



Diagnostics for life

VitaDX obtains the CE mark for its first solution dedicated to bladder cancer diagnosis: VisioCyt®.

Paris, France February 6, 2020.

VitaDX is very proud to announce the CE marking of its first software solution dedicated to bladder cancer diagnosis: VisioCyt®. VisioCyt® combines fluorescence imaging with artificial intelligence to improve early detection of bladder cancer, using a simple urine sample.

Bladder cancer affects over 3 million people and 550,000 new cases are diagnosed each year worldwide.

The 5-year survival rate of patients is highly correlated with the stage of the cancer at the time of the diagnosis. Indeed, when the cancer is detected early, the survival rate is over 95%, whereas when the cancer progresses or even metastasizes, it is close to 5%.

Furthermore, there are effective and inexpensive treatments to treat early cancers. However, when the cancer progresses, available treatments are much less effective, debilitating for the patient, requiring a lifelong follow-up and very expensive for healthcare systems.

Early detection of bladder cancer is therefore essential in order to optimize patient management, improve survival rates and reduce the cost of care for healthcare systems.

The routine exam in the presence of bladder cancer symptoms, urine cytology, consists in the observation of cells, extracted from a urine sample, under a microscope to detect morphological alterations. This analysis is effective in detecting high-grade cancers with a sensitivity of more than 80%, whereas for low-grade cancers it is not very effective with a sensitivity of 20%.

Since January 2017, VitaDX has conducted a clinical trial in collaboration with 14 French hospitals involving 1000 patients. In this study, very promising performance measurements of the VisioCyt® solution were obtained with an observed sensitivity of over 85% and a specificity higher than 75%.

These results were presented orally at the Carrefour Pathologie and the Congress of the French Urology Association, two key annual events in the bladder cancer sector.

"The CE marking of our first device VisioCyt® marks a key step in the development of VitaDX, which will now enter into a commercialization phase. We are confident that VisioCyt® will bring real benefits to patient care while helping to reduce healthcare costs. "Allan Rodriguez, Chief Executive Officer of VitaDX.

"We are very proud to have reached this milestone, which represents the culmination of our teams' commitment over the last 4 years and opens new opportunities for future developments of the company. "Thibaut Troude, Chief Technical Officer of VitaDX.

About VitaDX

VitaDX International SA was founded in April 2015 to exploit research carried out over the past 10 years within the Paris Hospitals (Assistance Publique - Hôpitaux de Paris, AP-HP), the University of South-Paris and the CNRS, with the objective of becoming a major player in early cancer diagnosis by exploiting image processing and artificial intelligence. The VitaDX team is currently composed of 20 people working on the development of the company, in two locations Rennes and Paris. The company's first solution dedicated to the early bladder cancer diagnosis will be launched in the first quarter of 2020.

Since its creation, VitaDX has been supported by a number of organizations, particularly the Brittany and Ile-de-France regions, BPI, Genopole and the SATT Paris-Saclay, as well as private investors; business angels and 3 investment funds Go Capital, Auriga Partners and Odyssee Venture. The company is a member of the Medicen, Images & Réseaux, Systematic Paris-Région, Cap Digital and Atlanpole Biotherapy competitiveness clusters as well as the ID2Santé technological innovation center and HEC Challenge +.

For more information: www.vitadx.com

Contacts

VitaDX International : Allan RODRIGUEZ - allan@vitadx.com - 01.43.21.44.55 - 06.98.46.24.68