PRESS RELEASE

Abionic Announces FDA Registration for World's Most Rapid Allergy Test and abioSCOPE® Diagnostic Testing Platform

- Test detects sensitization to four common respiratory allergens in United States
- Scheduled to be commercially available in the US in 2018

Lausanne, Switzerland, October 20, 2017 – Abionic SA, a developer of disrupter nanotechnology based rapid diagnostic solutions, announced today that its rapid allergy test, IVD CAPSULE Aeroallergens, and the easy to use testing platform, abioSCOPE® have been registered in the United States by the Food and Drug Administration (FDA). Abionic intends to commence commercialization of IVD CAPSULE Aeroallergens in this market in 2018.

Using the abioSCOPE platform, sensitization to common respiratory allergies can be tested directly from a single drop of blood, allowing patients to save several visits and invasive tests and while guaranteeing medical diagnosis of the highest quality. The IVD CAPSULE Aeroallergens determines patient's sensitization to cats and dogs' major allergens, as well as common grass and tree pollens. Depending on the results, allergy experts who run laboratories that meet CLIA standards for moderately complex testing have now access to a new technology that allows them to quicker and better assess what triggers allergic symptoms, which is key to optimize clinical management of the disease.

Blood samples from a panel of allergic and non-allergic patients have been tested and an excellent correlation between the IVD CAPSULE Aeroallergens on abioSCOPE and the laboratory gold standard method have been demonstrated. With a first result in 5 minutes and a total assay time of as little as 8 minutes for determination of IgE levels to the four allergens of the test, the abioSCOPE is the most rapid quantitative IgE antibody assay available.

"The FDA registration for the abioSCOPE and our first allergy test is a major milestone for Abionic and an important regulatory step that sets the stage for commercialization and a staged market entry of this revolutionary technology. We can now look to offer a rapid, easy to use testing platform, providing allergy sufferers a more convenient and time efficient testing experience," stated Dr. Nicolas Durand, CEO of Abionic. "There are 25 million adults in the US who suffers from allergic rhinitis, a number that is constantly increasing. We are now working to secure the right distribution partners to ensure we can address this major market in 2018."

About the abioSCOPE®

The abioSCOPE is an instrument that provides rapid medical diagnostic test results. It is composed of a fully automated fluorescent microscope, a mounting plate (the abioDISC), onto which is placed a single-use disposable IVD CAPSULE. Following preparation, a sample is placed into the IVD CAPSULE and the abioDISC is inserted into the abioSCOPE, in the same way that a DVD is inserted into a player. Using patented nanotechnology and diffusion phenomena, molecules interact together in biosensors and form specific molecular complexes. These complexes are optically detected by means of the integrated laser. In a few minutes, the results are then presented on a high-resolution touch screen and might be transferred in the allergist information system. The abioSCOPE can be used by any healthcare professional having CLIA certified facilities and does not require extensive training. In addition to FDA registration, the abioSCOPE has CE Mark.

About Abionic
Abionic has developed and commercialized the abioSCOPE, a rapid diagnostic platform used in clinical laboratories and at the point-of-care to improve medical diagnosis. This revolutionary nanotechnology-based test system provides healthcare professionals with tools that help them to make a diagnosis from a single drop of patient's blood. The first abioSCOPE applications are in allergy and sepsis. Abionic already commercializes a test measuring total IgE and one used to detect the five main respiratory allergens in Europe. Moreover, the company has developed a 5 minutes' sepsis test for which it is expected to receive FDA 510(k) clearance in 2019.

Abionic products, such as the abioSCOPE (the reader), the tests containing nanofluidic sensors and the abioGUIDE (the application for smartphones and tablets) have been developed and assembled within the company.

Founded in 2010, Abionic developed its nanotechnology within the Swiss Federal Institute of Technology in Lausanne (EPFL). For further information, visit www.abionic.com.

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