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## DEVELOPMENT OF A PENTAVALENT GROUP B STREPTOCOCCUS (GBS) GLYCOCONJUGATE VACCINE IN AFRICA

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A vaccine against Group B Streptococcus (GBS), utilized in a maternal immunization strategy to reduce the burden of GBS mortality and morbidity in infants, has potential for use all over the world, but would have the greatest impact in low-resource countries that have limited access to interventions. Currently there is no vaccine against GBS. The Biovac Institute (Biovac), a private public partnership in South Africa, is developing a pentavalent, polysaccharide-protein conjugate vaccine (PCV) against GBS — using state-of-the-art technology and targeting the most common strains.

A vaccine providing more than 90 % coverage against GBS infection would need to include at least 5 serotypes including serotypes Ia, Ib, II, III and V. Production of a low-cost pentavalent vaccine would require optimization of unit processes to achieve high yields without compromising product quality.

The presentation will describe (1) the selection of high capsular polysaccharide (CPS) producing isolates; (2) development of manufacturing processes to produce CPS for serotypes Ia, Ib, II, III and V; (3) development of a glycoconjugate process, which involves covalently linking the CPS to a carrier protein; (4) results of a monovalent conjugate vaccine mouse study; and (5) further animal and clinical studies planned. While the GBS project affords Biovac the opportunity to establish end-to-end vaccine product development capability, equally importantly, it will also begin to shift the paradigm regarding Africa by demonstrating that vaccine projects of this complexity and magnitude can be done in Africa by Africans. It will contribute significantly to advancing Africa's capability to respond to vaccine epidemics and infectious diseases of regional relevance.