International Alliance for Biological Standardization

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Workshop on Assessing Consequences of Maternal Immunization on Foetal Outcomes

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Title: Summary of the RSV vaccine findings on prematurity and how it informed impact studies

Prof. Shabir Madhi, University of Witwatersrand, South Africa

Maternal vaccination with the Respiratory Syncytial Virus (RSV) pre-fusion F- protein vaccine have been demonstrated to be efficacious and effective in protecting against severe RSV lower respiratory tract infections. Nevertheless, a signal suggestive of an increased risk of preterm birth in vaccine recipients, almost exclusively in upper-middle income countries, led to caution in the prescribed gestational age when vaccination has been recommended for use. The lower gestational age at which RSV maternal vaccine is recommended varies between countries, ranging from 24 weeks up to 32 weeks of gestational age. The vaccine efficacy trials in which a possible association with preterm birth were undertaken during the COVID-19 pandemic, with the excess of cases among vaccine recipients temporally associated with resurgent waves of COVID-19. Observational studies post-implementation of maternal RSV vaccine have not observed any association to preterm birth. As the causes of preterm birth are multi-factorial, observational studies could be heavily influenced due to confounders Consequently, to provide a definitive answer as to whether or not maternal RSV vaccination is associated with preterm birth, a randomised controlled trial is underway, which has been powered to evaluate as a co-primary endpoint the safety of maternal RSV vaccine in relation to preterm birth.