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Announcement no. 09

International search on patent application for new diagnostic application of the APC-PCI test

BioPorto has received the International Search Report and Written Opinion on the company's patent application related to the diagnostic use of the APC-PCI marker to select patients with severe sepsis for special treatment. The new diagnostic application opens up a considerably larger market for the test than its previous use.

Whereas it has long been known that the APC-PCI test could be used to confirm the presence of blood clots, its diagnostic use to select sepsis patients, which is the subject of BioPorto's patent application, is a new one which could in all probability obtain patent protection. The novelty search and first assessment by the international patent authority cite documents on closely related subjects, but it is the opinion of BioPorto and the company's patent advisers that the most relevant claims could be granted as an issued patent. This process will take place when the patent application enters the national phase.

Application

APC-PCI stands for activated protein C-protein C inhibitor complex, which is formed in very small amounts in the blood when blood clotting is activated and the clotting-regulating protein C is also activated. Activated protein C (APC) has inhibitory actions on both blood clotting and inflammation, so that the recombinant protein (marketed by Eli Lilly under the name Xigris) can be used to treat patients with severe sepsis. However, this treatment is expensive and only a small proportion of patients seems to benefit from it, as seen by a modest fall in the mortality of the treated group. The modest effect of treatment has meant that its use has not become as widespread as was hoped, despite the fact that Xigris is the only treatment documented to reduce mortality in these patients.

If it were possible to predict with greater certainty which patients with severe sepsis would benefit from APC treatment, the treatment could be used rationally on these patients only. This would reduce mortality and offer a considerable cost saving by avoiding the treatment of patients who would never respond, while also avoiding unnecessary serious side effects.

It is precisely this use of BioPorto's APC-PCI test for selecting patients for treatment with APC which is the subject of BioPorto's patent application. The use of the test could lead to up to a 3-fold increase in the cost-effectiveness of the treatment, with a saving of 2/3 of current costs incurred by the unnecessary treatment of unresponsive patients. This reduction in costs might be able to reestablish APC treatment as a therapeutic option for patients with severe sepsis.

Potential

The new diagnostic application of the APC-PCI test for selecting sepsis patients opens up a considerably larger market for the test than its previous use as a confirmatory test for the presence of blood clots (thromboses). There are 900,000 hospital admissions of patients with sepsis per year in the USA alone. If the test were used rationally on these patients, this would lead to 2.7 million tests per year in the USA and over 7 million tests per year in the whole western world.

BioPorto expects to launch the APC-PCI ELISA kit this year, for research use only, however, so that it can be used, for example, in clinical studies and validation processes.



It will then take a number of years to introduce and gain acceptance of this new marker on the market. For this reason the latest development in the patenting process is not expected to influence the company's balance for the year 2008.

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About BioPorto

BioPorto develops and markets antibodies and antibody-based products, including tests to diagnose human disease, both for the benefit of individual patients and to promote efficiency in the health sector. The Company's developments include a test (NGAL) to diagnose and monitor acute kidney damage.

BioPorto's strategy is to develop new methods based on its antibody portfolio that can be patented and achieve a wide use in the diagnosis of various diseases.

BioPorto was founded in 2000 and has about 25 employees. The Company's shares are listed on NASDAQ OMX Copenhagen (symbol: BIOP B). BioPorto is owned by a group of shareholders, none of whom owns more than 5%. www.bioporto.com