Tenth Anniversary of the Phase-II Study Group in the Association for Medical Oncology (AIO) of the German Cancer Society

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The Phase-II Study Group of the AIO was established during the 17th German Cancer Congress in Munich in March 1984. The history, background, structure and function of the study group have been described earlier in this journal [1]. The aim of this group is to initiate and perform early clinical trials in Germany for the introduction of new antineoplastic compounds for clinical use, this being in the interest of pharmaceutical industry as well as of clinical researchers in oncology. From the early beginning 16 pharmaceutical companies and more than 25 clinical institutions cooperated in this group. The Phase-II Study Group focused its attention on clinical research based on international standards and on national drug regulation and legislation. Own guidelines and a master protocol for phase-II trials were published in 1985 [2]. The NCI guidelines for clinical trials in oncology today, being well known as 'Good Clinical Practice (GCP)', were adopted and special appointments for practical application of monitoring, audit and data processing were introduced [3]. An own Biometric Center for the group was founded at the German Cancer Research Center in Heidelberg. In 1989, the group extended its activity towards phase-I trials and an own subgroup, the Phase-I Study Group of the AIO, was founded. Subsequently, in 1992 basic research for development and formulation of new antineoplastic compounds was integrated by founding a group called 'Arbeitsgruppe Wirkstoffentwicklung in der Onkologie (AWO)'.

Up to now more than 40 compounds have been studied, such as Anaxirone (TGU), Idarubicin, Pirarubicin, Tauromustin (TCNU), tumor necrosis factor (TNF), Ilmofofosine, Droloxi-fene, Vinorelbine, Miltefosine, interferon-beta, Iododoxorubicin and – more recently – Lobaplatin and Taxol. A considerable

number of papers were published in this journal and elsewhere. From 1989 to 1991 four international symposia (Frankfurt, Dresden) dealing with 'New Drugs in Oncology' were held. Later special sessions were organized at the yearly meetings of the German Society of Hematology and Oncology. Regular reports on the work of the group are published [4]. The future concept of the study group is that new promising compounds coming from various sponsors or developed within the AWO are studied by the Phase-I Study Group in early clinical testing and thereafter by the Phase-II Study Group in different tumor entities. The group has

additional interest in retesting old compounds in new schedules and protocols. Requirement for future work is to intensify international cooperation. Recently, own Standard Operating Procedures (SOPs) were developed to fully implement the GCP guidelines and further improve of the quality of the studies performed by the group. On behalf of the 10th anniversary of the group the SOPs are published in this issue of 'Onkologie'.

References

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