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ASIA EDITION

GSK melanoma phase III misses co-primary endpoint

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Singapore: GlaxoSmithKline's (GSK) Dermai study, a phase III, randomized, blinded, placebo-controlled Mage-A3 cancer immunotherapeuticii (CI) trial, which contains Agenus'QS-21 Stimulon adjuvantiii, a component of GSK's novel adjuvant system AS15, did not meet its first co-primary endpoint. In an independent analysis, the study did not significantly extend the disease-free survival (DFS) period as compared to placebo in the overall Mage-A3 positive trial population.

In line with the Independent Data Monitoring Committee's (IDMC) unanimous recommendation, GSK will continue the study until the second co-primary endpoint is assessed. This co-primary endpoint is based on predefined criterion that was agreed upon by regulatory authorities. This analysis, which is based on gene signature, is designed to prospectively identify patients who may have the capability to be more immunologically responsive and therefore can potentially benefit from treatment.

If further analysis shows that the predefined gene signature subset data are successful, there is the potential that a regulatory filing could be considered. GSK anticipates that these data will be available in 2015. Until then, GSK will remain blinded to all safety and efficacy data. The IDMC for the DERMA study indicated that the current review of the safety information raised no concern for the continuation of the trial.

QS-21 Stimulon adjuvant is key component of many vaccines currently in clinical development. Agenus expects to report phase II data for HerpV, Agenus'QS-21 Stimulon containing investigational therapeutic vaccine for genital herpes, during the fourth quarter of 2013. GSK is expected to announce phase III results from Magrit, the Mage-A3 non-small cell lung cancer (NSCLC) clinical trial during the first half of 2014. In addition, GSK is expected to provide an update to the RTSS program for the prevention of malaria.

Dr Garo H. Armen, chairman and CEO, Agenus, said that, "We continue to believe that cancer immunotherapeutics have the potential to deliver significant benefits to patients and we look forward to the analysis of gene signature data. In the near future, we expect to report results of several other QS-21 Stimulon adjuvant containing programs."