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Actinium Provides Update on Iomab-B SIERRA Trial and Expected Topline Results from Ad Hoc Analysis in 2020

- Single ad hoc interim analysis for SIERRA trial to be exercised at the Company's discretion in Q2 2020, making topline data results available in Q4 2020

- Robust enrollment and screening for SIERRA in March and April 2020 with enrollment expected to continue at majority of sites despite COVID-19 pandemic

NEW YORK, April 16, 2020 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company") today provided an update on the Iomab-B pivotal SIERRA (Study of Iomab-B in Elderly Relapse or Refractory Acute Myeloid Leukemia) trial incorporating the impact of the coronavirus disease (COVID-19) pandemic.

Sandesh Seth, Actinium's Chairman and CEO, said, "Our team has done an excellent job continuing to advance our clinical programs, operations and business objectives during the COVID-19 pandemic. March was one of the higher enrolling months in the SIERRA trial with multiple patients enrolled after the COVID-19 pandemic emerged in full force with active screening continuing. The majority of our SIERRA trial sites have informed us that enrollment is expected to remain active despite COVID-19 given the acute need for treatment, the curative nature of BMT and the lack of viable alternatives to Iomab-B."

He continued, "Given the status of the SIERRA trial we expect to exercise an ad hoc analysis in the second quarter of 2020, which would make topline primary endpoint data available later in 2020. I am proud of our team for rising to the challenge of the COVID-19 era and am confident we will continue to execute and meet key milestones for SIERRA."

Outlook for Iomab-B Pivotal SIERRA Trial

A majority of clinical sites in the Phase 3 SIERRA trial, including top enrolling sites, have reported that patient recruitment and enrollment in the study will continue during the COVID-19 pandemic, because of the acute nature of the disease, the high unmet needs of patients

with relapsed or refractory AML, the potentially curative nature of BMT and the differentiated profile of Iomab-B. Patient enrollment in March 2020 was higher than average and recruitment and screening remains active at the majority of sites during April. Actinium anticipates that sites currently not actively enrolling due to COVID-19 will likely resume recruitment and enrollment in the summer timeframe.

Currently, the SIERRA trial is approaching the upper bound of the range within which the Company may exercise an ad hoc analysis of the topline results. The trial is powered for up to two interim analyses of the primary endpoint exercisable at Actinium's discretion and triggered by an enrollment range of 70 up to 110 patients. The primary endpoint of SIERRA is durable Complete Remission (dCR) of 180 days.

Data from the SIERRA trial at 50 percent of enrollment showed positive engraftment, safety and 100-day non-relapse transplant related mortality results which are considered predictive of patient outcomes based on prior trials with Iomab-B. Based on these data and the current status of enrollment, Actinium plans to exercise an ad-hoc analysis that could generate topline data for the primary endpoint in late 2020 and early termination of the trial if positive. Based on the statistical plan of the study, a single ad hoc analysis would result in a minimal alpha spend of no more than 0.00925, depending on the number of patients included in the ad hoc analysis.

Details of the recent SIERRA data and the ad hoc analysis considerations are highlighted below:

Select Iomab-B SIERRA Interim Data Presented to Date

- **Universal BMT access and engraftment with Iomab-B**

Midpoint results showed that 100% of patients receiving the therapeutic dose of Iomab-B underwent BMT and successfully engrafted. This is in contrast with the control arm where only 18% of patients achieved remission and underwent BMT, resulting in an 82% failure for the primary endpoint in the control arm.

- **Lower 100-day non-relapse transplant mortality and favorable safety profile with Iomab-B**

At 50 percent of enrollment, 6% of patients on the Iomab-B arm experienced 100-day non-relapse transplant related mortality rate (TRM) versus 29% for the control arm. Detailed safety data showed that patients receiving Iomab-B had markedly lower rates of sepsis and septic shock compared to those transplanted in the control arm (2.9% vs. 21.6%) and half the rate of febrile neutropenia (22.9% vs. 45.9%).

- **Implications for ad hoc analysis and topline data**

The combination of universal engraftment and low rate of 100-day TRM resulted in 29 patients on the Iomab-B arm potentially evaluable for the primary endpoint versus five patients on the control arm, nearly a 6x difference, after evaluation at 100 days post BMT. In multiple clinical trials that previously studied Iomab-B, high levels of engraftment were shown to be predictive of long-term survival outcomes. In the proof of concept trial that informed the SIERRA trial, 100% engraftment was reported with nearly 20 percent of patients achieving

2-year overall survival with some patients surviving greater than eight years. At full enrollment SIERRA will be deemed successful if the efficacy of Iomab-B arm is 2x the control arm.

Dr. Mark Berger, Actinium's Chief Medical Officer, said, "Our goal is to demonstrate Iomab-B's clinical benefit and make it available to patients as quickly as possible. To that end, we continually assess data available to us, such as the positive feasibility, engraftment and safety data at 50 percent enrollment that we have previously highlighted. Based on our assessment of these data and the current status of SIERRA, we are encouraged to exercise the ad hoc analysis as we believe it is the best interests of patients, especially given the minimal alpha spend and therefore the minimal impact it is expected to have on the final statistical analysis. We are heartened by the commitment of the majority of SIERRA sites that continue to recruit and enroll patients despite the COVID-19 pandemic, based on the value of Iomab-B's differentiated profile to these acutely ill patients who otherwise cannot receive a potentially curative therapy."

About Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing ARCs or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium's lead application for our ARCs is targeted conditioning, which is intended to selectively kill patient's cancer cells and certain immune cells prior to a BMT or Bone Marrow Transplant, CAR-T and other cell therapies or gene therapy to enable engraftment of these transplanted cells with minimal toxicities. With our ARC approach, we seek to improve patient outcomes and access to these potentially curative treatments by eliminating or reducing the non-targeted chemotherapy that is used for conditioning in standard practice currently. Our lead product candidate, Iomab-B is being studied in the ongoing pivotal Phase 3 **S**tudy of **I**omab-B in **E**lderly **R**elapsed or **R**efractory **A**cute Myeloid Leukemia (SIERRA) trial for BMT conditioning. The SIERRA trial is over fifty percent enrolled and promising single-agent, feasibility and safety data has been highlighted at ASH, TCT, ASCO and SOHO annual meetings. Beyond Iomab-B, we are developing a multi-disease, multi-target pipeline of clinical-stage ARCs targeting the antigens CD45 and CD33 for targeted conditioning and as a therapeutic either in combination with other therapeutic modalities or as a single agent for patients with a broad range of hematologic malignancies including acute myeloid leukemia, myelodysplastic syndrome and multiple myeloma. Underpinning our clinical programs is our proprietary AWE (Antibody Warhead Enabling) technology platform. This is where our intellectual property portfolio of over 100 patents, know-how, collective research and expertise in the field are being leveraged to construct and study novel ARCs and ARC combinations to bolster our pipeline for strategic purposes. Our AWE technology platform is currently being utilized in a collaborative research partnership with Astellas Pharma, Inc.

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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