

## **PRESS RELEASE**

Lund, April 27<sup>th</sup>, 2010

For release 9 a.m. CET, April 27<sup>th</sup>, 2010

### **TFS Phase I unit passes second successful inspection by the Swedish Medical Products Agency (MPA)**

TFS Trial Form Support International's (TFS) clinical research unit at the Karolinska University Hospital in Stockholm, Sweden was once again successfully inspected by inspectors from the Swedish Medical Products Agency (MPA) on January 18<sup>th</sup>, 2010.

The clinical research unit, integrated with Karolinska Trial Alliance (KTA), expanded its facilities in November 2009 adding a further 16 beds to the unit. The expanded clinical research unit now hosts 30 beds in two facilities located at the Karolinska University Hospital.

The first subject dosing at the expanded facility was performed on 30<sup>th</sup> November 2009 in a multiple ascending dose study in patients.

The inspection was conducted by inspectors from the Swedish MPA as part of their routine First-in-Man (FIM) inspection program to verify whether the organization, personnel, processes and facilities at Karolinska Trial Alliance are suitable for conducting First-in-Man studies in accordance with the applicable regulations, CPMP/ICH/135/95 and LVFS 2003:6.

*"Quality is one of the fundamental building blocks on which TFS and the Phase I unit is built. All studies conducted at the unit are audited by TFS Quality Assurance department and we are continually working together with the unit to improve procedures and processes in order to achieve and maintain the highest standards. It is of course very gratifying to receive official recognition of this work and we are proud to once again receive confirmation that the unit is approved for First-in-Man studies",* says Mr. Alistair Bone, Director Global Quality Assurance at TFS.

The inspector's conclusion was that the new expanded facility met the requirements for this type of clinical sites and the unit was seen to fulfill the MPA's GCP requirements. No major or critical findings were observed and the MPA inspectors considered the inspection to be complete. The clinical research unit's continuous suitability will be followed-up by future routine inspections.



TFS TRIAL FORM SUPPORT INTERNATIONAL

## **PRESS RELEASE**

*"First in man studies and translational medicine is not a question of quantity, but rather of science, of quality and safety. With the new unit we can meet all aspects on human safety and add further capacity. The MPA inspection gives us green light to all our procedures, adding to the conclusions previously drawn by FDA. For our partners in pharma, medtech, biotech and advanced therapies this is reassuring when they seek piloting data for go/no go decisions",* says Professor Pierre Lafolie, Head of Karolinska Trial Alliance at the Karolinska University Hospital.

The clinical research unit received its first MPA inspection in March 2008 followed by an inspection by the US Food and Drug Administration (FDA) in January 2009. The FDA inspection covered the research unit's GCP compliance and furthermore included the GLP compliance in laboratory departments of clinical chemistry, pharmacology and microbiology.

The research unit is highly specialized in First-in-Man (FIM)-, Proof of Concept (PoC)-, microdosing- and imaging studies utilizing mainly Positron Emission Tomography (PET). Studies at the unit involve both healthy volunteers and special patient populations.

*"The successful inspection of the expanded unit is an important landmark for us. I believe the combination of industrial and academic expertise of both TFS and Karolinska is very central for our success. The primary location of the unit in the heart of Karolinska University Hospital becomes even more crucial when it comes to including patients in early advanced first-in-man studies. It means we can ensure the safety and best care of the patients as well as reaching recruitment targets"* says Mrs. Eva Lundqvist, Director Academic Alliances at TFS.

### **For further information please contact:**

Director Global Quality Assurance, Mr. Alistair Bone  
Telephone: +46 46 280 18 00

To review the abbreviated Inspection Report visit:  
[www.trialformsupport.com/business/earlyclinicaldevelopment](http://www.trialformsupport.com/business/earlyclinicaldevelopment)

### **Information about TFS Trial Form Support International (TFS)**

TFS Trial Form Support International (TFS), with headquarters in Lund, Sweden, is the largest non-listed European clinical Contract Research Organization (CRO). Clinical services are provided by three business areas; Early Clinical Development, Project Delivery and Contract Placement Solutions, with annual net revenue greater than € 38 million, global operations in 16 countries, and more than 480 employees worldwide. Detailed information about TFS business areas, global locations and recent press releases can be obtained through its website at [www.trialformsupport.com](http://www.trialformsupport.com)

### **Information about Karolinska Trial Alliance (KTA)**

Karolinska Trial Alliance (KTA) within Karolinska University Hospital is a unit that supports research around pharmaceuticals, diagnostics and medical devices. KTA's unit conducts early clinical trials together with TFS Trial Form Support International AB as their partner.



TFS TRIAL FORM SUPPORT INTERNATIONAL