

New independent market research says 84% US healthcare professionals likely to use Orviglance imaging agent in target population

Ascelia Pharma today announced and welcomed the results of independent market research showing that 84% of healthcare professionals will likely use Orviglance® for magnetic resonance imaging (MRI) in patients with cancer in the liver and reduced kidney function.

The independently conducted survey asked 270 healthcare professionals in the US (radiologists, oncologists and nephrologists) about their choices of imaging and contrast agents in patients with cancer. The primary driver of their MRI contrast agent decisions is patient safety, and in particular the need to minimize the risk of Nephrogenic Systemic Fibrosis (NSF), a side-effect associated with the currently available gadolinium agents in patients with reduced kidney function – the target population for Orviglance. They were also concerned about allergies and gadolinium toxicity.

For patients with cancer in the liver and severely impaired kidney function respondents currently prefer not to use a contrast agent when performing an MRI (unenhanced), even though this reduces the ability to detect and visualize cancer lesions.

When presented the product profile of Orviglance, 84% of participants say they are likely to or definitely will use Orviglance for the target patient population. These results are consistent with quantitative research completed in 2018 and confirm strong user support as Ascelia Pharma prepares for the launch of Orviglance.

Julie Waras Brogren, Ascelia Pharma's Chief Commercial Officer, commented: "The positive reactions to Orviglance from the research participants are incredibly encouraging. This convincing research confirms the clear unmet need for an effective alternative to unenhanced MRI and a safe alternative to GBCAs; and underlines that Orviglance can improve outcomes for patients whose current diagnostic options are suboptimal."

Orviglance is a novel manganese-based oral contrast agent for MR imaging developed to improve the detection and visualization of focal liver lesions (including liver metastases and primary tumors) in patients with severely reduced kidney function. It has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA) and is currently in Phase 3 development, following Phase 2 clinical trials in which it demonstrated high quality imaging compared to MRI without contrast agent.

NSF is serious and potentially life-threatening and a known side-effect of GBCAs in patients with severe kidney impairment. Several regulatory agencies (including the FDA and EMA) issued warnings about the use of gadolinium-based agents. More than 15% of respondents in the survey have experienced a case of GBCA induced NSF.

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About us

About Ascelia Pharma

Ascelia Pharma is a biotech company focused on orphan oncology treatments. We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway. The company has two drug candidates – Orviglance® (Mangoral) and Oncoral – in clinical development. Ascelia Pharma has its global headquarters in Malmö, Sweden, and is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.

About Orviglance (previously referred to as Mangoral)

Orviglance (manganese chloride tetrahydrate) is a novel oral contrast agent for MR-imaging developed to improve the detection and visualization of focal liver lesions (including liver metastases and primary tumors) in patients with reduced kidney function. These patients are at risk of serious side effects from the currently available class of gadolinium-based contrast agents. Orviglance, which has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA), is currently in Phase 3 development, including the global multi-center SPARKLE study.

Attachments

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