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Investor News

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Clear commitment to innovation

Bayer: Four potential blockbusters in the Pharma pipeline

- Good prospects for Xarelto™, VEGF Trap-Eye, Alpharadin and regorafenib
- Market launches in the next 18 months planned
- Research and development budget for 2012 approximately EUR 3 billion again

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Leverkusen, December 20, 2011 – The Bayer Group plans to continue investing heavily in research and development and expects its Pharmaceuticals business in particular to generate substantial sales with the new products that are scheduled to be launched in the next 18 months. "We have achieved major progress with our Pharma pipeline in 2011 and are therefore lifting our sales forecasts for several products," said Bayer CEO Dr. Marijn Dekkers. "Overall, we believe that four of the drug products currently in advanced development have the potential to become blockbusters, meaning that each of these products can generate peak sales of EUR 1 billion per year and more." They include the ophthalmological substance VEGF Trap-Eye and the cancer treatments Alpharadin and regorafenib. In the case of the thrombosis drug Xarelto™, Bayer continues to expect peak sales of more than EUR 2 billion per year following the granting of regulatory approval by the European Commission in the new indications this week. Assuming that relevant authorizations are obtained, the combined annual peak sales potential of these products will therefore amount to a total of EUR 5 billion.

Bayer currently has some 40 Pharmaceuticals projects in total in clinical development. The company is again planning a research and development budget of EUR 3 billion for the coming year, with two-thirds of it going to the HealthCare business. "Perseverance is a vital quality in research, and that is particularly true for the pharmaceuticals business. Following our efforts in past years, our pipeline is now beginning to bear fruit," said Dekkers.

Bayer has achieved promising results in several Phase III studies, with the profiles of the products exceeding the original expectations in some cases. "This could result in new therapeutic options for many patients at last - for example in stroke prevention or cancer treatment," said Dekkers. "And we believe that these products can make a significant contribution to the future growth of our company."

Thrombosis drug Xarelto™ granted important approvals in Europe

At the beginning of this week, the oral anticoagulant Xarelto™ (rivaroxaban) was granted regulatory approval by the European Commission in two major indications: prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation; and treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism following an acute DVT in adults.

"Xarelto™ can help patients reduce their risk of stroke. We want to contribute to preventing the far-reaching consequences that stroke has on the lives of patients and their families," explained Dekkers. Xarelto™ also has the advantage that patients only have to take one tablet per day, and it does not require either regular blood monitoring or specific dietary restrictions. "This good news confirms our expectations that Xarelto™ will be able to achieve peak sales of more than EUR 2 billion across all indications," said Dekkers.

Xarelto™ is already marketed for the prevention of venous thromboembolism (VTE) in adults following elective hip or knee replacement surgery, making it the only new oral anticoagulant for adults to be granted regulatory approval in three indications throughout the EU. In the United States, Xarelto™ was granted regulatory approval by the FDA for the prevention of stroke in patients with non-valvular atrial fibrillation in November 2011. The U.S. marketing rights are held by Bayer's partner Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson.

In addition, the positive results of another Phase III study investigating rivaroxaban in patients after an acute coronary syndrome (ACS) were recently presented. Patients dosed with 2.5 mg rivaroxaban twice daily in conjunction with the current standard treatment were associated with a significantly reduced rate of myocardial infarction, stroke and cardiovascular death. There was also a significant reduction in the rate of deaths from any cause. Rivaroxaban was associated with higher rates of major bleeding events, but the risk of fatal bleeding was not elevated. Bayer and Janssen

Pharmaceuticals plan to file rivaroxaban for regulatory approval in secondary prevention of acute coronary syndrome before the end of 2011 in the United States and Europe.

Major progress in ophthalmology

Bayer also has a promising development candidate in the field of ophthalmology: VEGF Trap-Eye. This substance is being investigated in the treatment of various eye diseases, including wet age-related macular degeneration (AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME) and myopic choroidal neovascularization (myopic CNV). VEGF Trap-Eye has a peak sales potential of up to EUR 500 million in the indication wet AMD. If the product receives regulatory approval in all of the planned indications, it too could become another blockbuster for Bayer.

Some weeks ago, positive two-year results were reported for two Phase III trials in wet AMD, one of the most common causes of blindness in patients aged above 65.

In the United States, VEGF Trap-Eye was granted regulatory approval under the trade name EYLEA™ (aflibercept) Injection in the indication wet AMD in November 2011. Exclusive marketing rights for the United States are held by Bayer's partner Regeneron. In the rest of the world, including Europe and Japan, Bayer holds the marketing rights and is preparing to launch the product in the indication wet AMD in 2012. To prepare the way for the launch of VEGF Trap-Eye for wet AMD in China, Bayer and Regeneron recently began a Phase III study there as well. In the indication CRVO, Bayer plans to file for regulatory approval outside the United States in 2012. Phase III trials in the other above-mentioned indications began in early 2011 and are progressing according to plan.

Another two hopeful candidates in oncology

In oncology, Bayer has achieved important progress with Alpharadin and regorafenib. "Both active ingredients exhibited significant improvement of overall survival in trials," said Dekkers. This result was achieved both by Alpharadin in the treatment of prostate cancer with bone metastases and regorafenib in the treatment of advanced colorectal cancer.

Alpharadin is a novel substance to treat forms of cancer which have spread to the bone. Its efficacy in patients with castration-resistant prostate cancer (CRPC) and symptomatic bone metastasis has been successfully tested in a pivotal Phase III trial. Alpharadin has

been granted Fast Track status by the U.S. Food and Drug Administration, which means that the drug product can be reviewed in a simplified procedure. Bayer plans to submit the registration dossier in the United States and Europe in mid-2012. This product licensed in from Algeta ASA could also have blockbuster potential if it receives marketing authorization in further indications.

Another oncology project in an advanced stage of development is regorafenib, a novel oral multi-kinase inhibitor. Regorafenib is currently undergoing Phase III clinical development in the treatment of metastatic colorectal carcinomas (mCRC) and gastrointestinal stromal tumors (GIST). One Phase III trial investigated regorafenib in the treatment of patients with mCRC whose disease had progressed under all approved therapies. The study was stopped early after an interim analysis produced a positive result, as the primary end point – statistically significant improvement of overall survival – had already been reached. Bayer plans to submit the regulatory filings in the indication "mCRC" in 2012.

The results of another currently ongoing Phase III trial in the indication GIST are expected in early 2012. The FDA has granted regorafenib Fast Track status in both indications. In the indication GIST, regorafenib has also been granted "Orphan Drug" status, which is associated with further benefits. In the two above-mentioned indications regorafenib has potential annual sales of up to EUR 500 million. Together with other possible indications, this product could likewise achieve annual sales of EUR 1 billion.

"The results for Alpharadin and regorafenib are positive news for patients. And they show that our products could potentially become new treatment options in their indications," said Dekkers.

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