AIDS MALIGNANCY CLINICAL TRIALS CONSORTIUM (AMC)

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PRESS RELEASE

MODIFIED CODOX-M/IVAC-RITUXIMAB IS SAFE AND EFFECTIVE FOR HIV-ASSOCIATED BURKITT LYMPHOMA

AMC STUDY: #048

Rockville, MD, [date]:

Even in the era of highly active antiretroviral therapy (HAART) Burkitt lymphoma (BL) remains greatly overrepresented in people living with HIV. In fact, BL may be as much as 34 fold higher than in those without HIV. BL affects people even with high CD4+ cell counts and low HIV viral loads.

BL treatment in the general population typically involves very toxic and intensive chemotherapy which cures about 75% of patients, while less toxic regimens have led to cures in less than half the patients. In the era prior to HAART, patients with HIV/AIDS could not tolerate chemotherapy for lymphoma. Studies, including those by the AMC, showed that the most common type of aggressive lymphoma, diffuse large B cell lymphoma, could be treated with standard chemotherapy with extremely good outcomes. Standard chemotherapy did not work well against BL and doctors were concerned that more intensive chemotherapy regimens would not be well tolerated and contribute to greater morbidity and mortality in this patient population.

This multicenter phase II clinical trial was designed to determine whether modifications of the multi-drug program could successfully treat HIV-associated BL while making the treatment more tolerable. In trial AMC-048, the AMC modified the doses and timing of the drugs in the CODOX-M/IVAC back bone to reduce toxicity This reduced the rate of serious adverse events and eliminated severe mouth sores. Adverse effects from chemotherapy were generally expected and manageable and 68% of 34 patients enrolled in the study completed all recommended cycles of treatment. Overall, 70% of enrolled patients were alive and in remission at 2 years of follow-up. These results are comparable to those achieved with complex and multi-agent chemotherapy regimens used to treat BL patients without HIV.

The modified CODOX-M/IVAC regimen studied in the AMC provides additional data on the importance of treating patients with HIV and BL with curative intent. It also provides further information on a less

toxic option than the more standard multi-agent platform that has traditionally been used to treat non-HIV infected patients with BL.

Reference:

Noy A, Lee JY, Cesarman E, Ambinder R, Baiocchi R, Reid E, Ratner L, Wagner-Johnston N, Kaplan L. (2015). AMC-048: Modified CODOX-M/IVAC-rituximab is safe and effective for HIV-associated Burkitt lymphoma. *Blood*. Jul 9;126(2):160-6. ***(Link to PubMed Abstract)***

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AIDS Malignancy Consortium Trial #048: Prospective Phase II Study of A High Dose, Short Course Regimen (R CODOX-M/IVAC) Including CNS Penetration and Intensive IT Prophylaxis in HIV-Associated Burkitt's and Atypical Burkitt's Lymphoma

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For more information about HIV-malignancies please visit our website:

http://www.AIDScancer.org