



Innovation in oncology

Celsion
Corporation

The new focus at Celsion

To make a truly significant difference in the world of oncology, Executive Management at Celsion Corporation has singularly focused the company on developing and commercializing more efficient, effective oncology treatments. Now positioned to address important unmet medical needs, Celsion is gaining momentum in this crucial therapeutic category.

Optimizing chemotherapeutics through improved delivery

Singly or in combination with radiation, traditional chemotherapy has long been the mainstay in the fight against cancer. The issue with this treatment option has always been the ability to increase the dose of the anticancer agent delivered to the cancer cells without increasing the associated side effects. The goal then is to develop oncology therapeutics that demonstrate a greater ability to target cancerous tumors in order to maximize efficacy and minimize the burden of side effects caused by systemic toxicity.

Celsion, through an exclusive development and commercialization license from Duke University, has obtained a new, proprietary technology to produce lysolipid thermally sensitive liposomes (LTSL). The first in a new generation of liposomes, LTSL improves on previous liposomal technologies through its unique low heat-activated release of encapsulated chemotherapeutic agents right at the cancer site. These new liposomes are composed of lipid molecules that quickly change structure when heated to a specific temperature, creating channels in the liposome bilayer that allow encapsulated drug to rapidly disperse into the surrounding tissue. As a result, LTSL enables delivery of higher concentrations of proven chemotherapy drugs directly to the tumor to help stop the progression of cancer and minimize systemic toxicity.

The science of LTSL has already been reviewed and validated by major scientific institutions and investigators. The technology, further developed by Celsion, is being used to enhance existing chemotherapeutics.

First on the horizon: ThermoDox®—doxorubicin dramatically enhanced with LTSL

In partnership with Duke University, Celsion has encapsulated doxorubicin, a frequently used cancer drug, in heat-activated liposomes. The new product is called ThermoDox, and indications are expected for both Hepatocellular Carcinoma (HCC, or primary liver cancer) and Recurrent Chest Wall breast cancer (RCW).

In Hepatocellular Carcinoma (HCC)

Celsion is currently initiating enrollment in a global Phase III clinical trial program to demonstrate the efficacy and safety of ThermoDox in HCC. In combination with radiofrequency ablation, ThermoDox will deliver high concentrations of drug directly to the tumor. The primary end point of the trial is progression-free survival. Preclinical results indicate that LTSL-enhanced ThermoDox is dramatically more effective than other chemotherapeutic formulations.

The annual world-wide incidence of HCC is 660,000.

RCW is diagnosed
in 15,000 patients
in the United States
alone every year.

In Recurrent Chest Wall breast cancer (RCW)

At the same time, Celsion is planning Phase II studies in RCW patients using ThermoDox in combination with microwave energy. RCW patients are typically breast cancer survivors who have suffered a recurrence after all traditional treatments have been exhausted. The primary end points of this trial are objective tumor response and quality of life. The safety and efficacy of ThermoDox in RCW is being demonstrated in a Phase I dose-escalation study that will pave the way for a robust Phase II registrational trial.

A healthy pipeline points to a promising future

Celsion's pipeline of proven chemotherapeutics enhanced with LTSL includes docetaxel (in preclinical development) and platinum (in formulation development).

In the future, Celsion intends to apply various lipid and focused-heat technologies in order to provide more effective, better targeting, concentrated cancer therapies.



Use in proven chemotherapeutics lowers development risk while accelerating approval and time to market

Because LTSL is being introduced in established treatments, clinical programs will be less complex, and the approval process and time to market will be streamlined.

Expect success—as a commercialization partner or as an investor

There are a number of factors that make Celsion an extremely attractive commercialization partner and investment opportunity, including

- A clinical focus on offering novel treatments to patients with minimal options
- A unique technology platform (LTSL) that is expandable into many therapeutics and indications
- The necessary cash resources to complete the Phase III HCC clinical trial for ThermoDox
- A new executive team with extensive pharmaceutical development and commercialization experience gained at leading pharmaceutical companies and research institutions

Celsion is poised to build on its past successes and, with the right partners and investors on board, advance the efficacy and the tolerability of chemotherapeutics, helping to ensure better patient outcomes and improved quality of life.



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An ideal partner

A sound investment opportunity

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