

CellControl – breakthroughs for cancer patients

CellControl, a young German biotech and oncological specialty company, is a new player that recently entered the European biotech arena. Located in the renowned 'Innovation And Founders Center' (Innovations- und Gründerzentrum) of Martinsried near Munich, the company seems to have found just the right home to suit its aspirations, as CellControl may be one of many new players in the field, but its concept is truly unique.

Above all, CellControl's combination of products and services is unique. With diagnostic test procedures on the one hand and therapeutic products on the other, CellControl is one of the pioneers in the field of 'theranostics.' Having just recently emerged from the fusion of therapy and diagnostics, this market is said to have enormous growth potential: According to expert estimates, the diagnostics part alone will roughly triple to US\$3.5 billion by 2010. Theranostics is particularly important in the field of oncology: It is now known that cancer is as multifaceted as the number of patients concerned, which means that no one therapy will be effective for all patients suffering from the same type of tumor. As a consequence, therapeutic approaches of the future will have to be preceded by diagnostic elements. In other words, before selecting the



optimal medication for a patient, he or she will have to be tested as to his or her probable response – or resistance.

Diagnostic test procedures are one of the mainstays of CellControl's business. The first product out of the pipeline is ChemoSelect®, a new-generation chemosensitivity test. With

ChemoSelect® up to seven cytostatic agents, single or in combination, can be tested with regard to their probable effect on a specific patient's cells. The test requires a relatively small number of cells (1×10^5) and results are available in only 24 hours. This clearly distinguishes ChemoSelect® from traditional

procedures that – apart from being limited to the measurement of chemoresistance only – require the tumor cells to be cultivated for up to two weeks. During this period there may be changes in the cells not necessarily caused by the presence of the substances tested, which makes the test results rather unreliable.

ChemoSelect® is based on a highly innovative biosensor technology: The patient's cells are placed onto a microchip which continuously measures their metabolic activity over time, as influenced by the cytostatic agents tested. Even minute changes are detected and recorded accurately. This permits identification of those substances most strongly suppressing or inhibiting cellular growth: If the metabolic activity decreases, the substance tested can be assumed to be effective. This way, ChemoSelect® helps physicians not only to exclude substances, but also to select the drug therapy most likely to be effective for specific patients.

For the second mainstay of CellControl's business, a strong foundation is provided by the therapeutic products program comprising three highly innovative tumor vaccines for gynecological cancers. The lead compound is ACA 125, an antibody for ovarian cancer. This therapeutic vaccine has recently undergone clinical trials phase I/II, the results of which were published by Clinical Cancer

Research: Of 42 patients treated with ACA 125, 28 responded very strongly, showing an average survival time of 19.9 months – as compared to 5.3 months for non-responders. Side effects were negligible, with a total of 750 applications analyzed. This result is all the more impressive when considering that the average study participant had undergone 2.1 chemotherapies prior to the ACA 125 treatment – and pre-treated patients are hardly the best target group when it comes to triggering immunological responses. Forthcoming registration trials will test the concept not only in second, but also in first line treatment, where an even higher benefit for the patient is expected. The technological platform for ACA 125 has received the well-regarded Schmidt-Matthiesen award of the AGO (the German Society for Gynecological Oncology) for its highly specific and innovative mechanism of action.

CellControl is guided in this effort by an international, high-caliber advisory board. Its members consider the program a milestone in proving the clinical relevance of solid anti-idiotype tumor vaccines. Speedy and reliable patient recruitment is ensured by the support of major investigator networks. Though CellControl has all the resources in place to carry the product to registration, the company considers joining forces with a development partner who can

contribute sales capacity outside Europe, especially in North America. Despite its position in a niche 'orphan' indication, the product has enormous sales potential: 80% of all ovarian cancers are CA-125 positive and therefore eligible for this treatment, the medical need is immense, and therapeutic options are very few – a combination of factors likely to limit both price sensitivity and competitive pressure.

The ACA 125 is a prime example of CellControl's strategy, which is to build on the basic research performed in the scientific community to develop mature and marketable products – with the distinct objective to achieve therapeutic breakthroughs for patients. In addition, CellControl is looking to continuously in-license products from other sources, thus bringing its professional marketing network to bear.

Which leads to another point that puts CellControl in a class of its own: From R&D to clinical trials to marketing and distribution, all business functions required are fully integrated in-house. This places the company in a superb position for the marketing of oncological specialties which, since they are highly research-driven, require superior expertise and a sales team nimble enough to serve the corresponding market niches.

CellControl has set out to conquer the market. And its chances of success are good, even when faced with competition from larger players. Besides its leading-edge technology, another major success factor is the company's professional team: All management members bring in extensive and complementary experience, gained in positions with international research institutions, large-scale pharma companies, and a leading management consultancy. ■

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