NEWSLETTER SSG XXI – PAGIST, 25/JUNE/2013

Dear Investigator & Study Coordinator/Research Nurse in SSG XXI,

Our trial SSG XXI, known as PAGIST, has now been enrolling patients for more than a year with a slow start during the spring of 2012. Due to a poorer inclusion than expected we have now welcomed three excellent German trial sites; Berlin, Mannheim and Essen, all of which have been very good collaborative centers with SSG in the earlier SSG XVIII/AIO trial. Since a start meeting held by SSG in Berlin in April, all three have now included their first patients. The national coordinator for Germany is Peter Reichardt with effective help by Annette Reichardt.

Amendment

According to views from the German legal authorities and Ethical boards we had to amend some points in the protocol, mainly concerning some eligibility criteria (allowed laboratory values, blood pressure, QT-time etc). This produced a version 1.4 of the protocol now used in Germany; the other countries are still using v 1.3!

However, we are now in the process to get approval for a further version, 1.5, in all countries, i.e., conversion from 1.3 to 1.5 for the Nordic countries, and from 1.4 to 1.5 for Germany. Except the changes to 1.4 we have added a few things: a) GSK claims a further liver function test three (3) weeks from start of treatment (recommended for all patients in both trials and standard use) because some cases of rapid liver deterioration between weeks 2 and 3 have been reported; b) we have clarified that the trial will recruit in total 72 *evaluable* patients, i.e., patients who had got at least one dose of the drug AND have been accepted as correctly included according to eligibility criteria. Patients not fulfilling these criteria may thus be substituted.

Once we have the approvals from authorities and ethics you will be informed and get access to the new version and a list of changes.

Enrollment

So far, 32 patients have been enrolled with Göteborg (Gothenburg) in a clear lead with 6 patients followed by Uppsala with 4 and Oslo, Lund, and Berlin with 3 each.

Interim analysis

According to the protocol, following a Simon´s two stage design, an interim analysis will be performed when 22 patients have been evaluated for clinical benefit after 12 weeks treatment when at least 6 patients must fulfill this criterion to allow the study to go on. We have just passed that point but we need some weeks to collect missing CRFs before the analysis may be done. However, the result of this procedure is expected during the summer, and before this it is allowed to recruit further patients.

SAE reporting – change of routine

To secure a safe and rapid distribution of SAE reports not only to the SSG secretariat but also to GSK in England we will now and for the rest of the trial change routine for SAE reporting. Up to know, centers have only sent the report to SSG, and from here a copy has been sent to GSK England. From now on, all centers must fax the report to two receivers: a) SSG as now; b) GCSP Department: Stockley Park, att. Asako Takata, at fax no +44 (0)208 754 7822.

Do not forget.....

....to send completed CRFs by mail to the SSG secretariat without much delay (keep a copy at the site!);

....the blood sample for plasma through level at the week 12 visit just before the daily dose of pazopanib (i.e., approximately 24 hours after the last dose) – try to adapt the visit time! For details – se appendix 2!;

....to contact your national coordinator or someone of us in the SSG XXI-team as listed below if you have any questions!

Thank you for your cooperation in this trial!

Best wishes from the SSG secretariat

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