



Fact Sheet

Bayer Schering Pharma Development Projects

Business Unit: Oncology

Development candidate L19-IL2 – Immunocytokine combining targeted activity against the tumor with local activation of the body's own immune system

- Good tolerability due to high selectivity pursued
- Preliminary clinical data indicate efficacy in various cancer indications

Status: June 2007

<p>Project description</p> <p>L19-IL2 is an immunocytokine developed to target tumors and is currently in the early phase of clinical development. The therapeutic approach with L19-IL2 consists of bringing about a selective immunomodulatory effect of interleukin-2 in the tumor tissue. Preliminary data from a Phase I/II study suggest that L19-IL2 may reveal clinical activity in certain cancers such as renal cell carcinoma. Due to its selectivity, L19-IL2 appears to be well tolerated. All observed toxicity in study patients has been mild and reversible.</p> <p>Active substance</p> <p>L19-IL2 is an immunocytokine developed to target tumors. The fusion protein consists of a human antibody fragment (L19) and the human chemical messenger interleukin-2 (IL-2) that activates cells of the immune system.</p>	<p>At a glance</p>
	<p>Name of the active substance</p> <p>L19-IL2</p>
	<p>Type of substance</p> <p>Human fusion protein from a monoclonal antibody fragment and a cytokine</p>
	<p>Targeted Indication</p> <p>Oncology (solid tumors)</p>

<p>The antibody fragment targets a component of fibronectin known as Extra Domain B (ED-B). Fibronectin is a component of the extracellular matrix and is widely distributed in tissue and body fluids. The ED-B domain of fibronectin is, however, predominantly found only where new tissue is developing, i.e. where there is tumor growth, but also in wound healing and during the build-up of the endometrium. ED-B is considered to be a marker of angiogenesis, the development of new blood vessels. This is where the dual mechanism of action of L19-IL2 takes effect: the L19 antibody fragment ensures specific binding to fibronectin ED-B, and the interleukin-2 chemical messenger causes the activation of the body's immune cells directly where the cancer-inhibiting effect is required, within the tumor.</p> <p>L19-IL2 has shown pronounced anti-tumor activity in preclinical models. The substance is being developed under a License and Development Agreement between Bayer Schering Pharma AG and Philogen S.p.A., Siena, Italy.</p>	<p>Administration form Intravenous infusion</p>
	<p>Mode of action Binding to the ED-B domain of fibronectin, local activation of immune cells by means of interleukin-2 leading to the destruction of cancer cells</p>
	<p>Status</p> <ul style="list-style-type: none"> ▪ Phase I/II studies completed ▪ Current Phase II studies in renal cancer
	<p>Collaborating partner Philogen S.p.A. Siena, Italy</p> <p>www.philogen.it</p>

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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