

# Actinium Announces Webinar to Discuss SIERRA Trial -- Upcoming Pivotal, Phase 3 Clinical Study for Iomab-B

NEW YORK, NY -- (Marketwired) -- 04/06/16 --

- SIERRA S tudy of I omab-B in E Iderly R elapsed or R efractory A ML
- Webinar scheduled for Tuesday, April 26, 2016 at 8:30 am ET

Actinium Pharmaceuticals, Inc. (NYSE MKT: ATNM) ("Actinium" or the "Company"), a biopharmaceutical Company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers, announced today that the Company will host a webinar to discuss the SIERRA trial, the Company's upcoming pivotal Phase 3 clinical trial for Iomab-B. The webinar will provide an overview of the use of hematopoietic stem cell transplant (HSCT), known as a bone marrow transplant (BMT) in relapsed or refractory Acute Myeloid Leukemia (AML) patients over the age of 55, an introduction to the SIERRA trial and anticipated timelines and milestones for the trial. Participant information for the webinar is as follows:

Date: April 26, 2016

Time: 8:30 am EST

Link: <a href="https://event.webcasts.com/starthere.jsp?ei=1098822">https://event.webcasts.com/starthere.jsp?ei=1098822</a>

# Speakers:

- Sandesh Seth, Executive Chairman, Actinium Pharmaceuticals
- Frank Smith, M.D., FAAP, FACP, Vice President, Medical Affairs, Medpace
- Felix Garzon, M.D., Ph.D., Senior Vice President, Head of Clinical Development, Actinium Pharmaceuticals

Felix Garzon, M.D., Ph.D., Actinium's Head of Clinical Development, Senior Vice President said, "Since FDA's acceptance of the IND for Iomab-B in December, we have successfully completed many of the steps necessary to commence the SIERRA trial including expanding our clinical operations team, securing Medpace as our CRO partner and actively engaging with major transplant centers as potential clinical trial sites. I am excited by our progress to date and am confident in our ability to successfully complete this trial efficiently and effectively."

Sandesh Seth, Executive Chairman of Actinium Pharmaceuticals stated, "The upcoming SIERRA trial is the result of years of hard work from the team at Actinium and from our collaboration with the Fred Hutchinson Cancer Research Center, and its clinicians and

researchers. The SIERRA trial represents a landmark event for the world of bone marrow transplant in elderly AML patients and we are intensely committed to the execution of this trial to meet the needs of this underserved patient population who have dismal therapeutic options. We look forward to hosting this webinar as an informational event for patients, physicians, investors and all others that are interested in lomab-B and the SIERRA trial."

## About the SIERRA trial

lomab-B will be used in preparing patients for hematopoietic stem cell transplantation (HSCT), the fastest growing hospital procedure in the U.S. The Company established an agreement with the FDA that the path to a Biologics License Application (BLA) submission could include a single, pivotal Phase 3 clinical study, if it is successful. The population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed Acute Myeloid Leukemia (AML) patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months and the secondary endpoint will be overall survival at one year. There are currently no effective treatments approved by the FDA for AML in this patient population and there is no defined standard of care. Iomab-B has completed several physician sponsored clinical trials examining its potential as a conditioning regimen prior to HSCT in various blood cancers, including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies in almost 300 patients have demonstrated the potential of lomab-B to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing post-transplant complications; and showing a clear survival benefit including curative potential.

#### About Iomab-B

lomab-B is a radioimmunoconjugate consisting of BC8, a novel murine monoclonal antibody, and iodine-131 radioisotope. BC8 has been developed by the Fred Hutchinson Cancer Research Center to target CD45, a pan-leukocytic antigen widely expressed on white blood cells. This antigen makes BC8 potentially useful in targeting white blood cells in preparation for hematopoietic stem cell transplantation in a number of blood cancer indications, including acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), Hodgkin's disease (HD), Non-Hodgkin lymphomas (NHL) and multiple myeloma (MM). When labeled with radioactive isotopes, BC8 carries radioactivity directly to the site of cancerous growth and bone marrow while avoiding effects of radiation on most healthy tissues.

## About Dr. Franklin O. Smith, III, MD

Dr. Frank Smith received his MD degree from the University of South Carolina School of Medicine and completed post-doctoral training in pediatrics at the University of Florida and fellowship training in pediatric hematology/oncology at the University of Washington and the Fred Hutchinson Cancer Research Center. Prior to joining Medpace, Dr. Smith was instrumental in helping build two prestigious stem cell transplant programs at both the University of Cincinnati Cancer Institute and at Riley Hospital for Children at Indiana University. He also was the Director, Division of Hematology/Oncology at Cincinnati Children's Hospital Medical Center and Vice-Chair of the Children's Oncology Group. He is

an adjunct Professor of Medicine and Pediatrics at the University of Cincinnati College of Medicine, and has had over 150 scientific manuscripts published in medical and scientific journals. Dr. Smith is active with various national and international committees and societies in the field of research and clinical care, including serving on the local and national boards of the Leukemia and Lymphoma Society, Chair of the Board of Managers for the Foundation for the Accreditation of Cellular Therapy (FACT) Consulting Services, faculty for the ASCO/AACR Clinical Cancer Research Workshop and as a member of the NCI's Central Institutional Review Board. Dr. Smith has also served on ad-hoc committees for the FDA including Special Emphasis Panels for Orphan Products Development.

## **About Actinium Pharmaceuticals**

Actinium Pharmaceuticals, Inc. (<a href="www.actiniumpharma.com">www.actiniumpharma.com</a>) is a New York-based biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers. Actinium's targeted radiotherapy products are based on its proprietary delivery platform for the therapeutic utilization of alpha-emitting actinium-225 and bismuth-213 and certain beta emitting radiopharmaceuticals in conjunction with monoclonal antibodies. The Company's lead radiopharmaceutical product candidate lomab-B is designed to be used, upon approval, in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. The Company plans to conduct a single, pivotal, multicenter Phase 3 clinical study of lomab-B in refractory and relapsed AML patients over the age of 55 with a primary endpoint of durable complete remission. The Company's second product candidate, Actimab-A, is continuing its clinical development in a Phase 1/2 trial for newly diagnosed AML patients over the age of 60 in a single-arm multicenter trial.

# Forward-Looking Statements for Actinium Pharmaceuticals, Inc.

This news release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause actual results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Actinium Pharmaceuticals undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

Contact:
Steve O'Loughlin
Vice President, Finance and Corporate Development
Actinium Pharmaceuticals, Inc.
soloughlin@actiniumpharma.com

Source: Actinium Pharmaceuticals