

ASAQ - NEW DATA AND POST REGISTRATION STUDY PLAN PROGRESS

F. Bompert

Sanofi Aventis, Gentilly, Paris, France

The fixed-dose combination of artesunate-amodiaquine (Coarsucam[®] or ASAQ Winthrop[®]) is the first antimalarial drug developed by a Public Private Partnership, namely a partnership between the FACT consortium, led by DNDi, and Sanofi Aventis. Since prequalification by the WHO in 2008, over 50 million ASAQ treatments were distributed in sub-Saharan Africa. This presentation will provide a brief update on recent data available on ASAQ efficacy and safety profile, in Africa, Asia and Latin America as well as food interaction data. The presentation will mainly aim at providing details on the progress of the “ASAQ field monitoring program » that aims to gather, through a variety of studies, important information that is rarely documented with antimalarials such as efficacy in “real life situations”, safety in patients with no biologically proven malaria, safety of repeated administrations, etc. This program, conducted in partnership with DNDi, MMV, academic teams and National Malaria Control Programs, will monitor over 20,000 patients in endemic countries. This innovative post-registration program was formalized as a Risk Management Plan, the first ever submitted to the WHO for an antimalarial drug. This initiative should provide crucial methodological information for the field monitoring of future antimalarials' efficacy and safety, as well as help build scientific expertise and pharmacovigilance capacity in malaria-endemic countries.