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A robust and reproducible process for production of a schistosomiasis vaccine

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Schistosomiasis causes significant morbidity and mortality in the developing world with recent studies indicating that the geographic extent and burden of the disease is higher than the official estimates. Although, Schistosomiasis is a treatable infection, the current treatments of choice do not provide an optimal strategy for controlling the disease. The high rate of post-treatment reinfection has made obvious the need for new approaches, such as vaccination, to complement the existing treatment initiatives. The increase in information regarding the mechanisms of immunity forSchistosomiasisinfection has indicated that surface antigensmay be effective vaccine candidates. Of this handful of proteins, some have already been shown to have potential as recombinant vaccines against Schistosomiasis at a pre-clinical level. In particular, the tetraspanin family of integral membrane proteins, highly abundant in the parasite tegument, has been shown to correlate with protective immunity in a mouse vaccine model, suggesting that this family of membrane proteins offers promise as a Schistosomiasis vaccine. The Pichia codon optimized DNA sequence of the extracellular domain of Sm-TSP-2 was synthesized and cloned into the Pichia expression vector pPinkα-HC. Here we describe the process development that led to the GMP manufacturing of one of the lead candidate antigens Sm-TSP-2 at a 20L scale fermentation, and its formulation for phase I clinical trials. Throughout the process we confirmed the yield of recovery, the purity, and the integrity of the recombinant protein, as well as a comprehensive biophysical characterization of the protein itself.

Biography

Elena Curti, Ph.D. is an Assistant Professor of Pediatrics at National School of Tropical Medicine at Baylor College of Medicine. She also directs the Analytical and Formulation Unit for the Sabin Vaccine Development Program at Texas Children's Hospital and BCM. Dr. Curti previously was a Research Scientist at Walter Reed Army Institute of Research (WRAIR) where she was working on new antigens discovery for the Malaria Vaccine Development Program. She is a native of Torino, Italy, where she obtained her degree in Biochemistry and Molecular Biology in 2000, followed by her Ph.D. in Biochemistry and Biophysics at the University of Leeds in United Kingdom, in 2005. She completed her post-doctoral training in Molecular Biology in 2009 at the National Institutes of Health, Maryland.

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