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MEDIA CONTACT:
Farzana Azam
Senior Director, Global Marketing
+1 (647) 261 3628
media.inquiries@celerion.com

Celerion adds USP <797>-compliant Clean Room, enabling efficient execution of microtracer and microdosing studies.

The addition of the USP <797> Clean Room to Celerion's Phase I core capabilities, enables sterile extemporaneous compounding in-house for microtracer studies. Clients benefit by accessing quality data earlier in drug development process.

(Lincoln, NE; March 02, 2011) – Celerion, the premier provider of innovative early stage drug development solutions, announces the completion of a Clean Room and pharmacist certification to comply with USP <797> guidelines. This enables in-house preparation for microtracer studies providing an alternative to the requirement for GMP manufacturing of the IV solution. The sterile preparation and administration allows clients a one-stop option thereby saving time and money.

A large number of bioavailability and First-in-Human (FIH) studies require sterile compounding. The USP <797> Clean Room allows for all types of complex extemporaneous compounding for low, medium and high risk investigational compounds. This allows Celerion to take a client's API, develop customized dosing and compounding that enable very selective dose levels to be administered. This solution combined with our experience in delivering early stage adaptive trial designed studies will allow clients to reach clinical proof-of-concept (PoC) faster.

"The addition of the USP <797> Clean Room continues to demonstrate Celerion's commitment to implement innovative solutions to generate critical data to enable decisions in drug development to be made earlier" said Phil Bach, Vice President of Clinical Research at Celerion. "The clean room when combined with our Lincoln, Nebraska, facility's radiolabel license, allows Celerion to offer execution of Phase 0, microtracer and microdosing studies producing data typically not available until later in drug development."

The unique design of this Clean Room includes three separate areas, one ante-room that serves two individual clean rooms. One clean room is a dedicated microtracer area which contains a Class A2 Biological Safety Cabinet for radiolabeled microtracer compounding. An additional clean room contains a laminar flow hood for traditional IV compounding. Both clean rooms are ISO 7, attached to an ISO 8 ante-room and are used for sterile compounding.

About Celerion

Celerion is the premier provider of innovative early stage clinical research solutions. Formed through the acquisition of the early stage development operations of MDS Pharma Services, Celerion has a full spectrum of resources to meet the needs of the pharmaceutical, biotechnology and generic industries for Phase 0 through IIa proof-of-concept studies. From facilities strategically located around the world, advanced scientific and technological expertise is applied to clinical research (Phases 0, I and IIa, NDA-enabling clinical pharmacology, ADME), clinical pharmacology sciences, bioanalytical services (discovery through late stage), and drug development services. For more information, visit www.celerion.com.