

MOUSE MONOCLONAL ANTIBODIES SPECIFIC TO TRYPANOSOMA CRUZI ANTIGENS

Technology Summary

Trypanosoma cruzi (T. cruzi) is the causative parasite agent of Chagas disease. Although, two drugs, Benznidazole (BZ) and Nifurtimox (NFX) are used to treat Chagas disease, treatment rarely results in a complete cure. T. cruzi infections are a chronic and lifelong disease with serological assays remaining positive over the lifetime of the infected host. Assays that detect biomarkers correlated with reduced parasitemia or parasite load after drug treatment are needed. Reduced levels of parasite biomarkers, such as secreted antigens would aid in the determination of drug efficacy.

FDA researchers have developed monoclonal antibodies (mAbs) against six T. cruzi antigens that are specific to their respective targets and show high binding affinities in the range of 1 x10-9 to <1.0 x10-12M. These *T. cruzi* mAbs can potentially be used to develop assays to detect antigens in *T. cruzi* patients either as a diagnostic test or an antigen assay to confirm disease status in Chagas patients. Currently, no assays that detect *T. cruzi* secreted antigens are available on the market.

Potential Commercial Applications

- Research tool
- Diagnostic test for Chagas Disease
- Antigen tests to confirm disease status

Competitive Advantages

T. cruzi antigen specific monoclonal antibodies

Development Stage:

• Development assays to detect *T. cruzi* in mice and Chagas patients

Inventors:

Alain Debrabant, Rana Nagarkatti, David Acosta

Publications:

 Nagarkatti, R. et. al. A novel Trypanosoma cruzi secreted antigen as a potential biomarker of Chagas disease. Sci Rep. 2020 Nov 11;10(1):19591. PMID: 33177582

Product Area:

Research materials, monoclonal antibodies, Trypanosoma cruzi, Chagas

FDA Reference No: F-2020-014

Licensing Contact:

Ken Millburne, J.D.

FDA Technology Transfer Program

Email: FDAInventionlicensing@fda.hhs.gov Phone: 240-402-2245