

NOVEL TUMOR SELECTIVE MRI CONTRAST AGENT

SPAGO Imaging develops a novel and proprietary tumor selective contrast agent for MRI, SPAGO Pix, which has the potential to significantly improve visualization of most soft tissue tumors.

Low specificity (false positive findings) has a significant clinical impact causing increased patient suffering and added costs due to unnecessary biopsies and supplementary procedures. Early and accurate diagnosis is vital to ensure treatment efficiency and increase long term patient survival.

SPAGO Pix has unique features with potential to;

- Enable detection of small tumors
- Reduce the number of false positives

It is a nanoparticle based contrast agent with exceptionally high relaxivity that selectively accumulates in tumor tissue. To date, excellent contrast between tumor and surrounding tissue has been obtained in a preclinical proof of concept study which indicates the potential as a clinical diagnostic. Further efficacy- and toxicity studies are ongoing and GLP toxicity studies will be initiated in 2012.

The focus for SPAGO Pix is initially breast cancer expanding to other soft tissue tumors.

TUMOR IMAGING – A CHALLENGE

Many patients are diagnosed with cancer every year worldwide. Tumor diagnosis is still a challenge and many patients are not diagnosed early enough to allow an effective treatment.

Current tumor imaging methods offer varying sensitivity, specificity, safety and cost. None of the methods to date are of a sufficient high quality to meet all aspects necessary for general tumor visualization. Mammography is fast, cheap and has good specificity but insufficient sensitivity, therefore missing a substantial number of tumors. Studies have shown that women at a high risk of developing breast cancer have substantially increased chances of being diagnosed at an early stage if regularly screened by MRI vs mammography alone^{1,2,3}. Mammography, as well as CT and PET, use ionizing radiation which increase the risk of cancer.

MRI provides high sensitivity without radiation but has unacceptable levels of false positives.

Although a very powerful imaging modality, MRI is not used to its fullest potential for tumor visualization, primarily due to the number of false positives generated (particularly breast cancer screening) and cost. There is a clear need to improve specificity but also sensitivity of the method to provide more accurate diagnoses. Shortened examination time would lower the cost and improve patient comfort. A new contrast agent that provides improved image quality that affects clinical decisions will, according to KOLs in the field, result in an increased use of CE-MRI and thus expand the use of MRI for tumor visualization to the benefit of the patients.

Most of today's contrast agents are based on small molecule gadolinium chelates. These rapidly distribute in the tissues leading to a short time-window for imaging and low contrast between tumor and surrounding tissue. Gadolinium has also been linked to NSF (Nephrogenic Systemic Fibrosis), a severe and debilitating disease that can affect patients with impaired renal function.

SPAGO Pix

SPAGO Pix;

- selectively accumulates in tumor tissue (EPR effect)
- has extraordinarily high signal strength (relaxivity), i.e. five times higher than today's contrast agents
- is based on non-gadolinium-containing nanoparticles
- will not cause NSF (Nephrogenic Systemic Fibrosis)
- can be produced in a few steps
- provides excellent contrast

The unique features of SPAGO Pix provide potential for detection of smaller tumors with higher specificity than what is possible with MRI and mammography today. This opens up new possibilities for screening of high risk patients without ionizing radiation as well as diagnosis, treatment planning and monitoring of cancer patients. More accurate and earlier diagnosis can lead to improved treatment and less suffering as well as lower healthcare costs and allow more patients to receive a highly sensitive tumor examination.

CHARACTERISTICS OF THE SPAGO IMAGING INVENTION

Sensitivity and Specificity

SPAGO Pix consists of paramagnetic non-gadolinium-containing nanoparticles with a relaxivity of 30/mM/s and a size suitable for passive tumor targeting (EPR effect). This combination provides excellent contrast between tumor and surrounding tissue as well as potential for shorter imaging times during a larger time window.

Safety

SPAGO Pix is an extracellular agent that will not cause NSF. It has a longer half life and smaller volume of distribution compared to today's contrast agents, allowing dosing of smaller volumes. The particle size is designed to allow renal excretion, but does not exclude elimination via liver and bile.

Material

The contrast agent is based on polymeric particles that can be produced in a few steps.

STATUS OF PROJECT

Preclinical proof of concept study has been performed and this indicates good clinical diagnostic value. Further efficacy and toxicity studies are ongoing and GLP toxicity studies will be initiated 2012.

An EP application covering composition of matter, formulation, process and field of use was filed 2011. PCT and national filings will follow.

THE MRI CONTRAST AGENT MARKET

The worldwide MRI contrast agent market was worth 1.1 billion USD in 2010, with an annual growth rate of 5-6%, and is expected to reach 2 billion USD by 2020. Tumor enhancement makes up approximately 20-25% of the MRI contrast agent market, or 250-300 million USD, growing 5-7% annually. The use of MRI for breast cancer imaging has seen explosive growth in the last decade, resulting in a market growth of 25-35% annually 2000-2010⁴.

The market for MRI contrast agents for tumor visualization is mainly driven by an increasing incidence of cancer globally. WHO predicts that global cancer incidence will increase from 12.4 million new cases in 2008 to 20 – 26.4 million new cases in 2030. Although cancer incidence is increasing, mortality rates are decreasing, which leads to an increasing number of follow-up exams in cancer survivors.

COMMERCIAL DEVELOPMENT STRATEGY

First indication for this tumor selective contrast agent is anticipated to be breast cancer due to the large medical need, a scientific and medical rationale and the large market opportunities.

SPAGO Imaging's strategy is to partner this project prior to FTIM. We are looking for a partner to help take SPAGO Pix into the clinic, and working together we would like to mature SPAGO Pix into a new generation of contrast agents. A preferred partner has a strong commitment to the development of new contrast agents for MRI and necessary development-, marketing-, and sales capabilities. This will shorten time to market and increase the probability of a successful launch of the product.

THE COMPANY

SPAGO Imaging AB was established in 2007 and is located in Lund, Sweden. The management- and R&D team, as well as board and advisors include professionals with many years of experience from business management and contrast agent- and pharmaceutical companies. SPAGO Imaging is a subsidiary of Accelerator Nordic AB.

REFERENCES

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