Diatech Receives $10 Million for Peptide Research

In a deal that may signal the beginning of a new trend for radiopharmaceutical start-up companies, Diatech, Inc. in Londonderry, NH, recently announced that it had received a $10 million investment from Hafslund Nycomed, a large company based in Oslo, Norway that makes contrast media products. Under a five-year cooperation pact with an estimated potential value of $50 million to Diatech, Nycomed's initial investment will ensure a 17% stake in Diatech's peptide imaging drugs market.

Diatech currently has six peptide products that are in various stages of clinical trials, including P-280 which is in Phase III trials for the detection of deep vein thrombosis. The other peptides are in Phase I and II stages and are being tested as diagnostic agents for pulmonary embolism, somatostatin receptors in endocrine tumors, atherosclerortic plaque and infections of unknown origin. Diatech has not yet submitted any of its peptide products to the FDA for approval. "Nycomed's investment will significantly underwrite the cost of conducting studies for FDA approval," said Brad Miles, a spokesperson for Diatech.

He said Nycomed will make additional payments if Diatech's products win regulatory approval. "This is a giant company that was never involved in nuclear medicine, and this is their first leap into this area," said Miles. Nycomed executives recognize the promise of an imaging tool that could pinpoint diseases at an earlier stage and illustrate disease progression at a cellular level with greater sophistication than existing technology, including contrast media agents that Nycomed markets for x-rays and ultrasound. ■

Supply of Molybdenum-99

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cern among nuclear physicians, but he feels the new facility will be worth the extra cost. "My gut feeling is for people using unit doses out of a radiopharmacy the cost increases won't add more than a couple or three percent to their budget," said Ehmig. "And I can't think of a better way to assure a more secure supply."

The DOE's Proposal to Convert Sandia

For years, SNM leaders and other nuclear medicine leaders have been urging the DOE to build a reliable back-up facility for the production of ^{99}Mo. The DOE is currently preparing an environmental impact statement (EIS) on the production of ^{99}Mo. The department's preferred alternative is the annular core research reactor (ARR), a 2-megawatt reactor at Sandia National Laboratories in Albuquerque, New Mexico. By upgrading the Sandia reactor to 4 megawatts and adding processing equipment, Wade Carroll, the EIS Project Manager at DOE, said the DOE could provide 100% of the U.S. demand for molybdenum on a short-term basis. Carroll said the department is not planning to re-enter the market as a competitive supplier. "It would strictly be a back-up at this point," he said.

Given Nordion's plans to build a MAPLE-X reactor to be used solely as a back-up, the DOE's current plans to ensure a back-up supply may seem duplicative. DOE officials say they are acting on a need expressed in the nuclear medicine community and that the U.S. cannot rely on the Nordion proposal to build the two reactors to assure an adequate U.S. supply in the future. Carroll said that a decision by the DOE is expected early next year on whether or not the department will produce ^{99}Mo and, if so, at what facility. "If Sandia is selected, production of moly could occur by October of next year at the earliest," he said.

Some industry observers remain skeptical of the DOE's effort. They say the project is bound to be delayed for months, if not longer, by the DOE's decision to put together a full-blown EIS. More than a few observers have expressed dismay at what they consider a lack of responsiveness from the federal agency. "We don't feel like they are listening to their customers," said Ehmig. The major concern is that DOE has moved too sluggishly to be of much help. "The DOE has great plans, and I have no doubts about their good intentions, but I do have doubts about their budget," said Peter Vermeeren, general manager of Mallinckrodt's nuclear medicine division.

Mallinckrodt: A New Producer of Moly?

In August, Mallinckrodt received a license from the Dutch nuclear regulatory agency to begin work on medical isotope production at facilities in Petten owned by the Joint Research Center of the European Community, according to Vermeeren. The company started a trial production run in September as a step in gaining approval from the FDA to provide ^{99}Mo for generators marketed in the U.S.

"We expect to produce moly by the beginning of 1996," Vermeeren said. "We will then be able to use our own moly in Europe and in the U.S. when the FDA approves it." Mallinckrodt launched their plans about three years ago in an effort to create a secure supply of ^{99}Mo to ship generators to their customers. Vermeeren said Mallinckrodt is planning to produce only enough molybdenum to supply the company's own needs. Mallinckrodt supplies about 25% of the global market for ^{99m}Tc generators, he said, and about 20% of the U.S. market. "We are not out to conquer the world market for moly production," he said. "We're just trying to create a more stable situation and a more acceptable situation for our customers worldwide." In the event of a sudden shutdown of the NRU reactor in Canada, Vermeeren said, "it would be possible for IRE and Mallinckrodt to crank up production to supply the world."

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