

36 months adjuvant Imatinib-treatment for high-risk-GISTs improves recurrence-free survival (RFS) and even overall survival (OS).

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For some weeks the international “GIST Community” has anticipated important news at the ASCO-Conference, running from 4 - 8 June 2011 in the Chicago/USA. Over 30.000 healthcare professionals, patient advocates and pharma representatives from all over the world meet annually for this important educational and scientific conference on cancer treatment.

GIST-patients and their doctors have been expecting new data from studies on adjuvant treatment with Imatinib (Glivec® in Europe/Australia, Gleevec™ in the USA) in GIST (Gastrointestinal Stromal Tumour). These new data came from the Scandinavian-German study (SSG) XVIII/AIO - a phase III trial. The purpose of the study was to compare 12 versus 36 months of adjuvant Imatinib as treatment for patients with a high risk for GIST recurrence after surgery. The primary endpoint was “Recurrence Free Survival” (RFS). From early 2004 until autumn 2008 - 400 patients were accrued into this study; the patients received 400mg/day Imatinib in both study arms.

The study was reported this Sunday afternoon at the “Plenary Session” announcing major findings in cancer research, at McCormick Place in Chicago. This session gave outstanding results for the international GIST-Community. The SSG-results were presented in Chicago by Prof. Heikki Joensuu, GIST-expert from Helsinki/Finland, who was the first doctor to treat a GIST-patient with metastatic disease with Imatinib in year 2001.

Immediately after the presentation Das Lebenshaus e.V. (Germany) – member of Sarcoma Patients EuroNet Assoc. – called one of the principle investigators in the study, and senior author of the paper PD Dr. Peter Reichardt. (He is an internationally recognised GIST-expert from the Sarcoma Centre Berlin-Brandenburg in Germany and a member of SPAENs European Medical Advisory Board. He also recruited most of the patients into the SSG-trial.) Dr. Reichardt explained the main results of the trial: Imatinib given for 36 months improves recurrence-free survival (RFS) and overall survival (OS) compared with 12 months of adjuvant treatment for GIST-patients who have a high risk of recurrence after surgery. RFS was longer in the 36 months group compared with the 12 months group: The 5-years RFS was 65.6% for the 36 months group vs. 47.9% for the 12 months group. But “vitally important” were the OS results: Patients assigned to 36 months of Imatinib have a higher probability of survival (5-year OS = 92.0%) compared to the patients in the 12 months group (5-year OS = 81.7%).

Peter Reichardt is really enthusiastic about these results and with the feedback received after the presentation in Chicago: *“Many members from of the international GIST-expert community expected that 36 months adjuvant Imatinib – would be better than 12 months regarding the RFS. But in addition: That the data for the overall survival would be so convincing is the main importance of these results. The findings mean very simply: The risk of dying within 5 years of first diagnosis of an operable high-risk GIST is actually halved by 36 months of adjuvant Imatinib compared to 12 months of treatment.”*

For many GIST-patients and physicians this brings to a conclusion a period of uncertainty. The 12 months data from the ACOSOG Z9001 raised the anxious question: What happens after 1 year of adjuvant therapy? The ASCO results today set a new standard: 3 years duration of adjuvant Imatinib-treatment for GIST-patients with a high risk of recurrence.

SPAEN recognises that in some countries the case for healthcare systems funding adjuvant treatment still has to be won. We hope that these results will convince funders to make a positive decision in favour of what we believe is now a new standard-of-care.

The 2011 ASCO data continues the “Imatinib Success Story” that started in 2000. At the same time, these results offer a “proof of concept” for targeted therapies in the adjuvant setting, building the hope that modern adjuvant treatment options will be developed in other types of sarcomas and other cancers.

Sarcoma Patients EuroNet will report more detailed results shortly. We will also provide an “ASCO Summary Report” on Sarcomas and GIST. Those who are interested in further GIST research results more quickly will find about 60 abstracts in English under: <http://abstract.asco.org>

SPAEN Sarcoma Patients EuroNet Assoc. is the European Network of Sarcoma, GIST, and Desmoid Patient Advocacy Groups. Acting in partnership with medical experts, scientific researchers, the healthcare industry and other stakeholders, SPAEN works to improve treatment and care of GIST, Desmoid and sarcoma patients in Europe through improving information and support, and by increasing the visibility of sarcoma with policymakers and the public. Further information can be found on <http://www.sarcoma-patients.eu>