

# Bayer researchers win the German Future Prize



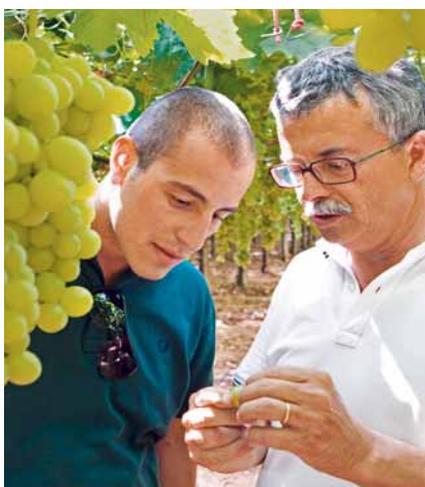
Award for top research: German President Horst Köhler (second from left) presents the German Future Prize 2009 to Bayer researchers Dr. Elisabeth Perzborn (left), Dr. Frank Misselwitz (second from right) and Dr. Dagmar Kubitza.

The German Future Prize 2009, awarded by the country's Federal President, went to an R&D team from Bayer: Dr. Frank Misselwitz, Dr. Elisabeth Perzborn and Dr. Dagmar Kubitza received the prize for achievements in technology and innovation from President Horst Köhler at a ceremony in Berlin. The Bayer scientists from Wuppertal were honored with this prestigious award for the development of the new anticoagulant drug rivaroxaban (Xarelto®). Thromboembolism is a life-threatening disorder which affects millions of people every year – often with a fatal outcome. In the western world, venous thromboembolism kills more than twice as many people as breast cancer, prostate cancer, HIV/Aids and road traffic accidents combined. Rivaroxaban is an anticoagulant with a novel mechanism of action. The active substance selectively targets a pivotal stage in the blood clotting process and inhibits the activity of the enzyme Factor xa, which plays a key role in the development of thrombosis. Rivaroxaban offers patients and doctors major advantages over the current standard therapies. Studies have shown rivaroxaban to be particularly effective in preventing venous thromboembolism following elective hip and knee replacement surgery in adults. Moreover, rivaroxaban is administered in tablet form and does not have to be injected like the current standard therapies.

## Future-focused project to protect the climate

Together with SBM Offshore, Bayer MaterialScience is planning a particularly innovative project on climate protection: the two companies want to develop a flexible wave energy converter for use in the Atlantic. With this technology, the previously unused resources of the seas are to be harnessed for environmentally friendly energy generation. The World Energy Council estimates that global wave energy resources are equivalent to about double the total quantity of electricity currently generated throughout the world. This new technology will be of particular interest to utility companies looking to expand their renewable energy portfolios. In 2015, there are plans to build a power plant on the open sea.

## High-quality fruit and vegetables



Focus on quality: through close cooperation with their suppliers, Giuseppe Cortese (left) and Angelo Marazia from Bayer CropScience help to improve quality in the vineyards.

As part of its Food Chain Partnership project, Bayer CropScience has signed a global cooperation agreement with The Greenery B.V., an international trading company specialized in the marketing of vegetables, fruit and mushrooms, based in The Netherlands. The agreement complements the 30 existing Food Chain Partnership projects in Central and South America, Europe, Africa and Asia. It has advantages for both consumers and producers: consumers have access throughout the year to high-quality produce for a healthy diet, while the producers are supported and advised by Bayer CropScience in the implementation of optimized crop protection programs (see also page 36).

## Safety with nanotechnology

In September 2009, Bayer MaterialScience received regulatory approval from the U.S. Environmental Protection Agency (EPA) for Baytubes®, its multi-walled carbon nanotubes (CNT). The addition of Baytubes® improves the mechanical stability and antistatic properties of polymers. Typical areas of application include rotor blades for wind power plants and sports articles such as skis. CNTs can also be used for an innovative safety technology that significantly reduces the risk of explosions in fuel tanks. For this purpose, Bayer MaterialScience has concluded an exclusive cooperation and supply agreement for Baytubes® with Hirtenberger PROSAFE Safety Technology GmbH (HPST), Hirtenberg, Austria. HPST is to use the Bayer MaterialScience product in the manufacture of newly developed special spheres designed to prevent the formation of explosive gas mixtures in fuel tanks.



Safety through Baytubes®: carbon nanotubes not only improve the stability of rotor blades (above) in wind power plants, they also increase the safety of fuel tanks.

## Progress with Nexavar in new indications

Bayer HealthCare and Onyx Pharmaceuticals have launched a Phase III study with Nexavar® for patients with locally advanced or metastatic differentiated thyroid cancer. The study observes patients with thyroid cancer who no longer respond to the usual treatment with radioactive iodine. The drug has also demonstrated positive effects in breast cancer: a combination therapy of Nexavar® with the oral chemotherapy agent capecitabine extended progression-free survival in patients with advanced breast cancer by 74 percent in an independent Phase II study. A further Phase II study with Nexavar® and paclitaxel indicated a positive trend in the combination arm. Further analyses are necessary here.

The drug is already approved in more than 90 countries to treat liver cancer and for the treatment of kidney cancer. The drug is also being evaluated by Bayer and Onyx, government agencies, oncological study groups and individual investigators as a single-agent or combination treatment in a wide range of other cancers.

## Our challenges

### Cases concerning traces of genetically modified rice

In lawsuits concerning genetically modified rice, rice farmers in the United States allege that they have suffered financial losses as a result of traces of precommercial genetically modified rice from Bayer CropScience that were discovered in the harvest in 2006. In two lawsuits in December 2009 and February 2010, a court in Missouri decided that Bayer had to pay compensation amounting to a total of approximately US\$3.5 million to five agricultural plaintiffs. In a third case in February 2010, a court in Arkansas sentenced Bayer to pay total compensatory and punitive damages of US\$1 million. In a fourth lawsuit in February 2010, a court in Arkansas ordered Bayer to pay compensatory and punitive damages of around US\$48 million in total to 14 rice farmers. Bayer disagrees completely with the findings of liability and the awards of compensatory and punitive damages, and will appeal the decisions.

### Patent infringement taken to court

Bayer has taken the Indian pharmaceutical company Lupin to court in the United States for patent infringement. Lupin applied for regulatory approval in the United States for a special formulation – a liquid for oral administration – of the broad-spectrum antibiotic Cipro®, for which patent protection runs until 2015.

### Dispute with generics specialist in India

In February 2010, a court in New Delhi, India, rejected Bayer's plea to prevent approval of a generic version of its patented cancer drug Nexavar®. Indian generics company Cipla had filed for registration even though Nexavar® has patent protection until 2020. Bayer has appealed to the Supreme Court and sued Cipla for patent infringement.

# Bayer strengthens sustainability commitment



Bayer is increasing its commitment to sustainability. To this end, the Group has launched an extensive program with eight lighthouse projects focusing on the fields of health care, nutrition and climate protection. Its objective is to integrate the company's products and its employees' know-how into international projects to promote sustainable development right across the globe. Chairman of the Bayer Board of Management Werner Wenning and Board member Dr. Wolfgang Plischke presented the Bayer Sustainability Program at a news conference in Leverkusen attended by approximately 120 journalists from 35 countries. More than 15 million people worldwide will benefit directly from the lighthouse projects that serve as the centerpiece of the Sustainability Program. In addition, by 2013, the Group aims to increase energy efficiency in production by 10 percent compared with 2008, corresponding to an annual reduction

International news conference in the packed Bayer Communications Center in Leverkusen: Bayer CEO Werner Wenning (at the lectern) and Management Board member Dr. Wolfgang Plischke (on the podium at left) explained the new Sustainability Program to journalists.

of 350,000 metric tons of greenhouse gas emissions. Furthermore, through a new technology for chlorine production, it will be possible to lower annual greenhouse gas emissions by a further 250,000 metric tons through 2020. Bayer's business activities are focused on sustainability. According to Wenning, "sustainable development forms an integral part of Bayer's corporate policy, which is geared toward high-quality solutions and long-term success." You can read more about the company's Sustainability Program on page 18 and in the sections on the focus issues of health, nutrition and climate protection, starting on page 30.

## Investing in the growing market of medical technology

Bayer MaterialScience (BMS) is helping to support the growing demand for innovative medical technology and is expanding its activities here. To this end, BMS has signed an agreement to acquire the British company PolyBioMed Limited. The aim is to enhance the design, manufacturing and end-use performance of medical products with innovative materials. As a result, BMS is looking to further develop its own polyurethane-based hydrophilic

coatings for medical devices with PolyBioMed's technologies. A subsidiary of Lombard Medical Technologies PLC, PolyBioMed is specialized in polymer coatings, surface treatments and biomaterials for the medical technology industry. The acquisition gives Bayer MaterialScience access to application areas such as coronary drug-eluting stents plus catheter systems for interventional cardiology, urology and neurology.

## Experiencing research up close

The new student laboratory in Leverkusen – the BayKomm Baylab – has been open since the beginning of 2010. Baylabs are designed in particular to get children and young people interested in the world of science. In the Baylab, the young visitors become researchers for a day on projects specially designed for their ages. The company's new Baylab – the fourth of its kind – shows how seriously Bayer takes the support of natural science education. Bayer also provides extensive support to schools, educational establishments and the scientific community through the Bayer Science & Education Foundation with around €1 million of funding each year. In addition, Bayer sponsors the "Jugend forscht" youth science competition and the Chemistry and Biology Olympiads.



Young researchers: in the Baylabs, school-children can carry out their own experiments under experienced guidance, for example to study their own DNA.

## Strategic step for modern plant breeding



New collaboration: in the Athenix laboratory in Research Triangle Park, North Carolina, United States, Laura Schouten examines maize cobs for signs of nematodes.

In November 2009, Bayer CropScience completed the acquisition of Athenix Corp., a biotechnology company headquartered in Research Triangle Park, North Carolina, United States. Athenix not only has the largest bank of *Bacillus thuringiensis* (Bt) genes in the industry, it also has an extensive herbicide toler-

ance and insect resistance trait development platform. Athenix is also working on nematode (threadworm) resistance, a field in which current chemical options are limited. The company has a valuable collection of proprietary microbes that may play an important role in future trait development.

## Our challenges

### New pipeline to safeguard supply of CO

Bayer MaterialScience (BMS) wants to supplement the existing integrated carbon monoxide system connection between Dormagen and Leverkusen by constructing a new CO supply pipeline between the chemical facilities of Dormagen and Krefeld-Uerdingen. The aim is to ensure the safe, smooth, cross-site supply of carbon monoxide. The building work has not been completed yet. The start-up of the pipeline is dependent on various permits being obtained from the district authorities in Düsseldorf and on the outcome of legal proceedings. Some residents are worried about health risks and have filed a suit. Bayer is very much aware of its responsibility to its neighbors and the region as a whole. The safety of the pipeline takes top priority for the Group and has been attested in several expert reports. The Landtag (State Parliament) of North Rhine-Westphalia found unanimously in 2006 that the pipeline serves the common good. In the following years, too, the parliament considered the project on several occasions and has always approved it – most recently in March 2010 – with a large majority. Bayer is keen to maintain close contact with the local community and continues to provide comprehensive information about the project.

### Blaze at the Ankleshwar plant

In March 2010, for as yet unknown reasons, a fire broke out at the Bayer CropScience site in Ankleshwar, India. The blaze was rapidly brought under control, but unfortunately one employee died during the incident. There was minimal impact to the rest of the site and the incident posed no hazard to the neighborhood at any time.

## Positive results from study on treatment of pulmonary hypertension

A first Phase II trial with the oral agent riociguat in pulmonary hypertension in combination with interstitial lung disease (PH-ILD) has successfully been completed. PH-ILD is a form of pulmonary hypertension for which no approved treatment options are currently available. The primary objectives of the study – to investigate the safety and tolerability of riociguat in patients – were achieved. The study demonstrated a reduction in pulmonary vascular resistance (PVR), together with a considerable increase in cardiac output and slight improvement of exercise capacity. Riociguat is the first member of a novel class of medicines known as soluble guanylate cyclase (sGC) stimulators. Bayer is investigating this active substance as a new approach to treat different forms of pulmonary hypertension. According to the WHO classification, there are five different groups of pulmonary hypertension.



Help for pulmonary hypertension: at present there are few drugs available for the treatment of pulmonary hypertension. Bayer researcher Dr. Johannes-Peter Stasch (left) and Prof. Hossein Ardeschir Ghofrani from Giessen University Hospital, shown here with a model of a lung, have confidence in the promising new active substance riociguat.

### Sustainability also of major importance in the growth market of China

Bayer is intensifying its commitment to sustainability in China, as is illustrated by the initiatives launched in 2009. In conjunction with Tongji University in Shanghai and the United Nations Environment Programme (UNEP), the Group organized the first Sustainable Development Forum. The forum, which provided the opportunity to pursue political discussions and share expertise at both a regional and international level, attracted more than 200 scientists, students and representatives from government and business. Bayer wants to support China in its efforts to follow a new course in matters of climate protection and energy efficiency. At the beginning of 2010, Bayer China was awarded the China Environmental Excellence Prize in the category “Best Corporate Performance on Environmental Protection.”



This category, which is specifically aimed at industry, is regarded as one of the most important environmental protection awards made in the People's Republic. Before now, only two companies with headquarters outside China have won the award.

Initiative for sustainability: together with Tongji University (left) and UNEP, Bayer organized the first Sustainable Development Forum.

### Research cooperation in cereal cultivation

Bayer CropScience and the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australia's national research agency, have signed a cooperation agreement to research the consequences of new-generation cereals in the context of global environmental and food security challenges.

Innovative crops can deliver greater yields while requiring less resources such as water and energy. To evaluate the likely advantages, a methodology is to be developed to assess the effects on the environment, including the influence of the new plants on the carbon footprint of cereal production. The new project scheduled to take two years will build on the cooperation between the two organizations that began in 1998.

## Better diagnosis of Alzheimer's disease

In November 2009, Bayer Schering Pharma announced the start of a Phase III study to investigate the efficacy and safety of florbetaben in the identification of beta amyloid plaques in the brain using positron emission tomography (PET). The plaques are a pathological feature of Alzheimer's disease and are the focus of new therapeutic options currently under development. Florbetaben may be able to support the development of these new therapies. Bayer expects study results of relevance for a marketing authorization application to be available in 2011.

## Fresh hope with bone metastases

Bayer Schering Pharma and the Norwegian company Algeta ASA will jointly develop and market the cancer drug Alpharadin™. Alpharadin™ is a new alpha-emitting radiopharmaceutical based on radium-223. The substance is currently being evaluated in a global Phase III trial for the treatment of bone metastases in prostate cancer patients who no longer respond to hormone treatment. Worldwide, prostate cancer is the second most frequently diagnosed form of cancer and one of the most common cancer-related causes of death among the male population.

## Greater focus on future-oriented technologies

Bayer CropScience aims to treble its seed and biotechnology business by 2018 with investments of some €3.5 billion. The expenditures will concentrate on research and development and the infrastructure of the BioScience segment, and do not include possible acquisitions. The systematic expansion of this business goes hand in hand with the strategic alignment of Bayer CropScience, which is aimed at offering farmers integrated solutions consisting not only of products but also of technologies and services.



Plants of the future: Kellie Milam prepares plant trials in the lab. Here, crops are equipped with important new properties such as herbicide tolerance and resistance to insects.

## Our challenges

### Combined oral contraceptives in the spotlight

As of April 12, 2010, there were about 1,750 lawsuits pending in the United States served upon Bayer involving Bayer's oral contraceptives Yasmin® and YAZ®. Plaintiffs allege to have suffered personal injuries, some of them fatal, from the use of Yasmin®, YAZ® and/or Ocella®, a generic version of Yasmin® marketed in the United States by Barr Laboratories, Inc. The plaintiffs seek compensatory and punitive damages, claiming in particular that Bayer knew or should have known of the alleged risks and should be held liable for having failed to disclose them or adequately warn users. Bayer believes it has meritorious defenses and intends to defend itself vigorously.

So far it appears that most of the lawsuits focus on side effects described in the product information of all combined oral contraceptives, including the Bayer products.

### Explosion in waste incinerator

In September 2009, there was an explosive reaction leading to a fire in the area around a discharging unit belonging to the waste incinerator at the Supply Center in Bergkamen. It occurred while waste containing metal alkyls escaped from a transport container being emptied. The fire was extinguished. The air pollutant measurements immediately initiated gave no reasons to suspect a health risk to employees or residents.