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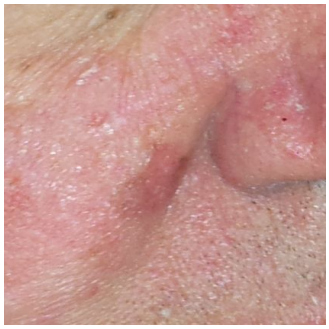
Navidea Lymphoseek® Gains FDA Approval



Navidea Biopharmaceuticals, a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, has announced U.S. Food and Drug Administration (FDA) approval of Lymphoseek® (technetium Tc 99m tilmanocept) Injection, which is indicated for use in lymphatic mapping procedures to assist in the localisation of lymph nodes draining a primary tumour in patients with breast cancer or melanoma. Lymphoseek is a receptor targeted radiopharmaceutical designed to identify these lymph nodes which have the highest probability of harboring cancer and assist in the staging of such patients.

Lymphatic mapping is a procedure in which lymph nodes that may contain tumour metastases are identified and biopsied to determine if cancer has spread beyond the primary tumor.

“We recommend lymphatic node mapping and sentinel node biopsy for patients with early stage breast cancer and in select cases of ductal carcinoma in situ,” said Anne Wallace, M.D., Professor of Surgery, UC San Diego School of Medicine; Director of the Breast Care Unit; UC San Diego Moores Cancer Center; and Principal Investigator for breast cancer in the Lymphoseek Phase 3 clinical trials. “The ability to reliably identify multi-node pathology-positive patients is important to optimise their post-surgery management and to spare certain patients from unnecessary surgery and potentially debilitating side effects. Products specifically designed to address reliable lymph node uptake and retention can provide significant clinical utility and help standardise the process of lymph node mapping.”

“Both the incidence rate and the death rate for melanoma continue to increase, in the United States and in many other parts of the world," said Vernon K. Sondak, M.D., Chair, Department of Cutaneous Oncology, Moffitt Cancer Center, Tampa Fla., and Principal Investigator for melanoma in the Lymphoseek Phase 3 clinical trials. "Most patients present with clinically localised disease, but microscopic metastases to the regional lymph nodes are common and are the major prognostic factor for these patients. Over the past 20 years, surgical staging of the regional nodes with intraoperative lymphatic mapping and sentinel node biopsy has emerged as the worldwide standard of care for patients with clinically node-negative intermediate and thick melanomas, and for selected patients with higher-risk thin primaries as well. New technologies offer the promise of improving intraoperative lymphatic mapping, allowing procedures to be done more quickly and potentially lessening the risk of misclassifying patients as node-negative when in fact their tumour has already spread to the regional nodes.”

The approval of Lymphoseek is based on data from more than 540 subjects receiving Lymphoseek. In pivotal Phase 3 studies that were conducted in 332 patients with either breast cancer or melanoma, Lymphoseek, on average, was present in 97 percent (range 94-100%) of resected, histology-confirmed lymph nodes. To date, no clinically significant drug-related adverse reactions have been reported. Lymphoseek has no contraindications and the most common adverse reactions were injection site irritation and/or pain (<1 percent).

“We believe today’s approval of Lymphoseek validates our ability to advance the field of precision diagnostics,” said Mark J. Pykett, V.M.D., Ph.D., President and CEO of Navidea. “Our vision is to improve diagnostic accuracy, clinical decision-making and patient care. We are gratified that our scientific achievements may benefit thousands of patients diagnosed with breast cancer and melanoma each year. We look forward to continuing the development of Lymphoseek into additional indications and to progressing our oncology and neurology pipeline.”

Lymphoseek will be sold and distributed in the U.S. by Cardinal Health, Inc. Navidea is also working to identify and partner with distributors in other markets outside the U.S.

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