



Rabies Monoclonal Antibody Product

Overview

Rabies Monoclonal Antibody Product Overview The company is working with the North China Pharmaceutical Group Corporation (NCPC) with headquarters in Shijiazhuang, to develop a human anti-rabies monoclonal antibody (Mab) product in China for post-exposure treatment of rabies. This product consists of a mixture of human anti-rabies Mabs initially developed at Thomas Jefferson University, Philadelphia. These Mabs have been shown to neutralize a wide range of rabies virus strains and to provide protection in animal efficacy models. Our product is intended to replace the currently used horse and human rabies immune globulin products that are in short supply in many countries and have related safety concerns. Our antibodies are produced by conventional cell culture technology under serum-free conditions and offer a safe and effective alternative to the current outdated serum products.

Introduction

Rabies, a viral disease of mammals, is a worldwide public health problem. The virus is usually transmitted through the bite of an infected animal and will result in death if medical treatment is not begun before symptoms appear. Globally, human deaths due to rabies are estimated at 60,000 per year, mainly in China and India. Additionally, approximately 10 million people a year undergo post-exposure treatment. Rabies post-exposure prophylaxis (PEP) consists of the use of anti-rabies immunoglobulin (RIG) together with the administration of rabies vaccine. The rationale for this PEP is based on the assumption that the passive administration of rabies virus neutralizing antibodies together with the induction of a strong immune response to the virus clears the virus before widespread infection of the CNS can occur. Rabies virus-specific antibodies in RIG are believed to neutralize the virus at the site of entry and, therefore, injection of RIG into the bite site as well as systemic administration is recommended. To date, vaccination by itself (i.e. no RIG) cannot be relied upon to prevent rabies, particularly under severe Exposure conditions. Currently the supply of RIG, derived from human or horse immune serum, is in short supply and has related safety concerns.

Product Development Status

The company completed animal model studies on two Mabs developed from the panel of Mabs created by Dr. Bernhard Dietzschold at Thomas Jefferson University. Development was done in collaboration with University of Georgia, Athens and the Centers for Disease Control (CDC), Atlanta. This work was supported by a Biodefense Partnership Grant from the NIAID. Our corporate partner, NCPC, has optimized the cell lines and processes for production of clinical material. NCPC submitted a dossier to the Chinese FDA in 2007 for the conduct of clinical trials. They have completed a phase Ia safety and pharmacokinetic study in 40 subjects dosing at 10, 20, and 40 IU/kg and a subsequent phase Ib study. They are currently conducting a phase II clinical study.