November 22, 2016

Actinium Issues Letter to Shareholders Highlighting 2016 Accomplishments and Anticipated Milestones for 2017

NEW YORK, Nov. 22, 2016 (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 it has issued a letter to shareholders highlighting the Company's accomplishments in 2016 and anticipated milestones for 2017.

Key Accomplishments To-Date in 2016

Iomab-B Pivotal Phase 3 Trial Initiated, Significant and Growing Support from Major Transplant Hospitals, Orphan Drug Protection Awarded and Process for EU Access Started

- The Phase 3 pivotal trial dubbed the SIERRA (**S**tudy of **I**omab-B in **E**lderly **R**elapsed or **R**efractory **A**ML) trial for Iomab-B was initiated in 1H:2016, as forecasted, representing a major step forward for this program given the manufacturing issues that were a key focus in 2015.
- Significant enthusiasm for Iomab-B and the SIERRA trial was seen at our Investigator Meeting in July with continued participation interest post-meeting from most of the leading bone marrow transplant (BMT) centers.
- Orphan Drug Designation awarded for Iomab-B in the US and the EU with potential regulatory, financial and marketing incentives.
- Initiated pursuit of Scientific Advice for Iomab-B from the European Medicines Agency (EMA) to explore regulatory pathway in the EU and awarded preferential Small and Medium-Sized Enterprise (SME) status providing enhanced support from regulators.
- Expected prominent position in major peer reviewed scientific publication and outreach program at the American Society of Hematology (ASH) annual meeting will continue to drive interest for Iomab-B and the SIERRA trial.

Promising Phase 1 Trial Results for Actimab-A Sets Stage for Ongoing Phase 2 Clinical Trial to Yield Potentially Best in CD33 Class Results

- Results from an analysis of the two Actimab-A Phase I trials in our HuM195-Alpha program showed that Actimab-A was well tolerated amongst patients who have few treatment options due to the toxicity of chemotherapy and also had promising efficacy.
- A key discovery made while analyzing these trials was that patients with high levels of immature white blood cells or Peripheral Blasts (PBs) had lower treatment response rates than those with lower PB's. This finding gave rise to the PB Burden Hypothesis which postulates that PB levels are predictive of, and inversely correlated with patient

responses to Actimab-A.
- The ongoing Phase 2 trial stipulates low PB burden below a key threshold as an inclusion criteria with use of hydroxyurea mandated to lower PB burden where necessary in order to maximize the addressable patient population.
- Importantly, the Phase 2 PB burden threshold corresponds to a response rate of fifty percent at equivalent dose levels in the Phase I trials. If these results are replicated in the ongoing Phase 2 they will imply that Actimab-A with its benign safety profile and relatively simple regimen and route of administration is a best in class treatment compared to other CD33 programs.

Regulatory and intellectual property related activity, strategic hiring sets stage for international expansion and growth

- Activity related to strengthening the intellectual property remains robust with key patents being filed and notices of allowance being received this year for Iomab-B, Actimab-A and the platform.
- Orphan drug designation for Iomab-B in the U.S. and EU was achieved this year as mentioned earlier. Pursuit of orphan designation in the EU for Actimab-A is expected imminently.
- An independent analysis indicates the EU market for Iomab-B is larger than the U.S. market with a favorable reimbursement outlook and the company has begun exploring regulatory approval strategies.
- Key managerial hires were made in the supply chain, quality control and clinical development areas to support the expanded clinical development and pipeline expansion activity expected going forward.

Positive Outlook for 2017 and Beyond

- Efficiently execute on the pivotal Phase 3 SIERRA trial to reach the first independent Data Monitoring Committee (DMC) report at 25% of enrollment by 1H:2017, 50% and 75% in 2H:2017 and maintain the pace of enrollment to enable topline results the following year.
- Report interim data from Phase 2 trial for Actimab-A by mid-2017 and explore the regulatory pathway for a pivotal trial based on this data.
- Complete enrollment of the Phase 2 trial by end of 2017 and report top line data results.
- Actively explore strategic partnership, licensing and collaborations as appropriate.
- Continue to expand our clinical development, regulatory and supply chain teams to support our continued growth and begin to explore early commercial efforts.
- Initiate additional clinical programs with the first trial expected to begin in 2017 and the second trial expected to begin in 2018.

The full letter to shareholders can be viewed and downloaded through the following link: *http://ir.actiniumpharma.com/shareholder-letters*.

Sandesh Seth, Executive Chairman of Actinium said, “2016 has been a key transitional year for the Company as Iomab-B began the pivotal Phase 3 SIERRA trial and Actimab-A began a Phase 2 trial underpinned by promising Phase 1 results. In addition, we focused on building a foundation for the future with key hires, expansion of our intellectual property portfolio, execution of key regulatory pathways and by bolstering our balance sheet. We

look ahead to 2017 with great excitement as we expect to have data for both of our clinical trials which we believe will validate their potential and serve to unlock value."

About Actinium Pharmaceuticals

Actinium Pharmaceuticals, Inc. (www.actiniumpharma.com) is a New York-based biopharmaceutical company developing innovative targeted therapies for 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 Iomab-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 high-dose chemotherapy and/or total body irradiation that result in significant toxicities. Actinium believes Iomab-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 Iomab-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. 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.

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