

## PRESS RELEASE

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# TFS research unit successfully inspected by the US Food and Drug Administration (FDA)

TFS Trial Form Support International's (TFS) research unit integrated with Karolinska Trial Alliance (KTA) at the Karolinska University Hospital, Stockholm, Sweden, was successfully inspected by the US Food and Drug Administration (FDA) in January 2009.

The research unit which is highly specialized in complex First-in-Man (FIM)-, Proof of Concept (PoC)-, microdosing- and imaging studies utilizing mainly Positron Emission Tomography (PET) was even successfully inspected by the Swedish Medical Product Agency (MPA) in March 2008.

*"TFS and KTA have, since the initiation of the research unit, made every effort to ensure that it fulfils the highest quality standards and we are of course very pleased to receive official verification from the FDA that the selected study lived up to FDA standards. Even if there was no 483 as a result of the inspection, TFS has learnt more about FDA expectations, which will hopefully mean that future studies will be conducted to even higher standards",* said Mr. Alistair Bone, Director Global Quality Assurance at TFS.

The inspection was conducted by an inspector from the FDA as part of their routine bioresearch monitoring (BIMO) In Vivo Bioequivalence inspections to determine if the clinical investigators and/or sites are in accordance with the current Good Clinical Practice Regulations. The inspection furthermore included the laboratory departments of clinical chemistry, pharmacology and microbiology which are integrated with the research unit as Center for Clinical Laboratory Studies, Karolinska University Laboratory. These laboratories are used as reference laboratories in connection to the early clinical development studies.

*"The successful outcome of this FDA inspection is another milestone in the close collaboration between Karolinska University Hospital and TFS and our common denominator - our customer. It shows the strength of combining two professional organizations in a joint venture to form the best from two worlds"* said Professor Pierre Lafolie, Head of Karolinska Trial Alliance at the Karolinska University Hospital.

The inspection was conducted between 19<sup>th</sup> and 22<sup>nd</sup> of January 2009, and no Form 483 or Warning Letter was issued as a result of the inspection. The inspector wished to stress that the TFS research unit at Karolinska seemed to be of good quality both with respect to the competence of the trial personnel and the facilities in which the studies were being performed. The TFS research unit was thus deemed to fulfill FDA requirements.



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*“Everyone who has experienced an FDA inspection knows the initial stress and adrenalin rush when an inspection is announced. Inspections are important and you want and need everything to be in perfect order for the inspector. In order to ensure that everything was ready for the inspection TFS and KTA put together a focused team and worked together with the sponsor and Quality Assurance to ensure that all study documents were available and filed. In order to prepare the staff we had an FDA-training session which was very informative and beneficial. Everyone involved in the inspection learned a lot, knowledge that we of course will bring with us for future studies”* said Mrs. Eva Lundqvist, Director Academic Alliances at TFS.

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

TFS is a full-service clinical CRO, providing the pharmaceutical, biotechnological, medical device, diagnostic and functional food industries with a wide range of clinical trial services. TFS services cover the whole clinical development programme from early explorative Phase I trials to registration trials in Phases II-III and post marketing surveillance trials in Phase IV. Over 470 highly competent employees dedicated to accuracy and service are working from multiple offices spread throughout 16 countries in Europe, India, Japan and the USA.

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

Karolinska Trial Alliance (KTA) located at the Karolinska University Hospital is a unit that supports research around pharmaceuticals, diagnostics and medical devices. KTA’s phase I unit conducts early clinical trials together with TFS Trial Form Support International AB in a private public partnership (PPA).



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