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**Developmental Therapeutics Branch  
Division of AIDS  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health**

**In Vitro and Animal Model  
Evaluation of Antiviral and Antiinfective Therapies**

The mission of the Developmental Therapeutics Branch (DTB) is to facilitate the discovery of therapies for HIV and AIDS-associated opportunistic infections and to assist in their development into clinical trial candidates. DTB provides the resources listed below to assist academic and industrial scientists in preclinical aspects of drug development. All rights to compounds developed with the assistance of DTB remain entirely with the compound sponsor. The sole interest of the government is to ensure that effective therapies are developed and licensed as quickly and efficiently as possible.

Confirmatory in vitro testing for anti-HIV activity can be performed in T-cells and macrophages using standard laboratory strains, clinical isolates, and drug-resistant strains of HIV. Various virologic endpoints are available, including evaluation of virucidal potential using cervical epithelial cells. Combinations of antiviral agents are routinely evaluated. In vivo testing against HIV can be performed using a SCID/hu murine model. SIV, FIV, FeLV, and MuLV animal models of AIDS are available. Immune-based therapies can be evaluated in these animal models.

Primary screening of potential therapies against a variety of opportunistic infections that affect AIDS patients can be performed. In vitro or in vivo models can be used to determine drug efficacy against Pneumocystis carinii, Mycobacterium avium complex, Toxoplasma gondii, Cryptococcus neoformans, Candida albicans, Histoplasma capsulatum, Cryptosporidium parvum, and Mycobacterium tuberculosis. High throughput biochemical screens which use purified target and host enzymes are available for some of these organisms.

Facilities are available to provide preclinical, critical path development resources necessary to satisfy IND requirements, including scale-up synthesis, formulation development

and manufacturing, analytical methods development, and quality control, complete pharmacokinetic and toxicology assessment in large and small animals, and immunotoxicity evaluation.

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