

Press release



First two ODD-support grants awarded to DNage and to-BBB technologies

The Hague and Leiden, 16 July 2010. *In the first half of 2010, the first two Orphan Designation Dossier (ODD)-support grants have been awarded to two small yet promising Dutch bio-pharmaceutical companies: DNage and to-BBB technologies. The ODD-support scheme is an initiative of the Dutch Steering Committee on Orphan Drugs and is executed by the Netherlands Organisation for Health Research & Development (ZonMw).*

In the EU a rare disorder is defined as a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the EU. These diseases often affect children, and mostly have a genetic basis. Current estimates for the number of rare disorders range from 5.000 to 8.000 with more than 25 million patients affected within the EU. Since the development of drugs for patients with rare disorders (orphan drugs) is usually not cost-effective for the pharmaceutical industry, a specific set of economic incentives has been implemented within the EU to stimulate the development of such drugs. These incentives are programs to support companies or persons in the development of orphan drugs, reduced fees for registration activities, and a limited market exclusivity following registration of the product. To qualify for these incentives a sponsor must first submit an orphan designation application to the European Medicines Agency (EMA). The Agency is responsible for reviewing designation applications from sponsors who intend to develop medicines for rare diseases. However, the final decision to grant an orphan designation rests with the European Commission.

To further stimulate the development of orphan drugs, the Dutch Steering Committee on Orphan Drugs supports Dutch pharmaceutical Small and Medium-sized Enterprises (SME), public and non-profit organisations with a small subsidy for the costs of writing and submitting the Orphan Designation Dossier (ODD) to the EMA. Depending on their ODD experience, applicants can be awarded 7200 or 3600 euro, provided their proposal meets all the formal criteria.

The first ODD-support grant was awarded to DNage for its product Prodarsan®, which is being developed for the treatment of Cockayne Syndrome. Cockayne Syndrome is an extremely rare disease in which people suffer from accelerated ageing due to deficiencies in their DNA repair machinery. Prodarsan® is currently in clinical development, and represents the first prospect of treatment for Cockayne Syndrome patients. Next to its lead product Prodarsan®, DNage is developing novel therapeutic targets and compounds for ageing related disorders such as osteoporosis and neurodegenerative diseases. "We are very pleased with this grant and we value the efforts and support by the Steering Committee to further stimulate orphan drug development in the Netherlands", says Gerben Zondag, VP Technology of DNage.

The second ODD-support subsidy was awarded to to-BBB technologies for their product glutathione-pegylated liposomal doxorubicine hydrochloride (2B3-101), which is being developed as treatment for brain cancer including glioma. Currently, the prognosis for patients with brain tumours, independent whether it's a primary tumour or metastasized from peripheral cancer, is generally poor. The company's vision is that the treatment of brain cancer will be seriously enhanced by combining doxorubicin, a well-established oncolytic drug, with its proprietary brain drug delivery platform. Based on promising preclinical efficacy and safety studies, the first clinical trial with 2B3-101 is planned to start late 2010. "We are very pleased to obtain this ODD-grant" says Willem van Weperen, CEO of to-BBB. "It gave us the opportunity to accelerate our submission for an ODD, which in the mean time has received a positive opinion. This grant, therefore, has already proven its usefulness."

"Both products are prime examples of a number of novel innovative medicinal products that are currently being developed by the small and medium-sized bio-pharmaceutical industry in the Netherlands. Many of which are directed to rare, but life-threatening or chronically debilitating disorders", says Remco de Vruh, Orphan Product Developer for the Steering Committee.

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About

Stuurgroep Weesgeneesmiddelen

The Dutch Steering Committee Orphan Drugs (Stuurgroep Weesgeneesmiddelen) was appointed by the Minister of Health in April 2001. The committee is an independent organisation and the members are representatives of umbrella organisations for patients and for pharmaceutical companies, physicians and a hospital pharmacist, scientists, a representative of the Dutch medicine evaluation board and a representative of the Dutch health insurances board. The steering committee has the mission to encourage the development of orphan drugs and to improve the situation of patients with a rare disease, especially to strengthen the transfer of information on rare diseases.

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DNage

DNage owns a unique technology platform in the field of DNA repair which is at the basis of development of many diseases associated with old age. As the average life expectancy is still rapidly increasing worldwide, such diseases represent significant medical, economic and social problems. There is a large need for new therapeutics and diagnostics to treat, prevent and delay the development of ageing diseases. DNage currently has one product (Prodarsan®) in clinical trials for the treatment of premature aging and several other programs in earlier phases of development including programs for neurodegenerative diseases, osteoporosis and nutritional products to prevent or delay ageing diseases.

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to-BBB Technologies BV

to-BBB is a Dutch biotechnology company in the field of enhanced drug delivery across the blood-brain barrier. The company is developing novel treatments for brain disorders by combining existing drugs with its proprietary brain drug delivery platform. The company's vision is that the treatment of currently unserved brain diseases will be best achieved by safely enhancing the blood-to-brain delivery of drugs.

to-BBB is headquartered in The Netherlands at the Leiden Bio Science Park and has established a fully owned subsidiary, to-BBB Taiwan Ltd., in Taipei, Taiwan.

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