Celltex Responds to Media Reporting on FDA Visit

Company Pioneering Regenerative Medicine Services Invited FDA to Inspect Lab

HOUSTON, June 27, 2012 /PRNewswire/ -- After an invitation from Celltex Therapeutics Corp., the Food and Drug Administration (FDA) visited the Celltex laboratory for two weeks in April, 2012. The FDA studied Celltex operations in depth in accordance with the "good tissue practices" (GTP) standards, as it routinely does with inspections of facilities such as Celltex which are registered pursuant to 21 CFR Part 1271. In their close-out report given to Celltex on the last day of their visit, the FDA had 14 main observations that it requested Celltex resolve.

Celltex has worked closely with the FDA — both during its visit and since — to provide requested details and documentation to answer its questions. We have resolved many of the FDA observations, and we are working to address the remainder. We have an open line of communication with the FDA and expect to maintain that in our cooperative relationship.

Celltex continues to provide stem cell banking and multiplication services without interruption and has not received any disciplinary action from the FDA.

Celltex's laboratory is currently operated by its licensing partner RNL Bio (dba Human Biostar), with lab technicians and scientists from RNL's Seoul, Korea headquarters. The main issues in the FDA observations arose from a language barrier. RNL scientists extensively document procedures, including validations, but they are recorded in Korean and were not able to be provided in English to FDA during its visit. Since the FDA's visit, the RNL procedures and other documents have been translated to English by an independent, professional translation service, and supplied to the agency. We are confident that the translated documents demonstrate the thoroughly validated scientific process that underpins the Celltex laboratory operations.

Celltex continues to strengthen its documentation and laboratory operations and has added to its staff Celltex personnel experienced in U.S. FDA compliance.

Some media reports and social media chatter suggest that Celltex is somehow acting illegally or providing unapproved treatments. These statements are inaccurate. Celltex is registered with the FDA as a facility that multiplies human cells and cellular products (HCT/Ps); in particular, adult mesenchymal stem cells. The FDA does not require a company to obtain FDA approval prior to distribution of its HCT/Ps. 21 CFR Part 1271. In addition, the FDA does not issue "licenses," so any reference that Celltex provides "unlicensed" procedures is inaccurate. Celltex's process for reproducing adult mesenchymal stem cells is legal, and there is no requirement that the cells be approved or licensed.

Celltex ensures that all of the cells it provides to physicians for therapeutic use are sterile, viable, intact mesenchymal stem cells. RNL's quality control scientists examine each patient's cells for their integrity and sterility prior to release, documenting those findings. Celltex and its partner RNL Bio process stem cells in a safe, sterile laboratory with procedures that ensure cell viability and integrity.

Celltex has taken the initiative to make autologous adult mesenchymal stem cell multiplication services available to physicians outside of academia for use with their patients. Celltex firmly believes in the great therapeutic potential for autologous mesenchymal stem cell multiplication services in regenerative medicine.

For more information, contact Celltex, 713-590-1000.

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