

PRESS RELEASE

BRAIN and Schering develop designer microorganisms for the production of steroid drugs

Zwingenberg and Bergkamen, May 2006 – Biotechnology-company BRAIN AG and Berlin based pharmaceutical corporation Schering AG co-operate to improve a production process for steroid-drugs. Using molecular biological methods a microbial production strain shall be optimised to reduce the amount of side products and to increase the amount of the desired steroid intermediate. The goal is the optimised fermentative production of steroid drugs using improved production strains fed with plant raw materials.

In pharmaceutical production processes the resources for relevant pharmaceutical raw materials gain increasing importance. Plants (e.g. soy, rapeseed and tall oil) and their content of steroidal components represent a cheap and sustainable source of pharmaceutical intermediates. Other than through chemical conversion further processing of these intermediates is increasingly performed using biological processes (bioconversion). Microorganisms employed in these processes on the one hand possess the enzymes to highly specifically deliver the desired stereoisomer of the compound but on the other hand the overall yield of the pharmaceutical substance wanted often is low and heterogeneous side products may occur due to the presence of additional competing enzymatic activities. In future production processes highly developed microorganisms („designer bugs“) shall contribute to an improved process with an increase in

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yield and higher economic efficiency.

In the course of the co-operation between the Zwingenberg-based biotech-company and world's leading pharmaceutical corporation, Schering AG, in the segment of contraceptives BRAIN will modify and improve such proprietary microorganisms which have been identified as being suitable for the biological production of steroidal intermediates. In the future, using molecular biological methods, optimised microbial biotransformation processes are expected to increase product yields and to supersede time consuming and complex product processing.

"By utilizing optimised microorganisms we want to improve industrial processes for the conversion of steroidal intermediates and make them more environmentally benign", says Dr. Simone Kardinahl, biochemist in the microbial process development at Schering AG, plant site Bergkamen. "The cooperation with BRAIN AG complements and accelerates our own activities in this sector", adds Dirk Rabelt, head of microbial production and process development at Schering AG, plant site Bergkamen. Currently, at Schering's largest production site in Bergkamen, some 1.400 employees work on different biotechnological as well as chemical production processes.

At Schering the business division gynaecology & andrology has a long and strong tradition and in 2005 was with 1.979 million € revenues (or 37% of the total) the strongest segment within Schering with total revenues of 5.308 million € in 2005. Following Betaferon® with revenues of 867 million € (indication multiple sclerosis), the contraceptive Yasmin® was ranked 2nd best with revenues of 586 million € and with 38% revenue increase compared to 2004 having the highest potential. Yasmin® currently is the mostly sold fertility control product world wide.

"The identification and development of customised microorganisms

hallmarks the growing importance of white biotechnology for efficient production processes“, says Dr. Jürgen Eck member of the board and Head of Research at BRAIN AG. “With our molecular biological technology platform we can selectively modify and improve the genomes of established production strains in order to exclude yield limiting genes. Through the use of these “designer bugs” more efficient transformations of steroidal intermediates shall be achieved”.

The optimisation of production strains is another outstanding example for the multiple options of white (industrial) biotechnology. BRAIN AG as one of the leading white biotech corporations currently experiences a growing demand from customers in the fine and speciality chemistry as well as in the nutrition-, cosmetics- and pharmaceutical industries.

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About BRAIN AG:

BRAIN Biotechnology Research and Information Network AG is an innovative company focusing on the discovery and development of novel enzymes and bioactives. Its novel EvoSolution® technology platform combines the untapped biodiversity of microorganisms and plants with modern methods of molecular biology. The company located in Zwingenberg within the research and industrial region Rhine-Main-Neckar has at its disposal a comprehensive BioArchive with over 100 million genes of unique and non-cultivable microorganisms. Based on these resources BRAIN identifies novel technical enzymes for biotechnological production and synthesis processes (biotransformation) in the chemical and life science industries as well as new bioactive substances and lead candidates for the pharmaceutical and cosmetics market, and develops the basis for their large-scale industrial production. The company, which was founded in Darmstadt in 1993, currently employs a staff of 45.

About Schering AG:

Schering AG is a research-based pharmaceutical company. Its activities are focused on four business areas: Gynaecology & Andrology, Oncology, Diagnostic Imaging as well as Specialized Therapeutics for disabling diseases. As a global player with innovative products, Schering AG aims for leading positions in specialized markets worldwide. With in-house R&D and supported by an excellent global network of external partners, Schering AG is securing a promising product pipeline. Using new ideas, Schering AG aims to make a recognized contribution to medical progress and strives to improve the quality of life: **making medicine work.**

Pictures:



BRAIN AG: Listed Bauhaus building in Zwingenberg

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BRAIN AG: Micro-organisms as they are used in modern biotechnological processes as production strains.

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Schering AG: Production site for chemical pharmaceuticals in Bergkamen.

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Pictures and text

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