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# **Actinium Announces Completion of Enrollment of Actimab-A CLAG-M Combination Trial in Patients with Relapsed or Refractory Acute Myeloid Leukemia Fit for Induction Therapy**

- Updated Phase 1 data to be presented at ASH with clinical development update expected before year end**
- ASH 2020 data presentation reported 100% remission rate in dose cohort 3 and 70% MRD negativity rate in patients achieving remission across all dose cohorts**

NEW YORK, Nov. 4, 2021 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company"), a leader in the development of targeted radiotherapies for patients with unmet needs, today announced that the Phase 1 trial studying Actimab-A with the salvage chemotherapy CLAG-M in patients with relapsed or refractory acute myeloid leukemia (r/r AML) who are fit for intensive therapy has completed the planned dose escalation and patient enrollment. Patients in the fourth and final dose escalation cohort received 1.0  $\mu\text{Ci/kg}$  of Actimab-A with the standard CLAG-M dose regimen. This novel combination trial is being conducted at the Medical College of Wisconsin. Updated Phase 1 data is expected will be presented at the American Society of Hematology (ASH) Annual Meeting in December and Actinium expects to provide an update on the future clinical development of this combination by year end.



Actimab-A CLAG-M combination data was presented at ASH 2020 from the first three dose cohorts, which highlighted:

- 100% remission rate (CR/CRi) in patients receiving 0.75  $\mu\text{Ci/kg}$  of Actimab-A with CLAG-M
- 83% remission rate in patients who received 3 or fewer lines of prior treatment
- 70% of patients achieving a remission were MRD negative
- 67% of patients in the study achieved a remission including patients receiving 0.25 and

0.50 µCi/kg of Actimab-A, which has shown to be subtherapeutic as a single agent in prior studies

- All patients had intermediate (N=5, 33%) or adverse (N=10, 67%) cytogenetics
- Patients had a median of 2 prior therapies (range:1- 5) including prior Venetoclax/HMA (N=7,47%) or bone marrow transplant (N=8, 53%)

These results compare favorably to outcomes with CLAG-M as a single agent, which was shown in a separate study to have a 55% overall response rate and a 39% MRD negativity rate.

Dr. Avinash Desai, Actinium's Chief Medical Officer, said, "This novel combination has produced promising data with high rates of remission and MRD negativity with an acceptable safety profile thus far. Despite multiple new drug approvals for patients with AML, including several targeted agents, outcomes for patients with relapsed or refractory AML remain poor, especially those with adverse molecular or cytogenetic features. Actimab-A enables the treatment of AML with radiation at a cellular level, which is a novel mechanism not achievable with traditional external beam radiation given the diffuse nature of blood cancers like AML. Given the sensitivity of AML and other blood cancers to radiation, we are optimistic in its potential to improve patient outcomes. We hypothesized that the combination of Actimab-A with CLAG-M would be tolerable given the non-overlapping mechanisms of action and lead to higher and deeper remissions. We have been very pleased with the data from the trial to date and look forward to advancing this novel combination once we have reviewed the data from all dose cohorts, including the data to be presented at ASH in December."

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

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing targeted radiotherapies to deliver cancer-killing radiation with cellular level precision to treat patients with high unmet needs not addressed by traditional cancer therapies. Actinium's current clinical pipeline is led by ARCs or Antibody Radiation-Conjugates that are being applied to 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. Actinium's targeted conditioning ARCs 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) has been studied in several hundred patients including in the recently fully enrolled, 150-patient, pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. Iomab-ACT, low dose I-131 apamistamab is being studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell Therapy with Memorial Sloan Kettering Cancer Center. In addition, we are leaders in the field of Actinium-225 alpha therapies. Actimab-A, our clinical stage CD33 targeting ARC alpha therapy has been studied in nearly 150 patients including our ongoing combination trials 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 160 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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