



OncoCyte Corporation Completes Initial Enrollment of Clinical Study of Urine-Based Bladder Cancer Diagnostic

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-OncoCyte's Proprietary Diagnostic Markers Tested on Patient Samples Collected by Pathologists at Leading US Medical Institution-

ALAMEDA, Calif.–(BUSINESS WIRE)–Dec. 15, 2014– BioTime, Inc. (NYSE MKT: BTX) and its subsidiary OncoCyte Corporation today announced that OncoCyte has completed enrollment in the initial clinical study of its urine-based bladder cancer diagnostic test. The study, which involved 100 patients, was conducted in collaboration with investigators in the Department of Pathology, Division of Cytopathology, at a leading medical institution with an international reputation for excellence and discovery. Initial results of the study have been submitted for presentation at a large upcoming cancer society meeting; eventual publication of the final results in a peer-reviewed clinical journal is also anticipated.

The goal of this clinical study was to assess the performance of OncoCyte's proprietary diagnostic technology in detecting the most common type of bladder cancer; namely, urothelial carcinoma (UC) (previously designated transitional cell carcinoma). Study investigators collected urine samples from patients undergoing urine cytology for the diagnosis of either primary or recurrent bladder cancer. Patient urine samples were assessed microscopically for the presence of cancer cells using the current standard-of-care method of cytopathology; in parallel, OncoCyte scientists analyzed the remaining portion of the urine samples for gene expression, including expression of OncoCyte's proprietary *PanC-Dx*TM markers. In some cases, the quality of the residual urine sample provided to OncoCyte did not allow for a valid analysis; in these cases additional replacement samples will be provided. A statistical analysis was performed and a panel of markers that discriminates UC from non-cancerous conditions was identified. The ability of the markers tested in the studies to determine the absence, presence, or progression of UC in patients will determine the specific nature of the bladder cancer test to be developed and the regulatory approval pathway that OncoCyte will pursue.

"There is a large and growing need for more sensitive, cost-effective, and less invasive methods to detect and monitor cancer in humans, particularly in bladder cancer. The completion of enrollment in this clinical study represents a major milestone in our efforts to develop a urine-based bladder cancer diagnostic. Importantly, the study not only was completed in the projected time frame but also the results to date have exceeded our expectations in terms of our diagnostic test performance. We are currently validating the results of this study in a larger prospective trial that will enroll up to 1400 patients. The larger study was initiated in July and has already enrolled over 300 patients at four sites; we are currently recruiting additional sites and plan on completing the study in 2015," said Joseph Wagner, PhD, OncoCyte's Chief Executive Officer.

Urothelial carcinoma (UC) constitutes more than 90% of bladder cancers in the Americas, Europe and Asia. Although most patients with bladder cancer can be treated with organ-sparing chemotherapy, UC has a relapse rate of nearly 70% and can progress to invasive, metastatic, and lethal disease. The regular surveillance and treatment of recurrent disease from the time of diagnosis for the remainder of a patient's life makes UC the most costly malignancy on a per patient basis. The problem is amplified because the two standard methods for surveillance – microscopic assessment of urinary cytology specimens and bladder cystoscopy– possess significant limitations with respect to both performance and cost. Although urine cytology does have a very high positive predictive value (low false positive rate), it has a low negative predictive value and a high indeterminate rate. Patients who have indeterminate urine cytology results commonly undergo cystoscopy, which is painful, time consuming, costly, and unnecessary in many cases since a neoplasm is often not present. In UC, as in virtually all other cancers, earlier and more accurate diagnosis, including diagnosis of disease recurrence, is generally associated with better outcomes and lower cost.

Overall markets for bladder cancer diagnostics are large and growing. Based on National Cancer Institute statistics released in 2012, it was estimated that in 2013 over 72,000 new cases of bladder cancer would occur in the United States and a total of over 550,000 men and women alive would have a history of bladder cancer and be subject to recurrence surveillance testing using cystoscopy or urine cytology. Given this large and growing clinical population, as well as the limitations of current diagnostic methods, a non-invasive and effective bladder cancer screening test could have a significant market opportunity.

About OncoCyte Corporation

OncoCyte, a majority-owned subsidiary of BioTime, Inc., is developing novel products for the diagnosis and treatment of cancer in order to improve the quality and length of life of cancer patients. Based on large unmet need, market size, and data generated thus far from patient sample screening, OncoCyte is initially focusing its efforts on developing *PanC-Dx*[™] diagnostic products for use in detecting breast, bladder, and lung cancers. *PanC-Dx*[™] is a class of non-invasive cancer diagnostics based on a proprietary set of cancer markers characterized, in part, by broad gene expression patterns in numerous cancer types. The *PanC-Dx*[™] biomarkers were discovered as a result of ongoing research within OncoCyte and BioTime on the gene expression patterns associated with embryonic development. This research has demonstrated that many of the same genes associated with normal growth during embryonic development are abnormally reactivated by cancer cells. These genes regulate such diverse processes as cell proliferation, cell migration and blood vessel formation. Many of these genes have not been previously associated with cancer. Moreover, expression of a large subset of these genes is conserved across numerous cancer types (e.g. cancers of the breast, colon, ovaries, etc.), suggesting these genes may control fundamental processes during cancer growth and progression. In addition to their potential value in developing diagnostic biomarkers, an understanding of the pattern of expression of these genes may also enable the development of powerful new cancer therapeutics that target rapidly proliferating cancer cells.

About BioTime

BioTime is a biotechnology company engaged in research and product development in the field of regenerative medicine. Regenerative medicine refers to therapies based on stem cell technology that are designed to rebuild cell and tissue function lost due to degenerative disease or injury. BioTime's focus is on pluripotent stem cell technology based on human embryonic stem ("hES") cells and induced pluripotent stem ("iPS") cells. hES and iPS cells provide a means of manufacturing every cell type in the human body and therefore show considerable promise for the development of a number of new therapeutic products. BioTime's therapeutic and research products include a wide array of proprietary *PureStem*[®] progenitors, *HyStem*[®] hydrogels, culture media, and differentiation kits. *Renovia*[™] (a

HyStem[®] product), is now in a pivotal trial in Europe as a biocompatible, implantable hyaluronan and collagen-based matrix for cell delivery in the treatment of HIV-related lipoatrophy. In addition, BioTime has developed *Hextend*[®], a blood plasma volume expander for use in surgery, emergency trauma treatment and other applications. *Hextend*[®] is manufactured and distributed in the U.S. by Hospira, Inc. and in South Korea by CJ HealthCare Corporation, under exclusive licensing agreements.

BioTime is also developing stem cell and other products for research, therapeutic, and diagnostic use through its subsidiaries:

- [Asterias Biotherapeutics](#), Inc. is developing pluripotent stem-cell based therapies in neurology and oncology, including AST-OPC1 oligodendrocyte progenitor cells in spinal cord injury, multiple sclerosis and stroke, and AST-VAC2, an allogeneic dendritic cell-based cancer vaccine. Asterias Series A common stock is traded on the NYSE MKT under the symbol AST.
- BioTime Asia, Ltd., a Hong Kong company, may offer and sell products for research use for BioTime's ESI BIO Division.
- [Cell Cure Neurosciences](#) Ltd. is an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological disorders. *OpRegen*[™] is currently in a Phase I/IIa clinical trial for the treatment of the dry-form of age-related macular degeneration.
- [ESI BIO](#) is the research and product marketing division of BioTime, providing stem cell researchers with products and technologies to enable them to translate their work into the clinic, including *PureStem*[®] progenitors and *HyStem*[®] hydrogels.
- [LifeMap Sciences](#), Inc. markets, sells, and distributes *GeneCards*[®], the leading human gene database, as part of an integrated database suite that also includes the *LifeMap Discovery*[®] database of embryonic development, stem cell research, and regenerative medicine, and *MalaCards*, the human disease database.
- [LifeMap Solutions](#), Inc. is a subsidiary of LifeMap Sciences focused on developing mobile health (mHealth) products.
- [OncoCyte](#) Corporation is developing products and technologies to diagnose and treat cancer, including *PanC-Dx*[™], with four clinical studies currently underway.
- [OrthoCyte](#) Corporation is developing therapies to treat orthopedic disorders, diseases and injuries.
- [ReCyte Therapeutics](#), Inc. is developing therapies to treat a variety of cardiovascular and related ischemic disorders, as well as products for research using cell reprogramming technology.

BioTime common stock is traded on the NYSE MKT under the symbol BTX. For more information, please visit www.biotimeinc.com or connect with the company on [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#), and [Google+](#).

Forward-Looking Statements

Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for BioTime and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the business of BioTime

and its subsidiaries, particularly those mentioned in the cautionary statements found in BioTime's Securities and Exchange Commission filings. BioTime disclaims any intent or obligation to update these forward-looking statements.

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