Sequestration Funding Cuts Jeopardize TB Clinical Drug Trials

ATS 2013, PHILADELPHIA – Innovative and potentially game-changing clinical trials to develop new drug regimens to prevent and treat tuberculosis (TB), the second leading global infectious disease killer, are in jeopardy due to federal “sequestration” funding cuts. New CDC-funded TB treatment study findings were announced today in Philadelphia at the American Thoracic Society annual meeting where, paradoxically, CDC scientists and participants were unable to attend. CDC TB experts were almost entirely absent from the ATS International Conference this year, also due to the implementation of federal budget sequestration. The new research findings unveiled by the Tuberculosis Clinical Trials Consortium (TBTC) at the ATS Conference today show a promising way forward for shortening the current six month treatment regimen down to a three to four month regimen.

The TBTC is one of the leading TB clinical research collaboratives in the world. Funded by the CDC through the Division of TB Elimination, the TBTC has conducted groundbreaking trials that have had a direct impact on the treatment of TB. In 2011, TBTC studies produced the first new drug regimen in decades for preventing TB infection from developing into active disease, reducing the regimen from a nine month daily course to a three month weekly course. This new regimen is the shortest and safest treatment for latent TB infection to date and has the potential to significantly improve treatment success rates of latent TB infection.

A TBTC investigator, Dr. Susan Dorman of Johns Hopkins University, presented important results demonstrating that high-dose rifapentine, when given together with other anti-TB drugs, was highly effective in converting sputum cultures to negative within two months. Based on these results, the TBTC is poised to launch a phase 3 trial in 2014 of a new treatment regimen, that if proven effective, would cut down the treatment for active TB disease from six months to just three or four months total. A shorter, safer, better-tolerated regimen would be transformative to TB control globally and would save many lives worldwide, but this clinical trial will not move forward unless funding is restored in FY2014.

Dr. Neil Schluger, Professor of Medicine, Epidemiology, and Environmental Health Science at Columbia University and Steering Committee Chairman of the TBTC, said, “if the plans for budget cuts of 25-31% go into effect this summer, the important work of the Consortium will be drastically curtailed.” He continued, “the funding reductions that the Consortium is facing over the next six months will halt two or three planned clinical trials in their tracks, and will slow down other important ongoing research, costing the US more money in the long run and countless delays in progress towards developing new TB treatments, which are urgently need to halt the global TB pandemic.”

Dr. Carol Dukes-Hamilton, co-chair of the TBTC and Professor of Infectious Diseases at Duke University, added, “funding cuts have already resulted in the closing of three long-term TB trial enrollment sites,” including her site in North Carolina. “We are deeply concerned that if the cuts proposed for the remainder of FY2013 go into effect, the research efforts of the Consortium will be damaged beyond repair.”