

APPLICATION BY CENTRE FOR INFECTIOUS DISEASE RESEARCH IN ZAMBIA(CIDRZ) TO CONDUCT PHASE 1/2A CLINICAL TRIALS /RESEARCH ON THE PROSPECTS FOR FIGHTING HIV.

Centre for Infectious Disease Research in Zambia (CIDRZ)

1.0 Background

The SAC considered the application from Centre for Infectious Disease Research in Zambia to conduct research on an ALVAC based vaccine (AFR/2017/08/02). This application was reviewed in 2016 in which the SAC had requested the applicant to provide additional information.

2.0 REVIEW COMMENTS FROM THE SCIENTIFIC ADVISORY COMMITTEE

1. Review of Form 1: Completeness of the form was satisfactory

Upon being furnished with the requested information, the SAC reviewed it in the Extra Ordinary SAC meeting held on the 25th August 2017 and made the following observations after Risk assessment:

a) DETAILS OF THE GMO MATERIALS USED

The SAC was satisfied with the methods that were used to construct the vectors and found these to be clearly described and adequately explained.

b) Transformation events

The various genes obtained from the HIV and the sequences from the proposed canary pox virus vector were found to be well described. The SAC noted that the proposed vaccine was a live attenuated vaccine made from vaccinia virus sequences. Information on the two other viruses, HIV and Canarypox, which were used to obtain additional genes or regulatory sequences was also provided. The Committee determined that the proposed vaccine met the expected safety threshold and the reviewed research literature indicated that the vaccine was well tolerated at all dose amounts. Among the genes that were proposed for use in the recombinant vector were the Nef-, Tat and gp120 which were by themselves non-infective.

c) Pathogenicity and Toxicology

The Canarypox virus which normally infects canary birds had been attenuated (weakened) by passing it through chicken embryo fibroblast cells (CEFs) which was a

standard procedure for live vaccine development and was determined to be safe to use.

Sufficient peer-reviewed literature on toxicology and related vaccine-development studies were provided.

d) Detection

Data on Western blot experiments and autoradiography results were presented, even though the Western blot membrane used was blank.

1.1. Geographical reference and site: The the phase 1/"a Clinical trials will be conducted in Lusaka, Matero.

2. **Enough references:** Pear reviewed papers were included
3. **Committee approvals:** Biomedical Ethics and ZAMRA approvals were submitted
4. **IBC registration:** Submitted
5. **List of personnel working on the research:** submitted

3.0 The Committee recommended to the Board to grant the permit.

4.0 Final Decision

Permit granted