



# Actinium Announces Iomab-B Poster Selected for Honorable Distinction Award at the 2019 Society of Hematologic Oncology Annual Meeting from Nearly Four Hundred Abstracts

- SOHO Honorable Distinction award adds to the growing recognition for Iomab-B and the SIERRA trial by leaders in the transplant and hematology community
- Pivotal Phase 3 SIERRA trial for Iomab-B over fifty percent enrolled remains the only randomized Phase 3 trial to offer potentially curative bone marrow transplant as an option for relapsed or refractory AML patients despite 8 AML drug approvals since 2017

NEW YORK, Sept. 23, 2019 /PRNewswire/ --Actinium Pharmaceuticals, Inc. (NYSE AMERICAN: ATNM) ("Actinium") today announced that a poster highlighting Iomab-B, its pivotal Phase 3 targeted conditioning candidate, was awarded Honorable Distinction at the 2019 SOHO (Society of Hematologic Oncology) Annual Meeting. SOHO is the only international society specific to the field of hematologic oncology and has grown to over 3,000 members. This year's SOHO annual meeting was attended by nearly 1,400 physicians, nurses and healthcare professionals and nearly four hundred abstracts and posters were presented including over 70 focused on AML or acute myeloid leukemia.



Benjamin Tomlinson, M.D., Assistant Professor, Adult Hematologic and Stem Cell Transplant Section, Seidman Cancer Center, University Hospitals Case Medical Center (Cleveland, OH) and lead author of the poster, said, "It is an honor for our work to be recognized by SOHO's scientific committee from the significant number of posters and abstracts that were submitted. The AML therapeutic landscape has evolved rapidly in recent years with eight therapies gaining approval since 2017 including targeted agents like Bcl-2, FLT3 and IDH inhibitors. While these therapies are important advancements for patients with

AML, they are not curative, and bone marrow transplant remains the only curative treatment option for patients with active relapsed or refractory AML. Iomab-B is highly differentiated as a targeted agent with a strong anti-leukemic effect as we have demonstrated in this poster selected by SOHO and targeted conditioning ability that led to all patients receiving Iomab-B achieving successful bone marrow transplant and engraftment. These findings are highly encouraging as I am not aware of any other agents that offer such a high probability of bone marrow transplant for this patient population. I look forward to continuing to participate in the SIERRA study and am excited for additional data in the future."

Mark Berger, M.D., Actinium's Chief Medical Officer, said, "This Honorable Distinction award from SOHO adds to the growing recognition for Iomab-B's value proposition as the only late-stage targeted conditioning agent for the older relapsed or refractory AML patient population. Since achieving twenty-five percent enrollment and making important changes to the trial protocol, including adding targeted therapies like venetoclax as options in the control arm and reducing the time to crossover evaluation to fourteen days, we have seen a dramatic increase in physician interest and enthusiasm for the SIERRA trial. This groundswell of interest continued to build after preliminary data from the first twenty-five percent of patients was presented in an oral presentation at the ASH annual meeting in 2018 and a late-breaking oral presentation at the TCT annual meeting in February 2019. These data demonstrated Iomab-B's ability to enable transplant universally, with deep donor chimerism and no non-relapse mortality at one hundred days post-transplant in the Iomab-B arm. Additionally, Iomab-B's ability as a single agent to rapidly deplete all circulating leukemic blasts prior to transplant has drawn strong recognition from the medical community, as evidenced by this award from SOHO. These data gained widespread visibility throughout the transplant and hematology communities and as a result, we have seen new sites come into the SIERRA trial bringing us to twenty sites in total at present. There has also been significant physician engagement, which drove us powerfully past fifty-percent enrollment. With the important fifty percent enrollment milestone achieved, we look forward to completing the SIERRA study and further demonstrating Iomab-B's value proposition at future medical meetings."

The poster presented at SOHO highlighted Iomab-B's ability as a single agent activity to rapidly deplete peripheral blasts leading to lower circulating leukemia tumor burden prior to BMT, which is critical for successful engraftment. It was observed that a single therapeutic infusion of Iomab-B resulted in a median reduction of peripheral blasts of 98% by day 3 and 100% reduction by day 8 following administration and prior to any other pre-BMT conditioning in the sixteen patients who were evaluated. Rapid reduction of peripheral blasts has been observed as an independent prognostic marker that is predictive of both CR or Complete Response and RFS or Relapse-Free Survival in patients with AML after receiving cytotoxic chemotherapy. Gianfaldoni et al<sup>1</sup> performed an analysis of 30 newly diagnosed AML patients who were treated with cytotoxic induction chemotherapy and found that a rapid reduction of peripheral leukemia blasts correlated with responses and all patients that achieved CR had a rapid reduction of their peripheral blasts. Elliot et al<sup>2</sup>, performed a retrospective analysis of 86 adult patients with AML and identified time to clearance of circulating leukemia blasts as an independent prognostic marker of RFS that superseded all other known risk factors including karyotype and number of cycles of induction therapy needed to achieve CR. As previously presented, all patients receiving Iomab-B in the SIERRA trial, including cross over patients, received a BMT and achieved engraftment without delay.

The poster selected by SOHO for honorable distinction can be viewed on Actinium's website ([here](#)) or the SOHO Annual Meeting website ([here](#)).

### **About the Society of Hematologic Oncology**

The Society of Hematologic Oncology (SOHO) is an international society designed specifically for clinicians, research scientists and related healthcare professionals who specialize in the research and treatment of patients with hematologic malignancies. SOHO's mission is to promote worldwide research and education through the exchange of scientific information. Organized by its founders and world class committees, SOHO is the only international society specific to this field. The 2019 SOHO Annual Meeting took place September 11-14 in Houston, Texas, with attendance from nearly 1,400 hematologic oncology professionals from across the globe. Nearly 400 abstracts were accepted for oral or poster presentation at the Annual Meeting. Published abstracts are available through the official journal of the Society, 'Clinical Lymphoma, Myeloma and Leukemia,' published by Elsevier. Online access is open to the public at [https://www.clinical-lymphoma-myeloma-leukemia.com/issue/S2152-2650\(19\)X0009-9](https://www.clinical-lymphoma-myeloma-leukemia.com/issue/S2152-2650(19)X0009-9) through December 31, 2019. For more information about the Society or to sign-up for FREE membership, go to the official website at <https://www.sohoonline.org/>.

### **About Iomab-B**

Iomab-B is an ARC or Antibody Radiation-Conjugate comprised of the anti-CD45 antibody apamistamab and the radioisotope iodine-131 that is intended to be a targeted conditioning agent prior to a BMT or bone marrow transplant. Iomab-B was developed at the Fred Hutchinson Cancer Research Center and has been studied in over 300 patients in multiple hematologic indications across 12 clinical trials in addition to the ongoing SIERRA study in older patients with active, relapsed or refractory AML or Acute Myeloid Leukemia prior to patients receiving an allogeneic BMT or bone marrow transplant. Iomab-B is Actinium's lead targeting conditioning ARC in its multi-target, multi-indication targeted conditioning pipeline that includes the Iomab-B and Actimab-MDS programs for BMT and the Iomab-ACT program that will study a lower dose of Iomab-B for lymphodepletion prior to CAR-T and other cellular therapies.

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

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on improving patient access and outcomes to cellular therapies such as BMT or Bone Marrow Transplant and CAR-T with its proprietary ARC or Antibody Radiation-Conjugate targeted conditioning technology. Actinium is also developing its proprietary AWE or Antibody Warhead Enabling technology platform, which utilizes radioisotopes including iodine-131 and the highly differentiated actinium-225 coupled with antibodies, to target a variety of antigens that are expressed in hematological and solid tumor indications. It is developing a multi-disease, multi-target pipeline of clinical-stage ARC's targeting the antigens CD45 and CD33 for targeting 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 (AML), Myelodysplastic Syndrome (MDS) and Multiple Myeloma (MM). Actinium's lead product candidate, Iomab-B, is in a pivotal Phase 3 trial for re-induction and conditioning prior to a BMT for patients with active relapsed or refractory AML or Acute Myeloid Leukemia. BMT is the only curative treatment option for this patient population and currently no standard of care exists. Actimab-MDS is its second pivotal program for targeted conditioning that will study the ARC comprised of the anti-CD33

monoclonal antibody lintuzumab linked to the radioisotope actinium-225 in patients with high-risk MDS in combination with RIC or Reduced Intensity Conditioning prior to a BMT. Its Iomab-ACT or Adoptive Cell Therapy program targets CD45 and utilizes a lower dose of iodine-131 than Iomab-B or lutetium-177 and is intended to be used for targeted conditioning or lymphodepletion prior to CAR-T and adoptive cell therapies as a replacement to non-optimized chemotherapies, such as Flu/Cy or fludarabine and cyclophosphamide, that is used in standard practice today. Actinium also has multiple clinical trials ongoing, in startup phase, or in planning, to use its CD33 ARC in combination with other therapeutic modalities such as chemotherapy, targeted agents or immunotherapy. It has initiated several combination trials, including a doublet combination trial with its CD33 ARC and venetoclax, a BCL-2 inhibitor, for patients with relapsed or refractory AML, a triplet combination trial with venetoclax and an HMA or hypomethylating agent and in combination with the salvage chemotherapy regimen CLAG-M (cladribine, cytarabine, filgrastim and mitoxantrone) for patients with relapsed or refractory AML. Actinium is also studying its CD33 ARC as single agent for patients with penta-refractory multiple myeloma. Its AWE technology platform enables Actinium's internal pipeline and with the radioisotope actinium-225 is being utilized in a collaborative research partnership with Astellas Pharma, Inc. Actinium's clinical programs and AWE technology platform are covered by a portfolio of over 100 patents covering composition of matter, formulations, methods of use, the DOTA linker technology for actinium-225 applications and methods of manufacturing the actinium-225 radioisotope in a cyclotron.

**Sources:**

- 1) Gianfaldoni et al. clearance of leukemic blasts from peripheral blood during standard induction treatment predicts the bone marrow response in acute myeloid leukemia: a pilot study. British Journal of Haematology, 2006 March 16; 134, 54-57.
- 2) Elliott et al. Early peripheral blood blast clearance during induction chemotherapy for acute myeloid leukemia predicts superior relapse-free survival. Blood. 2007 Dec 15; 110(13):4172-4. Epub 2007 Oct 1.

**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.

**Contact:**

**Actinium Pharmaceuticals, Inc.**

Actinium Pharmaceuticals, Inc.

Steve O'Loughlin

Principal Financial Officer

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

Hans Vitzthum

LifeSci Advisors, LLC

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

(617) 535-7743

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