Clinical trials show promise for prostate cancer drug

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A 30 percent reduction in mortality risk is one of the impressive results achieved in a global clinical drug trial for the treatment of prostate cancer. The full trial data are due to be presented today at one of the world´s most important oncology conferences, the ASCO GU. The development of the unusually effective cancer drug was also based on three clinical trials carried out by the Clinical Program on Urological Tumours at Vienna General Hospital. Participants in the trial at the hospital already had access to treatment using the drug for four years. Recently, the trial was terminated prematurely - the outstanding results prompted the supervisory board to make the drug available as quickly as possible to the placebo control group.

The symposia of the American Society of Clinical Oncology (ASCO) are considered internationally as the most important forums for the presentation of new research findings on cancer treatment. Urgently awaited data on a new androgen receptor antagonist are being presented today at the ASCO Genitourinary (GU) Symposium in San Francisco. The drug was developed for the treatment of so-called castration-resistant prostate cancer (CRPC) and inhibits the tumor growth triggered by the male sex hormone. According to the trial data, the drug can actually reduce the mortality risk of patients by 30 percent. Moreover, the risk of progressive tumor growth or the death of the affected person was reduced by 81 percent reduction as compared with a placebo group.

"The data presented today," explains Professor Michael Krainer, director of the Clinical Program on Urological Tumours at Vienna General

Hospital, "relate to patients who have not yet received any chemotherapy. The potential new application for this drug offers an effective alternative treatment for this group of patients." The drug was actually licensed in 2013 for patients who had already undergone chemotherapy. Based on the convincing outcomes observed in these patients, trials were quickly carried out on its use in so-called chemotherapy-naïve patients. The results of an intermediate assessment of this clinical phase 3 trial were so conclusive that the Independent Data Monitoring Committee (IDMC) recommended the termination of the trial. In this way, not only could the control group be given access to the new drug as quickly as possible, the overall licensing process could also be accelerated.

The clinical trial was carried out throughout the world at centers in the USA, Canada, Australia, Russia and European countries. The Urological Tumors research group at Vienna General Hospital has been involved in the development and licensing of the drug since 2009. As a result, it has been possible to treat numerous patients with the drug in the context of three clinical trials. The Viennese research group is one of the most renowned clinical monitors in the area of prostate carcinoma in Europe: several hundred patients have been enrolled in 17 clinical trials at the hospital since 2002. The spectrum of the clinical trials covers all modern therapeutic alternatives from chemotherapy through to hormone and immunotherapy. The group is, in fact, the largest research center throughout Europe for a special immune therapy drug.

"Participation in clinical trials gives patients early access to the very latest treatments and enables highly intensive monitoring," says Prof Krainer, explaining the benefits of clinical trials which he has observed through many years of experience. "In fact, we know that even patients in control groups benefit from participation in clinical trials. The overall experience of a highly motivated and internationally committed clinical monitoring team has a comprehensive impact here." However, even

patients who are not able to fulfil the strict acceptance criteria for such studies can be treated with the very latest drugs at centers like the Urological Tumors research group. Prof Krainer explains further: "So-called named patient programs enable us to treat patients, for whom there are no treatment alternatives, with drugs that are still undergoing the licensing process. Clinical studies thus offer real benefits for patients in several respects."

More information: Ferlay, J., et al., "Estimates of the cancer incidence and mortality in Europe in 2006." *Ann Onc* 2007; 18(3):581-92

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