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## **Actinium Highlights Actimab-A Phase 2 Trial Results in Older Patients with Unfit AML from ASH Annual Meeting Demonstrating Single Agent Activity of the CD33 Antibody Radiation Conjugate**

- Phase 2 trial successfully reached predetermined response criteria in difficult to treat over 60, unfit patient population and demonstrated minimal extramedullary toxicities**
- Actinium's CD33 program development to bifurcate as announced recently with high doses of the ARC or Antibody Radiation Conjugate being advanced for targeted conditioning to leverage myelosuppressive ability and with lower doses in combination trials including with venetoclax in relapsed refractory setting**
- Actinium's lomab-ACT program preclinical data supporting a next generation universal lymphodepletion solution for CAR-T highlighted in ASH program**

NEW YORK, Dec. 3, 2018 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or "the Company"), announced today that updated data from its Phase 2 trial of Actimab-A was highlighted in a poster presentation at the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting. The Actimab-A Phase 2 trial studied the ARC or Antibody Radiation Conjugate Actinium-225 – lintuzumab, which delivers potent alpha particle radiation to CD33 expressing cells, in patients with untreated AML over the age of 60 that are unfit for induction chemotherapy. Patients received fractionated doses of Ac-225 – lintuzumab on days 1 and day 8. The poster presented at ASH highlighted data from a second cohort of 27 patients that received 1.5 µCi/kg/fraction.



Dr. Mark Berger, Actinium's Chief Medical Officer said, "In this difficult to treat patient

population, we are pleased to have observed this level of single-agent activity from Actimab-A with the benefit of minimal extramedullary toxicities. These results strongly support continued development and we have prioritized highly attractive areas that can leverage the strengths of our ARC approach. A major initiative is our Actimab-MDS trial where we have a clear pathway to a pivotal trial established with the FDA for high-risk patients with myelodysplastic syndromes. Another exciting opportunity is via combination trials with agents like venetoclax in the relapsed, refractory AML setting where the apparent synergy of mechanisms can translate to a therapeutic advantage. In addition, we are pursuing other highly-differentiated opportunities for Actimab-A as a single-agent in patients with high unmet needs where the extremely high-potency of an ARC can be used safely at low doses. An example is our novel trial in AML patients with minimal residual disease post-remission."

Overall response rate in this dosing cohort was 22% (6/27) with 3 CRps and 3 CRis. Among responding patients, 2 had adverse cytogenetics and 1 had previous MDS. This data is in addition to previously reported data from 13 patients that were treated at an original dose cohort of 2.0  $\mu$ Ci/kg/fraction where a 69% overall response rate was reported. The dose was lowered to 1.5  $\mu$ Ci/kg/fraction due to myelosuppression lasting longer than 6 weeks, which resulted in a reduction in the incidence of prolonged thrombocytopenia from 46% to 30%.

The median age of patients in this cohort of the Phase 2 trial was 75 (60 -87) with 81% of patients having ECOG performance status of 1 (13/27) or 2 (9/27). Although patients had untreated acute myeloid leukemia (AML), 52% (14/27) of patients had prior hematologic disease with 79% (11/14) having myelodysplastic syndrome (MDS), 14% (2/14) having chronic myelomonocytic leukemia (CMML) and 7% (1/14) having myelofibrosis. A majority of patients had unfavorable cytogenetics with 56% (15/27) having intermediate-risk and 26% (7/27) having high-risk cytogenetics. In addition, patients were evaluated for CD33 splicing polymorphism and responses occurred irrespective of cytogenetic risk category or splicing genotype.

Actinium also highlighted that preliminary preclinical data from its lomab-ACT program was highlighted in the ASH supplemental edition of blood. Actinium's preclinical studies showed a considerable reduction in both lymphocyte and myeloid cell counts, inclusive of immune suppressive regulatory T cells and myeloid derived suppressor cells. Further, the cytoreduction by CD45-RIT was shown to induce the expression of immune homeostatic cytokines including IL-15. The abstract can be accessed here [http://www.bloodjournal.org/content/132/Suppl\\_1/5682](http://www.bloodjournal.org/content/132/Suppl_1/5682).

Sandesh Seth, Actinium's Chairman and CEO said, "Given the recent and increasing competition in AML, we believe the future development pathways selected by our team strategically differentiate Actinium's CD33 program in a manner that can maximize value creation. We have done this by focusing on an area with limited or no competition via Actimab-MDS in targeted conditioning. We have also leveraged our AWE or Antibody Radiation Conjugate technology platform to add a different modality, namely targeted radiation, to other areas of unmet or underserved needs as evidenced by our Actimab-A plus Venetoclax combinations and Actimab-A MRD trials. With our lead asset, lomab-B progressing well in its pivotal trial, the near-pivotal Actimab-MDS program and the lomab-ACT program for lymphodepletion prior to CAR-T, our multi-asset pipeline will enable our company to build a franchise opportunity in targeted conditioning which is almost singular in the industry."

## About Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals Inc. is focused on improving patient access and outcomes to cellular therapies such as bone marrow transplant (BMT) and CAR-T with its proprietary, chemotherapy free or sparing, 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 ARCs target the antigens CD45 and CD33 for patients with a broad range of hematologic malignancies including acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) and multiple myeloma (MM), acute lymphoblastic leukemia (ALL), Hodgkin's lymphoma and Non-Hodgkin's lymphoma. Actinium's lomab-ACT program is designed to be a universal lymphodepletion technology intended to eliminate the need for chemotherapy-based conditioning prior to CAR-T or other adoptive cellular therapies.

lomab-B, Actinium's lead targeted conditioning product candidate, is currently enrolling patients in the pivotal Phase 3 SIERRA trial in patients age 55 or older, with active, relapsed or refractory AML. Iodine-131-apamistamab (lomab-B), 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. lomab-B has been studied in over 500 patients in 10 clinical trials in numerous hematologic diseases. Actinium's lomab-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 lomab-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 lomab-ACT program can be accomplished through a single outpatient infusion. Actinium intends to advance its lomab-ACT program with CAR-T focused collaborators from academia and industry.

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 75 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](http://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 may contain projections or other "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 financial performance of the Company which the Company 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 (the "SEC"), including without limitation its most recent annual report on form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

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