used on urine samples. These tests include the screening EIA and supplemental Western blot tests.

Urine testing is noninvasive, less costly, does not require sample storage or a trained health care worker for sample collection, and is safer because there are no risks of accidental needle sticks. Also, while urine contains antibodies to HIV-1, it does not contain the actual virus. The availability of both a urine screening test and a urine supplemental test make it possible to perform a full diagnostic HIV-1 antibody algorithm without ever drawing blood.

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Statements in this press release that are not historical facts are forward-looking statements, including statements regarding market adoption of the HIV-1 urine testing system. Actual results may differ materially from the above forward-looking statements due to a number of important factors, and will depend upon the Company's ability, directly or through third parties, to successfully manufacture and market the HIV-1 urine testing system. Factors which may impact the Company's success are more fully discussed in the company's most recent quarterly report on forms 10-Q and 10-K.

For more information on how to purchase or evaluate the product, call Dick Van Maanen of Calypse at 510-749-5100.