

November 6, 2019



## **Actinium Announces Interim Results from Phase 1 Actimab-A CLAG-M Combination Trial in Patients with Relapsed or Refractory AML Accepted for Presentation at ASH 2019**

- 83% remission rate with Actimab-A CLAG-M combination demonstrates promising efficacy compared to 54% remission rate with CLAG-M alone**
- Combination of Actimab-A and CLAG-M demonstrates clinically acceptable safety profile in difficult to treat relapsed/refractory AML patients**

NEW YORK, Nov. 6, 2019 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium") today announced that interim results from a Phase 1 trial studying Actimab-A in combination with CLAG-M have been accepted for presentation at the 2019 American Society of Hematology (ASH) annual meeting that is being held December 7-10, 2019 in Orlando, FL. This is the first study to combine radioimmunotherapy and intensive chemotherapy in patients with relapsed or refractory AML. Actimab-A is an antibody radiation-conjugate (ARC) comprised of the CD33 targeting antibody lintuzumab labeled with the alpha-emitting radioisotope actinium-225 (Ac-225).



The ASH abstract reports on 9 adult patients with relapsed or refractory AML enrolled on the investigator-initiated trial at the Medical College of Wisconsin (MCW). Patients were a median age of 59 and had received a median of 2 (range 1-4) anti-leukemic treatments, including 4 patients who relapsed after receiving a bone marrow transplant (BMT). Patients received the salvage chemotherapy regimen cladribine, cytarabine, G-CSF, and mitoxantrone (CLAG-M) and a single dose of Actimab-A on either day 6, day 7, or day 8. Cohort 1 enrolled 3 patients who received 0.25 uCi/kg of Actimab-A and Cohort 2 enrolled 6 patients who received 0.50 uCi/kg of Actimab-A.

Details and highlights from Actinium's accepted poster include:

## **Title: Lintuzumab Ac-225 in Combination with CLAG-M Chemotherapy in Relapsed/Refractory AML: Interim Results of a Phase I Study**

### **Key Highlights:**

- 83% of patients (5/6) receiving 0.50 uCi/kg of Actimab-A and CLAG-M in the second dosing cohort achieved a Complete Remission (CR), Complete Response with incomplete platelet recovery (CRp) or Complete Response with incomplete hematologic recovery (CRi)
- 83% remission rate with 0.50 uCi/kg Actimab-A CLAG-M combination significantly higher than the MCW institutional 54% remission rate with CLAG-M alone<sup>1</sup>
- 83% remission rate at 0.50 uCi/kg included 50% (3/6) with a CR
- 33% of patients (3/9) enrolled in the trial subsequently received a bone marrow transplant
- Combining lower doses of Actimab-A with CLAG-M appears to have a clinically acceptable safety profile
- All patients completed the planned cycle of Actimab-A and CLAG-M
- No mortalities were observed on study

### **Poster Details:**

Publication Number: 2605

Session Name: 613. Acute Myeloid Leukemia: Clinical Studies: Poster II

Date: Sunday, December 8, 2019

Presentation Time: 6:00 PM - 8:00 PM

Location: Orange County Convention Center, Hall B

Dr. Mark Berger, Actinium's Chief Medical Officer, said, "It is quite encouraging to see a high overall response rate with the addition of Actimab-A compared to patients treated with CLAG-M alone. These preliminary results exceed our expectations and compare quite favorably to results seen with recently approved AML therapies, especially in these difficult to treat relapsed or refractory patients. We look forward to seeing additional results from this trial and are excited by the potential to advance the Actimab-A CLAG-M combination to a Phase 2 or potentially pivotal trial. In addition, the ability to combine Actimab-A with a powerful salvage regimen like CLAG-M with a manageable adverse event profile suggests that combinations with other agents, such as venetoclax, may also be tolerable and will lead to improved efficacy."

Sandesh Seth, Actinium's Chairman and CEO, said, "These results strengthen our conviction in the potentiating and synergistic properties of targeted radiation with other therapeutic modalities. We see opportunities to combine our ARCs with chemotherapy as highlighted in this study, with targeted agents as we have done with our Actimab-A venetoclax combination trial and potentially with immunotherapy. Additionally, the rate of patients going to transplant in this study, despite the low dose levels of Actimab-A administered, gives us great excitement for our Actimab-MDS program that will study significantly higher doses of Actimab-A as a targeted conditioning regimen prior to a bone marrow transplant in patients with high-risk MDS. It is exciting to see our CD33 program development strategy with low-dose combinations and high-dose targeted conditioning generate positive responses and we look forward to additional data from our ongoing and planned clinical trials."

## **About Actimab-A**

Actimab-A (actinium-225 lintuzumab) is an antibody radiation-conjugate that has been studied in over 100 patients in 4 clinical trials at several dose levels. A Phase 2 trial studying Actimab-A as a single agent produced a 69% overall response rate in older unfit patients with newly diagnosed AML. The findings from this study are supporting a development strategy that will study Actimab-A at high doses for targeted conditioning prior to bone marrow transplant in the planned pivotal Actimab-MDS program, and at lower doses in combination with other therapeutic modalities like the combination trial with the Bcl-2 inhibitor venetoclax and the combination trial with the chemotherapy regimen CLAG-M.

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

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing ARC's or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium's lead application for our ARC's 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. 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, lomab-B is being studied in the ongoing pivotal Phase 3 Study of lomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. Beyond lomab-B, we are developing a multi-disease, multi-target pipeline of clinical-stage ARC's 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 AML (Acute Myeloid Leukemia), MDS (Myelodysplastic Syndrome), MM (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 ARC's 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.

Sources:

1. Mushtaq et al. Comparison of Salvage Chemotherapy Regimens in Relapsed/Refractory Acute Myeloid Leukemia. ASH Annual Meeting 2018.

## **Forward-Looking Statements for Actinium Pharmaceuticals, Inc.**

The information in this press release contains forward-looking statements regarding future events, including statements about Actinium's expectations regarding the terms of the offering or completion of the offering. Actinium intends such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties related to market and other conditions, the satisfaction of customary closing conditions related to the offering and the impact of general economic,

industry or political conditions in the United States or internationally. There can be no assurance that Actinium will be able to complete the offering on the anticipated terms, or at all. More information about the risks and uncertainties faced by Actinium are more fully detailed under the heading "Risk Factors" in Actinium's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. Except as required by law, Actinium assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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