PAGIST (SSG XXI) NEWSLETTER 12-06-15

Dear investigators and research nurses/coordinators,

This is the first Newsletter for SSG XXI with the purpose to inform you about enrollment, potential problems or amendments, frequently asked questions or other items of interest related to this clinical trial.

The "PAGIST"-trial has now been started in Sweden, Norway and finally Finland during the spring. In Iceland the final approval is closely awaited, and in Denmark the applications will be submitted during June.

Enrollment by 12-06-15:

Gothenburg	3
Lund	1
Kuopio	1
Tromsö	1 (registered but never started therapy)
Bergen	1

Thus, 7/72 planned patients are registered, almost 10%. Since two other "pazopanib-in-GIST"-trials are on-going, and in the light of recently presented promising data on other 3rd line tyrosin kinase inhibitors, it is highly desirable to speed up the enrollment rate further, and therefore we actually plan a……

German participation

We have invited three large German centers (Berlin, Mannheim and Essen) with whom we have cooperated well in an earlier trial. They are all interested and our economical supporter, GSK, seems preliminary positive to support also this enlargement. Hopefully, they may join the trial later this year.

CRF-modification

The registration CRF is slightly modified in design since the start meetings. Of importance to note is that the "sum-of-the-longest-diameters" to be given on this CRF shall be that of the baseline CT, and it must not be completed at the time of registration since it may not yet have been evaluated by then. Thus, when you get this measure, complete the CRF and re-send that to the SSG secretariat.

Reminders

Please, use the SSG XXI protocol as your "master" when you see your study patients, not to forget e.g., routine blood samples to be taken and potential dose reductions as a consequence

of these or of adverse events, time points for CT evaluations and of LVEF monitoring, research serum samples at the week 12 visit (remind the patient not to take the drug before the visit that day; the sample is preferably taken 24 hours after last dose!).

Questions?

If you have any problems e.g., with interpreting the protocol, do not hesitate to discuss with your monitor, your national coordinator or the SSG secretariat (see e-mail addresses below!).

SSG home page

Study related material may be found at SSG´s homepage: www.ssg-org.net

Summer time

Enrollment in clinical trials always tend to decrease during summer – please, try to avoid this if possible since the eligible patients are not so very frequent. At the same time, we of course wish you all nice and sunny vacations!

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