Aegirbio commences FDA fast track process with the Company's COVID-19 test

Aegirbio's U.S. team has reviewed the U.S. Food and Drug Administration's (FDA) requirements for marketing COVID-19 tests on the U.S. market. Building on the previous work undertaken to market the product in Europe, the Company is now ready to commence the FDA authorization process. Aegirbio's systematic effort to document the Company's COVID-19 tests for a launch in Europe under the CE-IVD Directive is thus expanded, as the request for Emergency Use Authorization (EUA) is submitted in the United States.

The Company has further decided to invest in additional production capacity, expecting to reach a production capacity of approximately 100,000 tests per day as early as Q1 2021.

"I am happy and full of excitement as we now work to compile the necessary documentation to be able to introduce Aegirbio on the U.S. market sooner than originally envisaged. The work conducted together with Linköping University and the hospital of Pescara, Italy, has demonstrated that we can detect the COVID-19 virus in the saliva of infected individuals, and that we can discriminate between infected and non-infected individuals. We are therefore advancing towards commercialization as fast as possible.

The skills brought into Aegirbio through the Viraspec and Thyrollytics aquisitons are integrating with our existing resources in the Nordic countries and the United States to focus on COVID-19. It makes me particularly proud to see how well our different teams complement each other, and how quickly this has resulted in a launch plan for the United States as well; it bodes well for Aegirbio's future success," says Martin Linde, CEO of Aegirbio.

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About Aegirbio

Aegirbio is a Swedish diagnostics company offering tests to monitor and optimize the dosing of biological drugs by means of a unique, patented technology platform. Biological therapies is the fastest growing segment of the pharmaceutical industry; a quarter of all drugs are projected to be biological in 2020. At the same time, drug concentrations vary tremendously (up to 100 times) in patients that receive biological drugs in standard doses.

The result of this one size fits all-approach is that patients with low drug concentrations do not respond to treatment, while excessive drug concentrations increase the risk of adverse effects in others. The uncertainty surrounding dosing results in overdosing or underdosing in about 55 percent of the cases, which causes unnecessary costs and suboptimal clinical outcomes.

The Company's tests for optimal dosing of biological drugs will be focused on neurological disorders, autoimmune diseases and cancer. In the first quarter of 2020, Aegirbio initiated sales in the U.S. of the MoNATor test for the drug Tysabri, which is used for treatment of the neurological disorder Multiple Sclerosis (MS). Aegirbio's goal is to launch a total of four tests before 2023. Diagnostics will be offered through laboratory testing as well as in the form of a P.O.C. (Point of Care) test for use in hospitals and health centres. The plan further includes P.O.N. (Point of Need) tests for use at home.

For more information, please visit Aegirbio's website, www.aegirbio.com

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