

HEALTH

Blood cancer patient undergoes first stem cell transplant using Israeli-developed StemEx cord blood technique

By ISRAEL21c staff November 08, 2007

A new venture between two Israeli companies has succeeded in transplanting stem cells in a blood-cancer patient for the first time with a technique that may lead to an alternative treatment to bone-marrow transplants.

Pharmaceutical giant Teva (NASDAQ: TEVA) and biomed company Gamida Cell have jointly announced their completion of the first successful stem cell transplant using the experimental StemEx technology developed by Gamida.

For many patients suffering from blood-based cancers such as leukemia and lymphoma, the odds of survival have historically been poor. Bone marrow transplant treatment improves prospects for some - but suitable donors can generally be found for only 50 percent of patients. For the other half, no match can spell no hope.

The StemEx technique, which involves a graft of expanded stem cells derived from umbilical cord blood, has been in clinical development by the Jerusalem-based Gamida Cell for the last five years. Gamida develops stem cell-based therapies to treat blood cancers and cardiac diseases.

After Gamida Cell entered into a partnership with Teva in March 2005, the product received "orphan drug" status approval from the US Food and Drug Administration, granting it certain benefits designed to fast track the product to market.

The stem cell transplant took place as part of the ExCell studies at the The Ireland Cancer Center of University Hospitals Case Medical Center. The trial, known as a "registration study," is currently enrolling patients to test the efficacy and safety of the StemEx technology on 100 patients aged 12 to 55 in Europe, the US and Israel who suffer from various hematological malignancies. According to Gamida Cell, the plan is to finish all trials and bring the treatment to market in 2009.

Leukemia, which affects more than 44,000 individuals in the United States each year, is a cancer of the blood-forming cells located in the bone marrow. Current best-practice treatment involves the transplantation of healthy bone marrow cells from a donor who is as

genetically identical to the patient as possible, with a similar white blood cell antigen profile. Obtaining a sufficient match can be difficult. But even where a suitable source can be obtained, there is still a high risk that the patient's immune system will reject the transplant, leading to severe side effects.

According to the US National Marrow Donor Program, each year in the United States alone, more than 70 percent of the 35,000 patients with life-threatening diseases who could benefit from a marrow transplant cannot be matched with a donor.

The StemEx study will recruit patients who have been unable to find a suitable bone marrow donor. By using stem cells derived from umbilical cord blood, which has less matching requirements than bone marrow, the technique widens the therapeutic options for such patients and reduces the risk of immune rejection.

Such cord blood technology has been around for nearly 20 years. But in the past, such treatment proved viable only in cases of pediatric leukemia, given the small quantity of cells obtainable from umbilical cord blood. The StemEx technology is able to increase this volume of cells in the laboratory, enabling adolescent and adult patients to undergo stem cell treatment for the first time.

The development is another step in the success story of Gamida Cell, a nine-year-old company which has benefited from Israel's prime position as the top per capita publisher of stem cell research in the world.

"Cell therapy products are no longer a vision of the future, but a solid deliverable for the present," said Gamida Cell CEO Dr. Yael Margolin.

"StemEx is an important innovation and an exciting part of Teva's research and development pipeline," added Dr. Aharon Schwartz, Teva's vice president of Innovative Ventures. Trading on Nasdaq since 1982, it is now the world's top producer of generic drugs, and was recently named by *Forbes* magazine as one of 130 "global superstars" in the business world.

Teva's strategic partnerships with numerous biotech startups like Gamida Cell is helping the company to continue the innovative path it forged when developing its first proprietary product, the Copaxone multiple sclerosis treatment.

"There is a need for improved options for patients who cannot find a matched bone marrow donor," said Mary J. Laughlin, a Case Western Reserve University doctor who is helping lead the study. "New technology such as StemEx may expedite the matching process for patients and cut transplant-related deaths."