Zentaris receives approval to market Impavido® in Germany

Frankfurt-based biopharmaceutical company becomes the first start-up company to receive approval for a compound that was discovered and developed in Germany

Frankfurt/Main, 7.12.2004. Zentaris GmbH announced today that Germany's food and drug agency (BfArM) has approved the anti-leishmaniasis drug Impavido® for release on the German market, thus making Zentaris the first start-up pharmaceutical company to market a drug that was discovered and developed in Germany. The preparation was approved in India in 2002 and has been on the market there since 2003. Impavido® will be available in Germany immediately.

Impavido®, whose active agent is miltefosine, has been approved for the treatment of visceral leishmaniasis, which after malaria counts as the most virulent tropical disease. Impavido® has registered cure rates exceeding 95 per cent in India, even in resistant cases. In Europe, Impavido® was administered to 39 leishmaniasis patients with HIV co-infections for whom all other treatments were unsuccessful. After four weeks of treatment, approximately two-thirds of these patients were either cured or their symptoms were greatly improved (Clinical Infectious Diseases 2004 39(10) 1520-23). European HIV patients still fall victim to leishmaniasis since their debilitated immune systems are unable to fight off the disease. Leishmaniasis recurs repeatedly in these patients owing to the HIV infection. It has been shown that in these patients as well, Impavido® can be administered both chronically and repeatedly. The leishmaniasis pathogen is widespread in southern Europe, where the disorder is known, particularly among dogs, which act as a vector for the spread of the disease to humans.

As the first oral leishmaniasis therapy, Impavido® has attracted a great deal of attention in medical circles, and is the first treatment in over half a century to have been developed specifically for this disorder. In addition to its high degree of effectiveness and oral delivery, Impavido® has a more advantageous adverse effects profile than the standard medications. Impavido® also enables patients to avoid a four-week hospital stay and thus greatly reduces the cost of therapy. The increasing worldwide resistance rate to the standard anti-leishmaniasis medications also makes Impavido® a milestone in the fight against the disease.

The results of mucocutaneous leishmaniasis therapy are also promising. This form of the disorder, which is widespread in South America (espundia) and the Middle East (oriental boil), leads to open sores on the arms, legs and face. Late sequelae are constituted by residual body scarring and facial disfiguration. Drug approval applications have already been filed for this indication in Pakistan and Colombia.
"We're proud to have been given this opportunity to demonstrate that a treatment that is highly regarded worldwide can still be discovered and developed in Germany. We feel that our work is in keeping with the highest tradition of the scientific community in Germany, which at one time was justifiably known as 'the pharmacist to the world.' We intend to perpetuate that tradition," noted Zentaris GmbH chairman Professor Dr. Jurgen Engel, who personally oversaw and promoted the development of Impavido®.

Impavido's active ingredient, miltefosine, was discovered at the Max Planck Institute in Göttingen by Professor Hans Jorg Eibl and Professor Clemens Unger and was developed into a medication by Zentaris in cooperation with WHO. According to WHO statistics, leishmaniasis exists in 88 countries, which means that approximately 350 million people worldwide live with the risk of contracting the disorder. Approximately 1.5 million people are infected with leishmaniasis each year and 60,000 people die from it annually.

About Zentaris GmbH

Zentaris GmbH, a wholly owned subsidiary of Canada-based AEterna Zentaris Inc. (TSX: AEZ; Nasdaq: AEZS), is an integrated research oriented biopharmaceutical company whose main focus is therapy for both malignant and benign tumours. With two products on the market, seven undergoing clinical trials and eight in the preclinical development phase, Zentaris is one of Europe's leading biopharmaceutical companies. Following the company motto, "Committed to cure," Zentaris's 89 employees at the company's Frankfurt facility develop innovative patient-friendly therapies. For more information, visit [www.zentaris.com](http://www.zentaris.com) or [www.aeternazentaris.com](http://www.aeternazentaris.com).

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