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## <u>Cell>Point Announces Agreement with the FDA on a Special Protocol</u> <u>Assessment for the Phase 3 Technetium-99m-EC-G</u> <u>Lung Cancer Imaging Trial</u>

**CENTENNIAL, Colo., March 12, 2012**—Cell>Point, L.L.C , announced today that it received a letter from the U.S. Food and Drug Administration (FDA) indicating that agreement has been reached pursuant to a Special Protocol Assessment regarding the design of its Phase 3 pivotal clinical study in lung cancer. The Phase 3 study will be conducted to assess Cell>Point's molecular imaging product, technetium-99m EC-G (EthylenediCysteine-n-acetyl-Glucosamine), for the diagnosis and staging of lung cancer. Patients who receive technetium-99m-EC-G are imaged using a Single Photon Emission Computed Tomography (SPECT) camera, commonly referred to as a gamma camera.

"We are extremely pleased to receive agreement from the FDA for this Special Protocol Assessment since it provides us confidence that our study design and statistical analysis plan has the potential to provide trial results that can lead to the approvability or our product," said David Rollo, M.D., Ph.D, President of Cell>Point.

Patients in the study will each receive SPECT/CT scans with technetium-99m-EC-G, and PET/CT scans with fluorine-18- FluoroDeoxyGlucose (18F-FDG). The results will then be independently

evaluated, scored and compared for diagnostic accuracy in diagnosing the presence and location of primary as well as metastatic lesions.

## **About Special Protocol Assessments**

A Special Protocol Assessment (SPA) is a binding declaration between the trial sponsor and the FDA indicating that the Phase 3 clinical study design, endpoints, and statistical analysis are acceptable to support regulatory approval of the product. Final marketing approval depends on study results and an evaluation of the benefit/risk profile.

## About Technetium-99m EC-G

Technetium-99m EC-G is a target specific radiopharmaceutical developed for use with SPECT cameras which are widely available throughout the world. In addition to imaging applications in oncology, Cell>Point is preparing to start a Phase 2 clinical study to evaluate technetium-99m-EC-G in imaging patients with coronary artery disease. One of the study objectives is to compare the clinical results of giving technetium-99m-EC-G to patients "at rest" against the results of a myocardial perfusion imaging "stress and rest" study performed on the same patients. Results from the Phase 1b study were very encouraging.

## About Cell>Point

Cell>Point is a commercialization-stage biopharmaceutical company developing universal molecular imaging agents and molecular therapeutics for the diagnosis, treatment and treatment monitoring of cancer, heart, and other diseases. Cell>Point has five drug-technology platforms under exclusive license from The University of Texas M.D. Anderson Cancer Center, a world leader in cancer research and care. Information on Cell>Point's drug candidates and licenses, recent press releases, and patents and patent filings can be obtained through its website at <u>www.cellpointweb.com</u>. The company is headquartered in Centennial, Colo., and has additional offices in San Francisco and Houston.

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