



# Actinium Presents Interim Data from Actimab-A CLAG-M Phase 1 Combination Trial at the 62nd American Society of Hematology Annual Meeting

- 100% remission rate in the third dose cohort of 0.75  $\mu\text{Ci}/\text{kg}$  of Actimab-A (lintuzumab-225Ac) and standard regimen of CLAG-M
- 70% of patients achieving remission were MRD negative with remissions and MRD negativity reported in all dose cohorts

NEW YORK, Dec. 7, 2020 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company") today announced that interim data from its ongoing Actimab-A CLAG-M Phase 1 combination trial in relapsed or refractory Acute Myeloid Leukemia (AML) were presented at the 62<sup>nd</sup> American Society of Hematology (ASH) annual meeting.



## ASH Oral Presentation: A Phase I study of Lintuzumab Ac225 in Combination with CLAG-M Chemotherapy in Relapsed/Refractory AML

In the third and planned final dose cohort of Actimab-A CLAG-M, 100% of evaluable patients achieved remission. The trial, which is being conducted at the Medical College of Wisconsin (MCW), is advancing to a fourth dose cohort of 1.0  $\mu\text{Ci}/\text{kg}$ . Across the first three cohorts, 67% (10/15) patients treated with 0.25, 0.50 and 0.75  $\mu\text{Ci}/\text{kg}$  of Actimab-A and the standard regimen of CLAG-M achieved a Complete Remission (CR) or Complete Remission with inadequate hematopoietic recovery (CRi). Further, 83% of patients (10/12) who received 3 or fewer prior lines of treatment achieved CR or CRi. Notably, 70% of CR/CRi patients were MRD (Measurable Residual Disease) negative indicating a deep remission with no detectable disease. MRD negativity is defined as  $\leq 0.1\%$  AML cells. These results, which include subtherapeutic doses of Actimab-A in the first two dose cohorts, represent a marked improvement over CLAG-M treatment alone (ORR: 55%, MRD negativity: 39%) implying potential mechanistic synergy. This novel Phase 1 combination trial is for patients with

relapsed or refractory acute myeloid leukemia (R/R AML) age 18 and above deemed medically fit for cytotoxic chemotherapy.

	Lintuzumab-Ac225 dose N (%)	CR + CRi
Cohort 1 (0.25 µCi/kg)	3 (20%)	33%
Cohort 2 (0.50 µCi/kg)	9 (60%)	67%
Cohort 3 (0.75 µCi/kg)	3 (20%)	100%

Dr. Mark Berger, Actinium's Chief Medical Officer, said, "We look forward to continuing our work with the investigators at MCW in the Actimab-A CLAG-M combination trial. Thus far we remain thrilled with the high rates of remission, MRD negativity and transplant in this trial, which highlights the potential this combination may have for patients with R/R AML. It is exciting to see the profile of this combination emerge not only for therapeutic purposes but also for its potential as a bridge to transplant as noted by the investigators at MCW. Our CD33 program is focused on exploring the synergistic effects of Actimab-A with other therapeutic modalities and evaluating these combinations as potential backbone therapies in R/R AML."

### **About Actinium's CD33 Program**

Actinium's CD33 program is evaluating the clinical utility of Actimab-A, an Antibody Radiation Conjugate (ARC) comprised of the anti-CD33 mAb lintuzumab linked to the potent alpha-emitting radioisotope Actinium-225 or Ac-225. CD33 is expressed in the majority of patients with AML and myelodysplastic syndrome, or MDS, as well as patients with multiple myeloma. The CD33 development program is driven by data from over one hundred treated patients, including a Phase 1/2 trial where Actimab-A produced a remission rate as high as 69% as a single agent. This clinical data is shaping a two-pronged approach for the CD33 program, where at low doses the Company is exploring its use for therapeutic purposes in combination with other modalities and at high doses for use for targeted conditioning prior to bone marrow transplant. Actinium currently has multiple clinical trials ongoing including the Phase 1 Actimab-A CLAG-M and Phase 1/2 Actimab-A venetoclax combination trials and is exploring additional CD33 ARC combinations with other therapeutic modalities such as chemotherapy, targeted agents or immunotherapy.

### **About Actinium Pharmaceuticals, Inc. (NYSE: ATNM)**

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 deplete a patient's disease or cancer cells and certain immune cells prior to a BMT or Bone Marrow Transplant, Gene Therapy or Adoptive Cell Therapy (ACT) such as CAR-T 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, I-131 apamistamab (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. The SIERRA trial is over seventy-five percent enrolled and positive single-agent, feasibility and safety data has been highlighted at ASH, TCT, ASCO and SOHO annual meetings. More information on this Phase 3 clinical trial can be found at

[www.sierratrial.com](http://www.sierratrial.com). I-131 apamistamab will also be studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell therapy and in a Phase 1/2 anti-HIV stem cell gene therapy with UC Davis. In addition, 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. Ongoing combination trials include our CD33 ARC, Actimab-A, in combination with the salvage chemotherapy CLAG-M and the Bcl-2 targeted therapy venetoclax. Underpinning our clinical programs is our proprietary AWE (Antibody Warhead Enabling) technology platform. This is where our intellectual property portfolio of over 130 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. Website: <https://www.actiniumpharma.com/>

### **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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