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Imagion Trial Review Backs Magsense For All Cancer MRI

IMAGION BIOSYSTEMS

Imagion says it will prioritize development of its Magsense nanoparticle technology as imaging agents for mainstream clinical magnetic resonance imaging (MRI) scanners.

Imagion said that an independent, blinded review by a panel of expert breast cancer radiologists corroborated its previously reported findings that Magsense had the potential to detect tumor cells in lymph nodes by MRI.

The company said that each radiologist ascertained that the Magsense human epidermal growth factor receptor 2 (HER2) imaging agent “produced a change in image contrast and that the contrast in nodes highly suspicious for tumor was distinctly different from the magnetic resonance imaging (MRI) contrast seen in non-involved nodes”.

The study’s principal investigator Dr Jane Fox said that the review was very encouraging”.

“The assessments by these experienced breast radiologists are in line with our thinking that these early patient results are showing that the Magsense HER2 imaging agent is adding valuable information that can be used to better assess a patient’s medical condition before starting treatment or planning surgery,” Dr Fox said.

Imagion said that the independent reviews were “consistent with the company’s previous assertion that the Magsense imaging agent provides new information for the radiologist not available through conventional methods, like ultrasound, and has the potential to aid in the clinical assessment of nodal metastasis in HER2 positive breast cancer”.

The company said the panel assessment has “significant implications” given that MRI was part of clinical workflows and clinical decision making with a large installed base of scanners and trained radiologists, which would “help drive faster clinical adoption”.

Imagion said the findings and change of priorities would eliminate near-term expense and risks associated with developing and introducing a new type of detection technology and showed the clinical potential for a pipeline of imaging agents targeting other cancers.

Imagion executive chair Bob Proulx said the outcome of the independent review was “welcome news, indeed”.

“We now have a clear indication that our Magsense magnetic nanoparticle technology could work with the existing medical imaging infrastructure to provide the clinical benefit to breast cancer patients we have been aiming for,” Mr Proulx said.

“This takes a lot of the technical risk out of the future and will significantly facilitate market entry by eliminating the need to design, make, sell, and support new machinery,” Mr Proulx said.

“We will continue to refine our proprietary relaxometry technology but can now confidently shift our resources to developing our nanoparticles for use with MRI, a ubiquitous imaging modality used in hospitals and radiology clinics throughout the world,” Mr Proulx said.

“We believe this will be more attractive for strategic partners and more likely for us to achieve commercial success sooner,” Mr Proulx said.

“Since all Magsense targeted imaging agents use the same underlying magnetic nanoparticle technology, the company plans to prioritize the development of its Magsense nanoparticle technology for use with mainstream clinical MRI scanners,” Mr Proulx said.

Imagion said that it had begun the regulatory process with the US Food and Drug Administration to bring the HER2 breast cancer clinical studies to the US where there would be access to a larger number of sites and a more substantial patient population.

The company said that the FDA had designated Magsense as a medical device, but recent US legislation stipulated that any MRI contrast agent be regulated as drugs through the imaging group within the Center for Drug Evaluation and Research.

Imagion said it did not expect the change to seek approval for its imaging agents for use with commercially available MRI scanners to significantly impact the time or cost associated with obtaining regulatory approvals.

Imagion was up 0.4 cents or 18.2 percent to 2.6 cents with 55.75 million shares traded.