2010-10-11 Kansainvälinen syöpäkongressi Esmo 2010 Milanossa:

Eturauhassyöpäpotilaan elinaika pitenee uudella lääkkeellä

Uusi lääkeaine abirateroni pidensi tutkimuksen mukaan levinnyttä eturauhassyöpää sairastavien potilaiden elämää melkein neljällä kuukaudella. Kansainvälisessä tutkimuksessa arvioitiin abirateronihoitoa etäpesäkkeitä lähettäneessä eturauhassyövässä, kun perinteisellä hormonihoidolla eikä solusalpaajahoidolla enää saatu vastetta.

Tutkimukseen osallistui 1 195 potilasta. Tutkimuksen tuloksena oli, että abirateronia saaneet potilaat elivät keskimäärin 14,8 kuukautta tutkimuksen alkamisesta verrattuna lumelääkettä saaneisiin potilaisiin, jotka elivät 10,9 kuukautta.
Tutkimuksen on rahoittanut Johnson & Johnson.

Lisätietoja tutkimuksesta antaa:
Urologian professori, ylilääkäri Teuvo Tammela, Tampereen yliopistollinen sairaala,
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Englanninkielinen tiedote alkaa tästä:

Abiraterone Acetate Significantly Improved Overall Survival for Patients With Metastatic Advanced Prostate Cancer

PR Newswire Europe: October 11, 2010

- Note: Data in This Release Correspond to ESMO Abstract LBA5
- Results Observed in Patients Treated With Abiraterone Acetate Plus Prednisone/Prednisolone Whose Disease Progressed After Docetaxel-Based Chemotherapy
- Based on the Results of This Phase 3 Study, Janssen Plans to File Marketing Applications for Abiraterone Acetate With Regulatory Authorities Worldwide

Results from a pre-specified interim analysis of a randomised, placebo-controlled Phase 3 study, COU-AA-301, demonstrate that patients treated with the investigational agent abiraterone acetate plus low dose prednisone/prednisolone showed a significant improvement in overall survival compared to patients treated with prednisone/prednisolone plus placebo. This study included 1,195 patients with metastatic advanced prostate cancer (also referred to as castration-resistant prostate cancer, or CRPC) previously treated with one or two chemotherapy regimens, at least one of which contained docetaxel.

The results of this randomised, placebo-controlled study were shared during a late-breaking presentation at the Presidential Symposium today at the 35th Annual European Society for Medical Oncology (ESMO) Congress.

Treatment with abiraterone acetate resulted in a 35 percent reduction in the risk of death (HR=0.65; 95 percent CI: 0.54, 0.77; p<0.0001) and a 36 percent increase in median survival (14.8 months vs. 10.9 months) compared with placebo.

Patients who received abiraterone acetate and low dose prednisone/prednisolone also showed significant improvements in secondary study endpoints when compared to the prednisone/prednisolone plus placebo group: time to PSA progression (TTPP) [median 10.2 months for abiraterone acetate vs. 6.6 months for placebo, HR=0.58 (95 percent CI: 0.46, 0.73); p<0.0001] and an increase in radiographic progression free survival (rPFS) [median 5.6 months for abiraterone acetate vs. 3.6 months for placebo, HR=0.67 (95 percent CI: 0.58, 0.78); p<0.0001]. Total PSA response, defined as greater than or equal to a 50 percent decrease from baseline, was achieved in 38 percent of patients treated with abiraterone acetate vs. 10 percent in the prednisone/prednisolone plus placebo group [p<0.0001].

Patients in the abiraterone acetate group experienced more mineralocorticoid-related adverse events than those in the prednisone/prednisolone plus placebo group. The most frequent adverse events were fluid retention (30.5 percent vs. 22.3 percent) and hypokalaemia (17.1 percent vs. 8.4 percent). Grade 3/4 hypokalaemia and hypertension were more frequent in the abiraterone acetate arm than in the placebo arm (3.8 percent vs. 0.8 percent and 1.3 percent vs. 0.3 percent, respectively). Liver function test abnormalities were observed in 10.4 percent of abiraterone acetate treated patients compared to 8.1 percent in the prednisone/prednisolone plus placebo group. Cardiac disorders were observed in 12.5 percent of abiraterone acetate patients vs. 9.4 percent of patients who received placebo. Mechanism-based adverse events were amenable to medical management and distinct from adverse events commonly associated with cytotoxic chemotherapy.

"Abiraterone has the potential to meet a significant unmet need so this news will be incredibly important to prostate cancer patients and their families," said Johann S. de Bono, MD, FRCP, MSc, PhD, The Institute of Cancer Research, The Royal Marsden NHS Foundation Trust, one of the lead COU-AA-301 investigators. "We are very pleased with the definitive results of this rigorous study, which show that abiraterone acetate may extend survival for men with metastatic advanced prostate cancer that progressed after treatment with docetaxel."

The Company plans to file marketing applications for abiraterone acetate with regulatory authorities in the US and Europe by the end of the year. Applications in the rest of the world will follow, according to local regulatory requirements. If approved, abiraterone acetate will be commercialised and distributed by Centocor Ortho Biotech, Inc. in the United States and by Janssen Pharmaceutical Companies in all other countries around the world.

"Globally, prostate cancer, the fifth most common cancer overall, is a significant public health problem," said Howard I. Scher MD, Memorial Sloan-Kettering Cancer Center, one of the lead COU-AA-301 investigators. "These results are important because men with progressive metastatic, castration-resistant prostate cancer often have a poor prognosis and currently have few treatment options."

A program that provides early access to abiraterone acetate for eligible patients is expected to be opened in the United States in October and will be opened in sites outside the United States in the following months, with the timing of the program contingent on local health authority and ethics committee approvals.

"The results of this abiraterone acetate Phase 3 study in patients with metastatic advanced prostate cancer bring us closer to achieving our goal of developing extraordinary preventive, diagnostic and therapeutic solutions based on our tumour microenvironment strategy," said William N. Hait, MD, PhD, Global Therapeutic Head, Oncology, Ortho Biotech Oncology Research & Development. "We believe that abiraterone acetate is an important medical advance, and we look forward to further developing oncology therapeutic options that may impact patients' lives."

Ortho Biotech Oncology Research & Development, a unit of Cougar Biotechnology, Inc., previously announced that the Independent Data Monitoring Committee recommended unblinding this Phase 3 study after a pre-specified interim analysis demonstrated a statistically significant improvement in median overall survival and an acceptable safety profile. The IDMC also recommended that patients in the prednisone/prednisolone plus placebo group be offered treatment with abiraterone acetate.

Study Design
This randomised, double-blind placebo-controlled Phase 3 study was conducted in 147 centers in 13 countries. Patients with metastatic advanced prostate cancer previously treated with docetaxel (N=1,195) were randomly assigned 2:1 to receive abiraterone acetate (1000 mg once daily) plus prednisone/prednisolone (5 mg twice daily) (N = 797), or placebo plus prednisone/prednisolone (N = 398). The primary endpoint was overall survival.
About Abiraterone Acetate
Abiraterone acetate is a novel, targeted, investigational, oral androgen biosynthesis inhibitor being developed for the treatment of metastatic advanced prostate cancer that has progressed after developing resistance to conventional hormonal therapies. This is also known as castration-resistant prostate cancer (CRPC).

About Prostate Cancer
Prostate cancer occurs when cancer cells form in the tissues of the prostate. The prostate is a gland located around the urethra (under the bladder) in men that produces part of the seminal fluid.[1] In some cases, cancer of the prostate can grow slowly compared with other cancers. However, depending on factors including characteristics specific to the patient and the tumour, prostate cancer can also grow very quickly[2] and spread to other places such as the lymph nodes, bones or other parts of the body. Prostate cancer is considered to be advanced once it has spread beyond the prostate region.1

Globally, prostate cancer is the second most frequently diagnosed cancer in men and the fifth most common cancer overall.[3] More than 900,000 new cases of prostate cancer were diagnosed in 2008 and more than 258,000 men died from the disease, a 16 percent increase from 2002. 3,[4] In the United States, an estimated 217,000 new cases of prostate cancer and 32,000 related deaths are expected to be reported in 2010.5 Prostate cancer represents almost one-third of all new cancer diagnoses in men (excluding basal cell carcinoma) and is the second-leading cause of cancer-related death in men. [5]

About the Ortho Biotech Oncology Research & Development, unit of Cougar Biotechnology, Inc.
Ortho Biotech Oncology Research & Development, a unit of Cougar Biotechnology, Inc. partners with affiliated units and companies in the Janssen Pharmaceutical Companies of Johnson & Johnson such as Centocor Ortho Biotech, Inc. and Janssen in the research and development of oncology and supportive care treatments.

About Janssen
Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS, Hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g. diabetes).

Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency. More information can be found at http://www.janssen-emea.com

About Centocor Ortho Biotech Inc.
Centocor Ortho Biotech Inc. redefines the standard of care in immunology, nephrology and oncology. The company was formed when Centocor, Inc. and Ortho Biotech Inc. were consolidated in late 2008, and was renamed Centocor Ortho Biotech Inc. Built upon a pioneering history, Centocor Ortho Biotech Inc. harnesses innovations in large-molecule and small-molecule research to create important new therapeutic options. Beyond its innovative medicines, Centocor Ortho Biotech is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services and quality care. For more information about Centocor Ortho Biotech, visit http://www.centocororthobiotech.com.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialise, actual results could vary materially from J&JPRD and/or Johnson & Johnson's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2010. Copies of this Form 10-K, as well as subsequent filings, are available online at http://www.sec.gov, http://www.jnj.com or on request from Johnson & Johnson. Neither J&JPRD nor Johnson & Johnson undertake to update any forward-looking statements as a

result of new information or future events or developments.)

References

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