

Fast and reliable results in cancer diagnostics:

Biotech startup oncgnostics receives CE mark for cervical cancer test „GynTect“

Jena, Sept-17 2015 – A new test for use in cervical cancer screening is CE-IVD marked in whole Europe with immediate effect. It may quickly yield reliable test results, which will allow to identify more cancer cases early and thus to yield better therapy outcome. Developed by the biotech startup oncgnostics (www.oncgnostics.com) GynTect detects changes in cells of the cervix uteri that may be indicative for the development or presence of cancer. In contrast to other methods available in cervical cancer screening GynTect will have the potential to decrease the high number of unnecessary cervical biopsies and surgeries.

Cervical cancer is the 3rd most common cancer in women worldwide, with 530,000 new cases and 270,000 deaths attributable to the disease annually (World Health Organization 2010). In the Asia region (south-east) the respective number are 175.000 new cases and 94.000 deaths attributable to the cancer annually. Currently, screening for cervical cancer is mainly based on the analysis of cellular samples (cytological scrape, the so-called Pap smear) of the cervix uteri. This test indicates if cellular changes are already present. As an alternative the utilization of HPV tests allows to demonstrate the presence of an infection with high-risk human papillomaviruses. These viruses are the causative agents of cervical cancer. However, only a small number of HPV infections lead to cancer. As a consequence additional examinations are required in order to get a safe diagnostic result.

Oncgnostics has now received CE IVD mark for its GynTect test for whole Europe. The company will launch the product in the coming months in Germany and some further European markets. Furthermore, market entry is also intended for the US and selected Asian markets.

Decrease the number of unnecessary surgeries

The new GynTect assay, developed by oncgnostics GmbH, allows to clarify within hours if a patient diagnosed with an abnormal Pap smear or a high-risk HPV infection has a disease that already requires treatment. For GynTect cells from a cervical scrape are analysed for the presence of so-called epigenetic markers. Detection of these markers may be indicative for the development or presence of cancer.

“Almost every woman experiences an HPV infection once in her lifetime, but only in very few cases this infection leads to cervical cancer. Nevertheless, cervical cancer is still the third most common cancer in women worldwide. More than half of all cancer cases are fatal. GynTect is a breakthrough regarding the possibility to avoid such unnecessary surgeries” Professor Matthias Dürst, leading expert in the field HPV and cancer, head of the Department of Gynaecologic Molecular Biology, University women’s hospital Jena, says.

Upon detection at early stage, cervical cancer is almost always curable

In contrast to other diagnostic methods used in cervical cancer screening, GynTect can provide clear results which speak for or against the presence of cancer. Even early stage

disease may be detected by this diagnostic method, thus allowing for an early and successful treatment. GynTect is performed using the same cervical scrape material that is required for the currently performed screening tests. GynTect offers patients with unclear Pap smear and/or positive HPV test results fast and reliable clarification and helps thus avoiding unnecessary surgeries. Only few HPV infections lead to cancer. Women infected with HPV who don't have cancer cells detectable in the Pap smear mostly don't need any surgery. They can obtain clarity with GynTect.

Prestigious VCs invest into the GynTect market potential

Seed financing by the High-Tech-Gründerfonds and the STIFT Thüringen have enabled the spin-off of oncgnostics from the University women's hospital Jena as well as the development of GynTect, a recent Series A round now allows the market entry with the test. Series A investors are, besides HTGF and STIFT, the bm-t (Beteiligungsmanagement Thüringen), Sparkasse Jena, and ITAI innovative GmbH

About oncgnostics GmbH

Oncgnostics GmbH was founded in 2012 as a spin-off from the University women's hospital Jena. Within the field of molecular diagnostics the Jena start-up is specialized on diagnostics of cancer. Oncgnostics diagnoses for specific epigenetic changes, so-called DNA methylations, in cancer cells. The epigenetic GynTect biomarkers, identified by a specific algorithm and patented in Europe, US, Canada and Japan, provide the basis of oncgnostics' business activities.

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