SantFerran, 74
Cornellà del Llobregat
E-08940 (Barcelona)
Phone 00 34 93 5151313

Oryzon will launch its first product onto the market: GynEC® Dx a non invasive test for the detection of endometrial cancer

Barcelona, September 14th, 2011. Oryzon announced today the positive outcome of its multicentric clinical trial for its new diagnostic test for the early detection of endometrial cancer. GynEC®-DX uses a gene-expression fingerprint to diagnose this cancer on uterine aspirates. The product has been developed in collaboration with Reig-Jofré Laboratories. The clinical trial has been performed in 16 Spanish hospitals and shows a reliability of 97%.
The company will launch a second product in Spain and Portugal for the early diagnosis of bladder cancer in the coming months. With these two products, Oryzon will set up its franchise on early-diagnostics and customized medicine

Barcelona, September 14th, 2011. The outcome of the clinical trial for **GynEC®-DX**, Oryzon's first product, has been presented this week at the 17th Biennial Meeting of the European Society for Gynaecological Oncology (ESGO) held in Milano (Italy). **GynEC®-DX**, is a new diagnostic test for the early detection of endometrial cancer developed jointly with Reig Jofré Laboratories and expected to be launched on the Spanish market by 1Q-2012. According to the conclusions of this multi-centric double blind prospective clinical trial conducted in 16 Spanish hospitals under the supervision of Dr. Jordi Ponce, at Bellvitge Hospital, and Dr. Antonio Gil, at the Vall d'Hebron Universitary Hospital in Barcelona, **GynEC®-DX** allows to rule out the presence of tumour in 97% of cases through a sample of uterine aspirate, thus allowing a better assessment of whether further analysis, as i.e. histeroscòpies, are indicated.

According to KOLs, there are two main problems with endometrial cancer, the most frequent tumour among women in Spain after breast cancer: the difficulty to detect all cases at an early stage and the discomfort, risks –and costs- associated with the current diagnostic tests, generally involving hysteroscopy. The new detection system developed by Oryzon, under the name **GynEC®-DX**, provides a solution to both problems.

"*We previously reported on the performance of molecular markers and the potential to analyze their levels in a sample that can be obtained in the gynecologists office with minimal discomfort to the patient*" explains Carlos Buesa, the C.E.O. of Oryzon. This previous study, done in collaboration with Dr. Jaume Reventos and Antonio Gil at the Vall d'Hebron Universitary Hospital was chosen for the cover page of the printed issue of the International Journal of Cancer. "*Nevertheless, that was a case control study, and we still had to show that our test could work in the real clinical routine. The results of the new double blind prospective study show that **GynEC®-DX** performed very well and that together with the aspirate analysis became as potent as the more invasive hysteroscopy*"

The results of the clinical trial conducted in 16 Spanish hospitals were presented last week at the 17th Biennial Meeting of the European Society for Gynecological Oncology. **GynEC®-DX** "*was characterized by a high negative predictive value of 97% and a sensitivity and specificity of 81% and 96% respectively".* The test even detected some cases erroneously classified as negative by anatomic pathology on the aspirate and even one case missed by hysteroscopy but diagnosed after surgery. In combination with the classical anatomic pathological analysis on endometrial aspirates, the test had a sensitivity and negative predictive value of 92 and 99%, equaling that of hysteroscopy, and

substantially reduced the failure rate of diagnosis on biopsies obtained by endometrial aspiration.

The main symptom of endometrial cancer is abnormal uterine bleeding. In peri-menopausal women, it is harder to decide whether uterine bleeding is abnormal, as in this phase of woman's life, the menstrual cycle is highly irregular. According to Carlos Buesa, "*60000 new cases of endometrial cancer are diagnosed in Europe every year, and more than 300,000 throughout the world. The cancer is considered highly curable – when detected early. Every year nevertheless, 74000 women die of the disease, and its incidence is increasing as the population ages. and due to the use of estrogen based therapies. In the case of Spain, we calculate that around 30,000 women in the peri-menopausal or post-menopausal period might benefit from this test to rule out or confirm the presence of endometrial cancer*".

The marketing of **GynEC®-DX**, planned for Q1 2012 represents an important milestone in the history of Oryzon, founded in 2000, "*as it will be the first product developed by the company to reach the market, a goal that very few European biotechnology firms have so far managed to achieve. With this launch, we will join this exclusive group and strengthen even further our position as one of the most competitive companies at the national and international level*", says Carlos Buesa.

At the moment, Oryzon is "*exploring different options for the international commercialization of this product and there are conversations under way with several multinational companies in the diagnostic sector*". In addition, Carlos Buesa also remarks that "*we are optimistic about the possibility of this test being included at public health-care services, as it would imply a diagnostic improvement, a substantial saving in the current costs related with the diagnosis of uterine cancer, shorter waiting times and less distress for patients*".

A very fruitful alliance

GynEC®-DX is the fruit of a collaborative biomarker discovery project started in 2006 by Geadic Biotec a Joint Venture between Oryzon and Laboratories Reig Jofré in collaboration with the Vall d'Hebron University Hospital. The biomarker discovery project implied an investment of over 4 million Euros, supported in part by the Regional Government of Catalonia. The multi-centric study was supervised by Dr. Jordi Ponce, from Bellvitge Hospital, and Dr. Antonio Gil, from the Vall d'Hebron Teaching Hospital in Barcelona and received funding from the Spanish CENIT program. The results of the biomarker discovery program are being exploited further by the alliance to develop monoclonal antibodies directed against endometrial cancer cells that will be tested in endometrial cancer models in the near future.

Other launches under way

Oryzon has been evaluating other opportunities in the field of molecular diagnostics and announced a partnership with New Zealand firm Pacific Edge Ltd just before the summer. According to the agreement, Oryzon holds an exclusive license to market the Cxbladder assay, which detects bladder cancer in urine in some European countries. Oryzon will run the Cxbladder test in its Clinical Analysis Lab, which was authorized by the Catalonian Government last year. "*The central lab is the axis and launching platform of our diagnostic and personalized medicine division*", explains Carlos Buesa. "*We have shown that our biomarker discovery platform is capable of developing personalized medicine products and bringing them to market. The goal is to become the leader in molecular diagnostics in Spain and to partner with leading diagnostic companies in Europe, US and other territories*".

SantFerran, 74
Cornellà del Llobregat
E-08940 (Barcelona)
Phone 00 34 93 5151313

About Oryzon

Founded in 2000, Oryzon (www.oryzon.com) has one of the most complete technological platforms for biomarker identification in Europe. With a strong specialization in genomics, proteomics and bioinformatics, the company has identified biomarkers for a variety of neoplasic and neurodegenerative diseases. Oryzon also develops new drugs, including monoclonal antibodies and NCEs directed against targets identified in its biomarker discovery programs. The company has a powerful platform for biomarker and target validation which includes technologies such as RNAi, microarrays, phage display and a structural genomic platform with a fragment screening approach (NMR and X ray crystallography).
.

For further information, please contact Sílvia Castells, Inforpress Group, Tel. 93 419 06 30, scastells@inforpress.es