

February 7, 2017



# Actinium Pharmaceuticals Announces Pipeline Expansion with Initiation of Clinical Trial of Actimab-M in Multiple Myeloma

- *Phase 1 trial will evaluate Actimab-M in treating patients with multiple myeloma who are unresponsive to currently available therapies*
- *Clinical trial initiated at Texas Oncology - Baylor Charles A. Sammons Cancer Center in Dallas, TX to be conducted by Principal Investigator and Trial Sponsor, Dr. Yair Levy*
- *Clinical pipeline now includes lomab-B pivotal Phase 3 trial, Actimab-A Phase 2 trial and Actimab-M Phase 1 trial*

NEW YORK, Feb. 07, 2017 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE MKT:ATNM) ("Actinium" or "the Company"), a biopharmaceutical company developing innovative targeted therapies for cancers lacking effective treatment options, announced today that a Phase 1 clinical trial studying Actimab-M in multiple myeloma has been initiated. Actimab-M is comprised of the CD-33 targeting monoclonal antibody HuM-195 coupled to the alpha-particle emitter actinium 225. CD33 is an antigen found on hematopoietic cells in certain blood cancers. It is commonly associated with myeloid malignancies including AML, but recent research has shown that CD33 can also be found on malignant cells of approximately 25%-35% of all multiple myeloma patients. Furthermore, the expression of this marker increases in relapsed and refractory myeloma. In addition, it predicts for a very aggressive course of disease. This makes CD33 a potential target for the treatment of this usually fatal disease. Although treatable, multiple myeloma is currently not considered curable and almost all patients eventually relapse or become refractory to available treatments as their condition progresses. In this new trial, Actimab-M will be used in patients who have progressing disease after 3 prior multiple myeloma treatment regimens or are refractory to QUAD (Cafzilomib, Lenalidomide, Pomalidomide, Dexamethason).

"I am very excited to lead in the development of this novel and promising approach," said Dr. M. Yair Levy of Texas Oncology - Baylor Charles A. Sammons Cancer Center. "Relapsed and refractory multiple myeloma is an area of high unmet medical need that we hope to address with Actimab-M. Myeloma is a very radiosensitive cancer, and does not present with the neutropenia and thrombocytopenia of AML. I would expect tolerability of this treatment to be better in this disease. Based on my previous experience with Actimab-A in AML and my research in the area of multiple myeloma, I believe that this targeted treatment could prove efficacious and be a part of our growing armamentarium against this disease."

Sandesh Seth, Executive Chairman of Actinium Pharmaceuticals said, "We are incredibly excited to see the initiation of this trial for Actimab-M in multiple myeloma. Not only does this

mark the beginning of the expansion of our clinical pipeline beyond AML, it also demonstrates the broad applicability of our radioimmunotherapy technologies that we intend to progress into new indications and patient populations. Further, this reinforces Actinium's commitment to developing therapies for patients with unmet needs. We look forward to providing updates as this trial progresses."

### **About Multiple Myeloma**

Multiple Myeloma is a blood cancer characterized by malignant transformation of the type of white blood cells called plasmocytes. These cells accumulate in the bone marrow and eventually lead to serious bone and kidney damage. Multiple Myeloma is the second most commonly diagnosed blood cancer after Non-Hodgkin Lymphoma with estimated about 30,000 new cases per year in the US. Almost 100,000 people in the US currently live with the disease. Average age at diagnosis is 70, and only 2% of cases occur in people younger than 40 years. There is currently no cure for Multiple Myeloma, although a number of drugs have been approved for treatment of the disease. However, most patients eventually stop responding to available treatments, which results in a high unmet medical need for relapsed and refractory forms of the disease.

### **About Actimab-M**

Actimab-M is comprised of the anti-CD33 monoclonal antibody HuM-195 coupled to actinium 225, an alpha-particle emitting radioisotope, and is the same construct of Actinium's Actimab-A, which is currently being studied in a Phase 2 clinical trial in patients newly diagnosed with acute myeloid leukemia (AML) who are over the age of 60. Actimab-A is being studied in AML at fractionated doses of 2.0  $\mu\text{Ci}/\text{Kg}$  administered via infusion on day 1 and day 7 as a single cycle while Actimab-M is being studied in multiple myeloma as a single infusion up to 1.0  $\mu\text{Ci}/\text{Kg}$  for up to 8 cycles not to exceed 4.0  $\mu\text{Ci}/\text{Kg}$  total per patient. The Phase 1 trial for Actimab-M is a multicenter, open label, dose-escalation study. Patients will be administered a starting dose level of 0.5  $\mu\text{Ci}/\text{Kg}$  of Actimab-M via infusion on day 1 of each cycle for up to 8 cycles with each cycle lasting 42 days. If this dose level is deemed safe, a second dose level of 1.0  $\mu\text{Ci}/\text{kg}$  will be explored for up to 4 cycles also of 42 days per cycle. Total dose received per patient is not to exceed 4.0  $\mu\text{Ci}/\text{kg}$ . In the event of dose limiting toxicities (DLTs) at the 0.5  $\mu\text{Ci}/\text{Kg}$  dose level, a dose level of 0.25  $\mu\text{Ci}/\text{Kg}$  will be explored. The Phase 1 trial will estimate maximum tolerated dose (MTD), assess adverse events, measure response rates (objective response rate, complete response rate, stringent complete response rate, very good partial response rate and partial response rate) as well as progression free survival (PFS) and overall survival (OS).

### **About Actinium Pharmaceuticals, Inc.**

Actinium Pharmaceuticals, Inc. is a biopharmaceutical company developing innovative targeted therapies for patients with cancers lacking effective treatment options. Actinium's proprietary platform utilizes monoclonal antibodies to deliver radioisotopes directly to cells of interest in order to kill those cells safely and effectively. The Company's lead product candidate lomab-B is designed to be used, upon approval, in preparing patients for a hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. A bone marrow transplant is often the only potential cure for patients with blood-borne cancers but the current standard preparation for a transplant requires chemotherapy and/or total body irradiation that result in significant toxicities. Actinium believes lomab-B will enable a faster

and less toxic preparation of patients seeking a bone marrow transplant, leading to increased transplant success and survival rates. The Company is currently conducting a single pivotal 150-patient, multicenter Phase 3 clinical study of lomab-B in patients with relapsed or refractory acute myeloid leukemia (AML) age 55 and older. The Company's second product candidate, Actimab-A, is currently in a multicenter open-label, 53-patient Phase 2 trial for patients newly diagnosed with AML age 60 and over. Actimab-A is being developed to induce remissions in elderly patients with AML who lack effective treatment options and often cannot tolerate the toxicities of standard frontline therapies. In addition, Actinium is developing Actimab-M, which is being studied in patients with relapsed or refractory multiple myeloma in a Phase 1 clinical trial. Actinium is also utilizing its alpha-particle immunotherapy (APIT) technology platform to generate new drug candidates based on antibodies linked to the element Actinium-225 that are directed at various cancers that are blood-borne or form solid tumors. Actinium Pharmaceuticals is based in New York, NY. To learn more about Actinium Pharmaceuticals, please visit [www.actiniumpharma.com](http://www.actiniumpharma.com) and to follow @ActiniumPharma on Twitter please visit, [www.twitter.com/actiniumpharma](http://www.twitter.com/actiniumpharma).

### **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.

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Source: Actinium Pharmaceuticals