



2004

BREAST CANCER

*Some important facts on the situation in
Central and Eastern Europe*



Dear colleagues,

Once again, "S&P" Pharmatest presents you a new edition of our Medical Report. We have this time chosen a very important item which is taking a huge share on the research & development areas of the pharmaceutical companies worldwide: breast cancer.

Breast cancer is the second leading cause of cancer deaths in women today (after lung cancer) and is the most common cancer among women, excluding nonmelanoma skin cancer. According to the World Health Organization, more than 1.2 million people will be diagnosed with breast cancer this year worldwide. The newest estimations show for example, that the amount of new cases in **Eastern Europe** will raise to ca. 112,000 patients, and the deaths will be of about 45,000 people.

The key to surviving breast cancer is the early detection and treatment. According to the American Cancer Society, when breast cancer is confined to the breast, the five-year survival rate is close to 100%. The early detection of breast cancer helps reduce the need for therapeutic treatment and minimizes pain and suffering, allowing women to continue leading productive lives.

Unfortunately, this is not a global truth. There is still a huge difference in prevention and treatment of breast cancer between Western countries and other regions in the world. Given the high standards of the health system in Western Europe, the early identification of breast cancer is done each time earlier (broad mammography from age 30 onwards, early identification methods free of charge,...). Therefore, in situ carcinoma are discovered and treated at an early stage before they can develop further. Inoperable breast cancers are therefore very difficult or even almost impossible to find in Western European countries such as **Germany, France, UK, Austria, Italy, Switzerland or Spain**.

In a second group of countries (**Central European** and **Baltic** new European Union member countries), the health system is making progress as the states are modernized and the early identification measures are gradually being put into practice. In these states, the amount of inoperable breast cancer is therefore rapidly sinking.

A third group is formed by countries with a strong rural population who have problems with free of charge early identification programmes. Countries such as **Russia, Ukraine, Bulgaria, Bielorrussia, Turkey**, and other countries in the periphery of Europe, as well as former Soviet republics are the ones with more cases of inoperable breast cancers, and where clinical studies researching new methods of fighting against it and its effects have the best conditions for success. Therefore nowadays, studies in inoperable breast cancers are only possible to perform in Eastern Europe. The recruitment rate of untreated patients would lie between 300 and 350 such patients in 6 months (between 15-30 patients per center in untreated inoperable cancer, as opposed to early stage patients, where each of our centres can hold a recruitment of between 50-70 patients in half a year).

In the last decade, an enormous amount of time and funds have been invested in the fight against breast cancer. Unfortunately, for the correct research in this field, a huge number of naïve, untreated patients are needed. As we have seen, it is almost impossible to find untreated breast cancer patients in an advanced state in eastern countries. Exactly that is the advantage of "S&P" Pharmatest Management: we have a large network of centres across Central and Eastern Europe, where the amount of new cases is extremely large and the typical centralization of patients in large specialized centres makes it very good for reaching a vast number of naïve untreated patients in a short period of time. Of course, all our centres are experienced in the performance of ICH-GCP trials for Western sponsors. In the last years we have performed numerous successful ICH-GCP studies with thousands of patients with early stages (T_1 - T_3 , N_{0-1} , M_0) of untreated breast cancer, including LQS, CTC and RECIST criteria.

We are thus taking the liberty of sending you a brief questionnaire on the next page which we ask you to fax back if interested.

Yours truly,

Dr. Alexander Siebel
Medical & Managing Director

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Your opinion is important for us. We would like to know what you think of us and our reports, so please take a few minutes to fill up this short questionnaire and fax it back to us (+49 30 6937500). By helping us, we become better for you.

- 1. Do you have R&D experience in Central and Eastern Europe?
2. For which indication would you like to receive more detailed information on Central and Eastern Europe?
3. What stage of breast cancer patients are you looking for in your studies?
4. For the study approval process in which of these countries would you like to receive further information?
5. What R&D fields are most important for you to be covered in Central and Eastern Europe?
6. What are the qualities you value the most for your choice of Central and Eastern Europe?

Name:
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