

November 4, 2020



# Actinium Announces Actimab-A Venetoclax First-in-Human Data Accepted for Poster Presentation at the 62nd American Society of Hematology Annual Meeting

- There were no DLTs in first dose cohort, combination advances to additional dose cohorts in R/R AML patients
- Encouraging initial response observed with subtherapeutic doses of Actimab-A support potential mechanistic synergy with venetoclax

NEW YORK, Nov. 4, 2020 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium") today announced that data from the Phase 1 portion of the Actimab-A venetoclax Phase 1/2 combination trial, has been accepted for poster presentation at the 2020 American Society of Hematology (ASH) annual meeting that is being held virtually December 5-8, 2020.



## Poster Details & Highlights

Poster Title:	Lintuzumab-225Ac in Combination with Venetoclax in Relapsed/Refractory AML: Early Results of a Phase I/II Study
Publication Number:	2875
Session Name:	616. Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Poster II
Session Date:	Monday, December 7, 2020
Presentation Time:	7:00 AM – 3:30 PM PT / 10:00 AM – 6:30 PM ET

- Combining Actimab-A ( $^{225}\text{Ac}$  lintuzumab) with venetoclax in patients with R/R AML has an acceptable initial clinical safety profile at the initial subtherapeutic dose level of 0.5  $\mu\text{Ci}/\text{kg}$  of Actimab-A.
- A partial response was observed after a single cycle of Actimab-A and venetoclax.
- Three R/R AML patients with a median age of 54 years (range 49-75) have been enrolled to date. The enrolled patients had a median of 2 therapies (2-3) and a median

bone marrow blast percentage of 30% (range 20 - >60). All 3 patients had poor risk with adverse cytogenetics, and each patient has an additional high-risk marker (FLT3-ITD+, antecedent JAK2+ myelofibrosis, or TP53 mutation).

- There have been no Actimab-A related dose limiting toxicities (DLT) or nonhematologic Grade 3 or greater related AEs.
- Results in the first Actimab-A dose cohort are encouraging, and the trial will continue to enroll to evaluate the hypothesis that there will be clinical synergy consistent with pre-clinical results.

Dr. Mark Berger, Actinium's Chief Medical Officer, said, "We have great excitement for this Actimab-A venetoclax combination trial and its potential for both fit and unfit patients with R/R AML. This preliminary first-in-human data is encouraging, particularly the reported patient response after a single cycle of venetoclax with a subtherapeutic dose level of Actimab-A. These initial results support the potential mechanistic synergy of Actimab-A with venetoclax and we are pleased by the progression in the clinic to the next dose level as there were no dose limiting toxicities with this combination."

Dr. Dale Ludwig, Actinium's Chief Scientific and Technology Officer, stated, "We believe that the combination of low doses of Actimab-A with selected therapeutic modalities that together have potential mechanistic or complementary synergies is an approach that has great therapeutic potential. Therefore, it is exciting to see the hypothesized mechanistic synergy between Actimab-A and venetoclax, which we demonstrated in preclinical studies, now advancing in the clinic. Venetoclax as a single agent has produced low response rates in patients with R/R AML so we find it highly encouraging to see an initial response with a dose of Actimab-A that has shown to be subtherapeutic as a single agent. I am eager to see additional results from the first dose cohort as well as the second dose cohort to further support the therapeutic potential of Actimab-A in combination with venetoclax."

The complete abstracts are available on the ASH website ([click here](#)).

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

Actinium's CD33 program is evaluating the clinical utility of Actimab-A, an 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 approximately one third of patients with multiple myeloma. The CD33 development program is driven by data obtained from well over one hundred treated patients, including results from a Phase 1/2 trial that was conducted in 58 patients with newly diagnosed AML, which was completed in 2018. This clinical data, as well as the Company's experience with lomab-B, is shaping a two-pronged approach for the CD33 program, where at high doses the Company is exploring its use for targeted conditioning and at low doses the Company is exploring its use for therapeutic purposes as a single agent, or in combination with other modalities. There are currently multiple clinical trials ongoing studying Actimab-A including a Phase 1 combination trial with the salvage chemotherapy regimen CLAG-M, a Phase 1/2 trial in combination with venetoclax and its Actimab-MDS planned pivotal program for targeted conditioning with standard chemotherapy. In addition, Actinium is exploring additional combinations with Actimab-A and other potentially synergistic 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 (Iomab-B) is being studied in the ongoing pivotal Phase 3 Study of Iomab-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 [sierratrial.com](http://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 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 alpha 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 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. 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.

**Contacts:**

Investors:

Clayton Robertson

Actinium Pharmaceuticals, Inc.

[crobertson@actiniumpharma.com](mailto:crobertson@actiniumpharma.com)

Hans Vitzthum

LifeSci Advisors, LLC

[Hans@LifeSciAdvisors.com](mailto:Hans@LifeSciAdvisors.com)

(617) 430-7578

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