

March 19, 2019



Actinium Reports Fourth Quarter and Year-End 2018 Financial Results and Provides Corporate Highlights

NEW YORK, March 19, 2019 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) reported its financial results for the fourth quarter and year ended December 31, 2018 as well as provided corporate and operational updates on clinical trials, research and development, recent hires, and intellectual property.

Company Highlights:

- Presented interim Phase 3 SIERRA trial data at the 2018 ASH and 2019 TCT Meetings. The SIERRA trial (Study of lomab-B in Elderly Relapsed or Refractory AML) is a 150-patient pivotal Phase 3 multi-center randomized trial that will compare outcomes of patients who receive lomab-B and a BMT or Bone Marrow Transplant to those patients receiving physician's choice of salvage chemotherapy, defined as conventional care, as no standard of care exists for this patient population.

Key highlights from the SIERRA Trial presented at ASH and the TCT Meetings include:

- All patients receiving a therapeutic dose of lomab-B engrafted despite active disease with high blast count (median 30%, or median 45% for crossover patients)
- 15 of 19 (79%) patients in the control arm failed to achieve a complete response
- 67% (10/15) of patients eligible for crossover successfully transplanted after lomab-B treatment
- All patients receiving lomab-B and a BMT (28/28) achieved Donor Chimerism prior to day 100
- 94% of patients initially randomized to receive lomab-B and a BMT (17/18) achieved Full Donor Chimerism > 95% prior to day 100 with 1 patient achieving 65% donor chimerism
- 90% of patients who crossed-over to receive lomab-B and a BMT (9/10), after salvage chemotherapy in the control arm failed to produce a CR or Complete Response, also achieved Full Donor Chimerism > 95% prior to day 100 with 1 patient achieving 86% donor chimerism

The SIERRA trial is currently enrolling patients at 18 sites in the U.S and Canada including many of the leading BMT sites based on volume. Patients with active, relapsed or refractory AML have dismal prognoses and are typically not offered potentially curative transplant as an option, largely because salvage treatments have a limited ability to produce a complete remission, which is necessary prior to

conventional BMT if conventional BMT is to be successful. However, with lomab-B targeted conditioning, a complete remission prior to starting the lomab-B conditioning is not necessary for a successful transplant. lomab-B is an ARC or Antibody Radiation-Conjugate that targets CD45, an antigen expressed on leukemia, lymphoma and immune cells, and delivers Iodine-131 that kills targeted cells via linear energy transfer. Key highlights from the SIERRA Trial presented at ASH and the TCT Meetings include:

- Initiated Actimab-A venetoclax combination trial. This novel Phase 1/2 trial will study Actimab-A in combination with venetoclax for patients with relapsed or refractory AML or Acute Myeloid Leukemia. Venetoclax is a BCL-2 or B-Cell Lymphoma 2 inhibitor, BCL-2 is one of several proteins encoded by the BCL2 gene family, which regulates apoptosis or programmed cell death. Venetoclax is jointly developed and marketed by AbbVie and Genentech and is approved for patients with CLL or Chronic Lymphocytic Leukemia, and SLL or Small Lymphocytic Leukemia and AML with an HMA or hypomethylating agent.

Response rates of relapsed or refractory patients with AML to venetoclax as a single agent have been reported to be 19%. In a recent [webinar](#), Actinium highlighted that one study observed that of 21 relapsed or refractory AML patients that responded to venetoclax and an HMA, 13 (62%) stopped venetoclax treatment with disease progression being the most common reason for discontinuation. The study also observed that no patients with secondary AML responded to treatment with venetoclax and patients with FLT3 mutations had lower response rates.

MCL-1 is another protein encoded by the BCL2 gene family that is also overexpressed in cancers, including relapsed or refractory AML, that prevents apoptosis and promotes resistance to venetoclax, which does not bind to MCL-1. It has been observed that MCL-1 levels can be depleted with radiation, but only external radiation was used in these studies. Actinium is studying the use of targeted internalized radiation from Actimab-A to deplete MCL-1 levels thereby removing the AML cells' resistance mechanism and rendering them more susceptible to venetoclax. Actimab-A is an ARC that delivers internalized radiation from the alpha-particle emitting isotope Ac-225 or Actinium-225 via the CD33 targeting monoclonal antibody lintuzumab

Actinium is conducting this combination study with the goal of offering a therapy to patients that do not respond or stop responding to venetoclax. In addition to the potential to deplete MCL-1 levels, Actimab-A's radiation mechanism of action is agnostic to cytogenetic mutations and has shown to produce responses in patients with secondary AML. Actinium is also planning a Phase 1/2 trial that will study Actimab-A in combination with venetoclax and a hypomethylating agent. This triplet trial will also enroll patients with relapsed or refractory AML and is expected to initiate in the first half of 2019.

- Advanced to second patient cohort in Actimab-A CLAG-M trial. Actinium is also studying Actimab-A in combination with the salvage chemotherapy regimen CLAG-M (cladribine, cytarabine, filgrastim, and mitoxantrone) in patients with relapsed or refractory AML. Chemotherapy and radiation are routinely used in combination

together with a majority of patients receiving external beam radiation. However, patients with AML are not treated with external radiation as the diffuse nature of the disease prohibits therapeutic levels of radiation from being used due to safety and toxicity concerns. Ac-225 is a potent isotope capable of causing lethal double stranded breaks in cell DNA but its energy is limited to a few cell diameters. CD33 is an antigen expressed on the surface of a vast majority of AML cells. This trial is evaluating the effect targeted internalized radiation via Actimab-A will have in combination with CLAG-M on safety and tolerability, response rates, rates of BMT, PFS or progression-free survival, and OS or overall survival.

In the first dose cohort, patients received 0.25 uCi/kg of Actimab-A. This combination trial is designed as a 3+3 dose escalation study. No DLT's or dose limiting toxicities were reported in the first patient cohort. As a result, and per the study protocol, the Institutional Review Board (IRB) at MCW authorized the initiation of the second dosing cohort, in which patients are receiving 0.50 uCi/kg of Actimab-A. Assuming no DLTs are observed in the second cohort, three patients will be treated and the study will progress to the third and final cohort that will study Actimab-A at a dose of 0.75 uCi/kg.

- Advanced to second module of collaborative research program with Astellas Pharma, Inc. (Astellas). The Company's previously announced research collaboration with Astellas is using its AWE or Antibody Warhead Enabling technology platform to conjugate and label select Astellas targeting agents with the potent Ac-225 payload. In January 2019, Actinium announced that it completed the first module of the collaboration and the second module had been initiated. Since launching its AWE Program in November 2017, Actinium has achieved the following milestones:
 - Appointed Dr. Dale Ludwig, a leading antibody therapeutics and antibody conjugate expert, as Chief Scientific Officer
 - Presented positive data at [ASH 2017](#) demonstrating the superior in vitro cell killing properties of Ac-225 labeled daratumumab or Darzalex™, Johnson & Johnson's blockbuster CD38 targeting therapy for multiple myeloma
 - Presented additional positive data from in vivo animal studies at [AACR 2018](#) demonstrating enhanced tumor control and survival with Ac-225 labeled daratumumab
- Significantly strengthened senior leadership team in core areas. Appointed Cynthia Pussinen as Executive Vice President of Technical Operations and Supply Chain. Ms. Pussinen brings 25 years of highly relevant experience to Actinium gained at Pfizer and Ipsen Biosciences, Inc. Most recently, she was Head of Strategic Portfolio Management, Worldwide Research & Development. In this role she led efforts to maximize the value of Pfizer's pre-Proof of Concept portfolio across 6 research units, including driving pipeline decision making, portfolio prioritization and clinical portfolio investment efforts across the R&D organization. Previously, President and General Manager of Ipsen Biosciences, Inc. where she led the operational and strategic directions of this subsidiary company, including maintaining an annual operating budget of more than \$100 million, and managing two sites with more than 220 employees.

Appointed Qing Ling, PhD, DABR to newly created position of Vice President, Head

of Radiation Sciences. This newly created position will drive innovation in line with Actinium's strategic vision related to its AWE technology platform. Dr. Liang will collaborate closely with clinical trial sites and their staffs, regulators and other key stakeholders to help advance and optimize Actinium's clinical ARC programs to deliver the best possible outcomes for patients. Dr. Liang is a Medical Physicist certified by the American Board of Radiology and prior to Actinium was Medical Physicist and Assistant Professor at Fox Chase Cancer Center at Temple University (Philadelphia, PA). Prior to that, she had worked at Mercy Health System (Janesville, WI), Turville Bay MRI & Radiation Oncology (Madison, WI), University of Wisconsin Hospital (Madison, WI), and UW Accredited Dosimetry Calibration Laboratory (Madison, WI).

Appointed Mamata Gokhale, PhD, RAC as Vice President, Global Head of Regulatory Affairs. Dr. Gokhale brings over 20 years of regulatory affairs experience to Actinium that began at the FDA as a reviewer before transitioning to industry where she worked at biotechnology and pharma companies including Amgen, Watson Pharma, Neumedicines Inc. and global Contract Research Organizations including Voisin Consulting Life Sciences and Paraxel International. At Amgen Dr. Gokhale successfully contributed to approvals and expansion of Prolia®, Xgeva®, Vectibix® and Sensipar®. Dr. Gokhale's regulatory experience includes developing regulatory strategies for small molecules, monoclonal antibodies, cell and gene therapies, leading and managing regulatory interactions, requesting orphan drug, breakthrough therapy and fast track designations and pediatric vouchers, resolution of clinical hold issues, developing target product profiles, core data sheets and conducting labeling negotiations.

- Significantly expanded patent portfolio. Through rejuvenated R&D activity Actinium's patent portfolio has increased to a total of 111 issued and pending patents in the U.S. and internationally, which is up from the 75 reported previously. This intellectual property portfolio, contained within 28 patent families, covers key areas of Actinium's business. The estate covers ARC generation, composition of matter, formulations, and methods of administration for solid and liquid cancers as well as radionuclide production including the manufacturing of Ac-225 or Actinium-225. Actinium's recent patent filings pertain to its planned pivotal Actimab-MDS targeted conditioning trial, ARC combination trials of Actimab-A with venetoclax and CLAG-M, as well as its next-generation ARC's resulting from its AWE technology platform. These follow recent patent filings from Actinium related to its lomab-ACT next generation lymphodepletion program for CAR-T and adoptive cell therapies that includes four pending patents and one provisional patent application for cancer and non-malignant diseases. These new filings are in addition to Actinium's broad intellectual property and patent portfolio that cover direct labeling, or conjugation and labeling of a biomolecular targeting agent to a radionuclide warhead, and its development and use as a therapeutic regimen for the treatment of diseases such as cancer. Actinium has patents on the use of the "gold standard" chelator DOTA, an organic compound used to attach, or conjugate, the radionuclide Ac-225 to monoclonal antibodies and any conceivable derivative thereof, as well key patents covering the manufacturing of Ac-225 in a cyclotron. In addition, Actinium extensive know-how and trade secrets in the application of its AWE technology platform to support its existing pipeline and potential collaborations.

- Research and development expenses for the year ended December 31, 2018 declined by \$0.7 million to \$17.0 million compared to \$17.7 million for the year ended December 31, 2017. The decrease was primarily attributable to the recognition of payments received from Astellas, with such payments accounted for as a reduction in research and development expenses, as well as lower expenses related to Actimab-A and lower non-cash stock-based compensation expense.

General and administrative expenses declined by \$2.5 million to \$6.7 million for the year ended December 31, 2018 compared to \$9.2 million for the year ended December 31, 2017, primarily due to lower compensation expense, resulting from lower non-cash stock-based compensation expense during 2018 and one-time charges paid to certain former employees in 2017.

Actinium reported a cash and cash equivalent balance of \$13.6 million as of December 31, 2018. In its Annual Report of Form 10-K which was filed with the Securities and Exchange Commission on March 15, 2018, the Company's audited financial statements contained a going concern explanatory paragraph in the audit opinion from Marcum LLP, its independent registered public accounting firm.

Net loss decreased by \$2.9 million to \$23.7 million for the year ended December 31, 2018 compared to \$26.6 million for the year ended December 31, 2017. The decrease was primarily due to lower general and administrative expenses and research and development expenses.

- Upcoming Conferences

Actinium's management will present at the Oppenheimer & Co. 29th Annual Healthcare Conference, being held March 19-20. The details of Actinium's presentation are as follows:

Presentation Details:

Date: Wednesday, March 20, 2019

Time: 1:35 pm Eastern Time

Room: Consulate

Venue: Westin Grand Central Hotel in New York City

In addition, members of Actinium's executive, clinical, R&D, commercial and CMC teams will be attending the AACR or American Association of Cancer Research Annual Meeting being held March 29 – April 3 at the Georgia World Congress Center in Atlanta, Georgia and the TAT or 11th International Symposium on Targeted-Alpha-Therapy being held April 1 – 4 at the Fairmont Chateau Laurier in Ottawa, Canada.

About Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals Inc. is focused on improving patient access and outcomes to cellular therapies such as BMT or Bone Marrow Transplant and CAR-T with its proprietary, chemotherapy free, targeted conditioning technology. Actinium is the only company with a multi-disease, multi-target, drug development pipeline focused on targeted conditioning. Its targeted conditioning technology is enabled by ARC's or Antibody Radiation-Conjugates that

combine the targeting ability of monoclonal antibodies with the cell killing ability of radioisotopes. Actinium's pipeline of clinical-stage targeted conditioning ARC's are designed to target the antigens CD45 and CD33 for patients with a broad range of hematologic malignancies including AML or Acute Myeloid Leukemia, MDS or Myelodysplastic Syndrome and MM or Multiple Myeloma.

Iomab-B, Actinium's lead targeted conditioning product candidate, is currently enrolling patients in the pivotal Phase 3 SIERRA trial in patients age 55 and older, with active, relapsed or refractory AML. Iomab-B (Iodine-131 apamistamab), combines the anti-CD45 monoclonal antibody labeled with iodine-131 for myeloablation prior to a bone marrow transplant. CD45 is expressed on leukemia, lymphoma and normal immune cells. Iomab-B has been studied in over 300 patients in 10 clinical trials in numerous hematologic diseases. Actinium's Iomab-ACT program is an expansion of its CD45 program that is intended to be a universal, chemotherapy-free solution for targeted lymphodepletion prior to CAR-T. Through targeted lymphodepletion, the Iomab-ACT program is expected to improve CAR-T cell expansion, reduce CAR-T related toxicities and expand patient access to CAR-T treatment and potentially other adoptive cell therapies. Due to its lower payload dose, lymphodepletion with the Iomab-ACT program may be accomplished through a single outpatient infusion. Actinium intends to advance its Iomab-ACT program with CAR-T focused collaborators from academia and industry.

Actinium's pipeline also includes a potentially best-in-class CD33 program with its ARC comprised of the anti-CD33 antibody lintuzumab labeled with the alpha-particle emitter actinium-225. Its CD33 program is currently being studied in multiple Phase 1 clinical trials for targeting conditioning, in combinations and as a therapeutic in multiple diseases and indications including AML, MDS and MM. Notable trials include the planned pivotal trial for Actimab-MDS for targeted conditioning prior to a BMT for patients with high-risk MDS, that is expected to initiate in 2019, and two Actimab-A venetoclax combination trials including the initiated Phase 1 doublet trial and the planned triplet trial with a hypomethylating agent.

Actinium is also developing its proprietary AWE or Antibody Warhead Enabling technology platform which utilizes radioisotopes including iodine-131 and the highly differentiated actinium-225 coupled with antibodies to target a variety of antigens that are expressed in hematological and solid tumor cancers. The AWE technology enables Actinium's internal pipeline and with the radioisotope Actinium-225 is being utilized in a collaborative research partnership with Astellas Pharma, Inc. Actinium's clinical programs and AWE technology platform are covered by a portfolio of over 110 patents covering composition of matter, formulations, methods of use and also methods of manufacturing the radioisotope Actinium-225 in a cyclotron.

More information is available at www.actiniumpharma.com and our Twitter feed @ActiniumPharma, [www.twitter.com/actiniumpharma](https://twitter.com/actiniumpharma).

Forward-Looking Statements for Actinium Pharmaceuticals, Inc.

This press release contains "forward-looking statements" within the meaning of the "safe-harbor" provisions of the private securities litigation reform act of 1995 regarding future events or the future performance of Actinium which Actinium undertakes no obligation to update. These statements are based on management's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially from the

anticipated or estimated future results, including the risks and uncertainties associated with preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of Actinium's products and services, performance of clinical research organizations and other risks detailed from time to time in Actinium's filings with the Securities and Exchange Commission, including without limitation its most recent annual report on Form 10-K for the period ended December 31, 2018, subsequent quarterly reports on Form 10-Q and Form 8-K, each as amended and supplemented from time to time.

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