



Fact Sheet

Bayer Schering Pharma Development Projects

Business Unit: Oncology

Development candidate sagopilone (ZK-EPO) – Potential for a new option to treat solid tumors

- Potential for a wide therapeutic window
- Promising in multi-resistant tumors

Status: June 2007

<p>Project description</p> <p>The novel anti-cancer agent sagopilone (ZK-EPO) is currently being tested in an extensive program of clinical Phase II studies in various oncological indications. The fully synthetic epothilone should show improved efficacy and safety in comparison with commonly used chemotherapeutics and is designed to also retain its efficacy within the cells of tumors with multiple resistance.</p> <p>Preliminary data from one of the current studies were published in June 2007. The Phase II study confirmed antitumor responses in patients with platinum-resistant ovarian cancer. The drug was well tolerated with peripheral neuropathy being the most common side effect observed.</p> <p>The medical background</p> <p>Despite numerous treatment options, the therapy of cancer still represents an enormous challenge for medicine. One</p>	<p>At a glance</p>
	<p>Name of the active substance</p> <p>Sagopilone (ZK-EPO)</p>
	<p>Type of substance</p> <p>Fully synthetic epothilone (low molecular weight active substance)</p>
	<p>Targeted Indication</p> <p>Ovarian cancer Breast cancer Lung cancer Prostate cancer</p>

<p>therapeutic approach consists of interrupting the cell cycle and thus stopping cell division. Two quite different groups of substances show a similar mechanism in this respect: the taxanes (originally isolated from the Pacific yew, <i>Taxus brevifolia</i>) and the epothilones (originally isolated from the bacterium <i>Solangium cellulosum</i>). They stabilize elements of the cytoskeleton, the microtubules, and thus inhibit cell division. In contrast to taxanes, epothilones may have the ability to bypass some of the resistance mechanisms of tumor cells. This resistance prevents the long-term success of cancer therapy in many patients.</p>	<p>Administration form Infusion</p>
<p>Sagopilone is the first fully synthetic epothilone in clinical development that may be able to fight not only tumors that are still responsive to chemotherapy but also tumors with multiple resistance, and achieve a better efficacy/tolerability ratio. Sagopilone is a stabilizer of microtubules that is rapidly taken up into the cell and inhibits the division of cancer cells. Moreover, sagopilone is not recognized by the so-called efflux pumps, through which other drugs are transported out of the cell. The bypassing of this mechanism represents an important approach in the development of cancer therapies.</p>	<p>Mode of action Stabilisation of microtubules thus resulting in inhibition of cell division, which should lead to cell death</p>
<p>Sagopilone Sagopilone is a novel epothilone, the molecular structure of which was designed specifically to provide advantages over other microtubule stabilizers such as taxanes and other epothilones. The goal in the development of this substance was to combine high binding efficacy with a well tolerated side-effect profile. In specific studies, sagopilone showed significant efficacy in many in vitro and in vivo tumor models. The research included tumors that are chemotherapeutically naive as well as tumors with multiple resistance that no longer respond to taxanes or anthracyclines. In addition, the water solubility of sagopilone is better than that of the taxanes and does not require the solvent Cremophor, and this may prevent the</p>	<p>Status</p> <ul style="list-style-type: none"> ▪ Wide-ranging program of current Phase II studies in various oncological indications ▪ First Phase III studies planned for 2008

occurrence of side effects.

Program of studies with sagopilone

Currently, an extensive program of Phase II studies is being conducted with sagopilone in Europe and North America. In the clinical studies, the novel epothilone is being tested in various oncological indications. These include ovarian and breast cancer as well as prostate cancer and various types of lung cancer.

The clinical studies serve to provide proof of efficacy and determine the response rates of the listed types of cancer to sagopilone. The individual studies cover a wide spectrum: the potential of sagopilone is being tested in monotherapy and in combined therapy, and the use of the active substance is being investigated both as a first-line therapy and as a treatment option in patients who have already received therapy.

Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma and as Bayer HealthCare Pharmaceuticals in the US and Canada. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide.

Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering

Pharma aims to make a contribution to medical progress and strives to improve the quality of life.

Research and Development at Bayer Schering Pharma

Bayer Schering Pharma concentrates its R&D activities on innovative treatment approaches for diseases with a high unmet medical need to improve patients' quality of life and prolong lives. In this context, Bayer Schering Pharma focuses on its core competencies and its many years of experience. Thus, Bayer Schering Pharma holds a leading position in many therapeutic fields: for example, in the treatment of hemophilia and multiple sclerosis, in contrast media and oral contraception. We are also striving for a leading position in oncology. With new approaches in cancer therapy, for cardiovascular diseases, gynaecological therapies and in molecular imaging, Bayer Schering Pharma aims to become an innovation leader in these fields. In addition, Bayer Schering Pharma further develops products already on the market in order to improve their application and/or extend their range of indications.

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Forward-looking statements

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