

Overview:

Celsense, Inc. offers novel imaging agents used to non-invasively visualize and measure biological processes at the cellular level in humans and other living organisms. The core innovations of the Company involve imaging agents that can be used to observe cell trafficking using fluorine magnetic resonance imaging (^{19}F MRI) techniques. Applications include the discovery and development of therapeutic agents (small molecules, recombinant proteins, cells, or genes), monitoring therapeutic delivery in clinical trials, and monitoring delivery for clinically approved therapeutics.

Cell Therapy:

The accurate delivery of therapeutic cells is fundamental to the efficacy and safety of any cellular therapy. A failure to observe a clinical response raises the question whether a sufficient number of cells were delivered to, and/or persisted at the desired site(s). Conversely, the manifestation of undesired side effects raises the question whether large numbers of cells were delivered off-target.

Existing methods to track the delivery, migration and persistence of therapeutic cells rely on the histological examination of biopsied tissues. In the clinic, these methods remain problematic due to a reliance on sampling and the need for a priori knowledge of where to sample. The availability of non-invasive imaging technologies for clinical use in cell therapy has previously been limited.

Often the clinical applicability of preclinical cell therapy data is questionable. Thus, the development process for cell therapies is heavily dependent on small phase I/II clinical trials. Historically, the results of many of these trials have been inconclusive due to the absence of cell trafficking data.

Inflammation:

Inflammation associated with graft rejection, disease, and injury often results in localized accumulations of immune cell populations. Monitoring the trafficking of immune cells can be an important diagnostic indicator of therapeutic efficacy and sites of action.

Our Products:

The Company's product set encompasses two reagent product platforms and software tools used by investigators and clinicians to interpret the MRI data set (see inset).

All of the Company's products are currently offered for preclinical use. *Cell Sense* is also available for use in human clinical trials. A Drug Master File for *Cell Sense* with the US FDA may be cross referenced.

Each of the contrast agents are further described in whitepapers available on the Celsense, Inc. website www.celsense.com.

Credentials to access a demonstration data set on *Voxel Tracker* will be provided upon request by emailing info@celsense.com.

Cell Sense is a fluorocarbon tracer agent used to label cells *ex vivo*, enabling investigators to noninvasively observe and measure the administration, migration and persistence of therapeutic and diagnostic cells using MRI. A combined MRI-Fluorescent version of *Cell Sense* is also available.

V-Sense is a fluorocarbon MRI tracer agent that labels leukocytes *in situ*, enabling the direct, non-invasive observation of localized inflammation. An MRI-Fluorescent version of V-Sense is available.

Voxel Tracker is a web-based workstation used to visualize and manage MRI data sets. *Voxel Tracker* was designed to optimize the value of the *Cell Sense* and *V-Sense* image data by seamlessly fusing the conventional proton and ¹⁹F images, and facilitate interpretation by calculating the apparent number of transplanted cells or inflammation index in a user defined region of interest.

Product Support: Celsense, Inc. provides detailed protocols and live support through a team of PhD scientists. This enables researchers to focus on answering their hypotheses rather than technicalities. Celsense, Inc. also invites proposals for contracted research.

The Company:

Celsense, Inc. is an emerging biotechnology company located in Pittsburgh, Pennsylvania, USA. Founded in 2005, the company's customers include leading pharmaceutical, biotechnology, and academic organizations worldwide. The mission of the company is to be the standard for cellular imaging in human health.

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