Greater Availability of Important Biomarker

A decision by the US Food and Drug Administration (FDA) to approve a special fast track of a Siemens Molecular Imaging multicentre investigational new drug (IND) application for F-18-labeled 3'-deoxy-3'-fluorothymidine (FLT) could pave the way for wider availability of this important molecular biomarker.

FLT has shown much promise in monitoring the proliferation of cancer cells and in the US has become the second most widely used biomarker after FDG.

The FDA decision has allowed multiple sources of FLT to be evaluated, reviewed and accepted for use under a single IND. In addition, the FDA has also agreed to base the IND review process for acceptance of the various investigational FLT products on the end-product specifications.

This decision could potentially allow all PET users to have access to an approved pharmaceutical product rather than having to go through the laborious process of obtaining special authorisation on a case by case basis.

Edward Plut, Senior Director, Product Management PETNET Solutions, explained the FDA decision is an important milestone not only for Siemens but also for PETNET. “Although FLT is not a unique product we want to expand the market by providing general access to this important radiopharmaceutical.

“This will mean that PET facilities will have access to FLT as easily and readily through the PETNET radiopharmaceutical network as they currently enjoy with FDG.

“By having full product registration PETNET we will be able to produce and deliver FLT to a greater number of PET centers, who in turn will be able to use this important biomarker on a greater number of patients to enable earlier, and more accurate detection and treatment of disease,” he said.