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BioPorto's The NGAL Test ™ registered for diagnostic use in Russia – status on progress in the BRIC countries

BioPorto's Russian distributor, Diakon, has obtained registration approval for The NGAL Test ™ from the Russian health authorities. The approval covers the use of NGAL test for the diagnosis of acute kidney injury.

Registration with the health authorities in each market is necessary in order to market a diagnostic product. Following the CE marking of The NGAL Test ™ in Europe, BioPorto prioritizes the BRIC countries (Brazil, Russia, India and China), which markets are expected to continue to grow, particularly due to the general improvement of health services. Through its Chinese partners BioPorto achieved two registrations in China, two registrations in India (import licenses) are obtained and now also registration in Russia is obtained. The application for registration in Brazil is pending, and is expected to be achieved in Q1, 2013.

In China, the health authorities' recognition of the test by registering and subsequently determining reimbursement for the test is crucial for doctors' use of the test. The application is pending and BioPorto expect higher sales when the grant is obtained.

The kidney biomarker NGAL
Every year about 13 million people are struck by acute kidney injury worldwide, of whom about 4 million die. Nevertheless, there has been no real progress in methods of diagnosing kidney injury over the last half century. Existing methods, such as serum creatinine determination, only signal kidney failure 24-72 hours after the injury has taken place. In contrast, NGAL rises to diagnostic levels within a few hours of kidney injury and thus enables the physician to make vital clinical decisions before the damage progresses to potentially fatal renal shutdown. In addition to helping the patient, cost-benefit analyses show that implementing NGAL testing will contribute to reducing hospital costs in the management of kidney injury and its consequences.

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