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Actinium Pharmaceuticals Announces Iomab-B SIERRA Trial Database Lock, Provides Corporate Update Highlighting Key Upcoming Milestones

- On track to report topline data from the Pivotal Phase 3 SIERRA trial for Iomab-B in Q4 2022
- Overall survival data from the Actimab-A CLAG-M combination trial expected in Q4 2022
- Additional updates on collaborations and pipeline progress demonstrating Actinium's leadership in the development of Actinium-225-based radiotherapies expected by year-end
- Approximately $116 million in cash and cash equivalents at the end of Q2 2022 expected to fund key value creating clinical, regulatory and R&D milestones through mid-2025

NEW YORK, Sept. 21, 2022 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company"), a leader in the development of targeted radiotherapies, today provided a business update and outlook, highlighting upcoming clinical milestones. Key milestones expected before year-end include: topline results for the pivotal Phase 3 SIERRA trial for Iomab-B; survival data from the Actimab-A CLAG-M trial; and additional updates related to progress with the Company's collaborations and internal research programs.

"Actinium is on track to deliver topline clinical results from our pivotal Phase 3 SIERRA trial for Iomab-B in the fourth quarter of this year. Iomab-B represents a potential paradigm change in the way difficult to treat relapsed or refractory (r/r) acute myeloid leukemia (AML) patients with active disease can be treated with a potentially curative bone marrow transplant (BMT)," said Sandesh Seth, Chairman and CEO of Actinium. "Iomab-B enables elderly AML patients who are relapsed or refractory to current therapies access to a bone marrow transplant without being in remission whereas current conditioning regimens require patients to be in remission. If successful, SIERRA trial results will demonstrate both improved access and outcomes in transplanted patients who currently survive just a few months as

they are not treatable with currently available drugs and cannot be transplanted. Over time, Iomab-B which has been tested in multiple, hard-to-treat blood cancers, has the potential to become a universal conditioning regimen that can improve access and outcomes compared to current non-targeted conditioning regimens for hematological malignancies."

"In addition to the impending pivotal trial results, we look forward to presenting survival data from the Actimab-A CLAG-M combination trial in Q4 2022. Prior results demonstrated a 67% ORR and high rates of MRD negativity in heavily pre-treated fit patients with r/r AML. Actinium also anticipates providing updates by year-end which will demonstrate the progress we are making with our research programs and collaborations, including our Iomab-ACT program for conditioning prior to CAR-T and other cellular therapies. Finally, our strong balance sheet provides ample runway through mid-2025 which enables us to deliver value creation driven by key clinical data, regulatory milestones and R&D program advancement. These updates will enable Actinium to continue to demonstrate its position as the leading, late-stage radiotherapeutics company developing highly differentiated product candidates in diseases with high unmet or underserved medical needs", added Mr. Seth.

Iomab-B and the Pivotal Phase 3 SIERRA Trial

Iomab-B has the potential to become a first-in-class, targeted radiotherapy to improve patient access to potentially curative BMT, while improving outcomes for patients with advanced blood cancers. The pivotal Phase 3 SIERRA trial will compare outcomes between patients age 55+ with active, r/r AML that receive Iomab-B and BMT and patients who receive physician's choice of salvage therapy, as there is no standard of care for this patient population.

- Topline efficacy and safety data from the SIERRA trial to be reported in Q4 2022
- The primary endpoint for the SIERRA trial is durable Complete Remission (dCR) of at least 180 days
- Secondary endpoints for the SIERRA trial are Overall Survival and Event-Free Survival
- At the annual meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR) in May, Actinium reported an approximate 5x greater difference in the number of patients potentially evaluable for the dCR primary endpoint at 100-days post-BMT in the Iomab-B arm compared to the control arm at full enrollment (153 patients)[1]
- 100% (66/66) of patients receiving Iomab-B accessed BMT and engrafted without delay and 100% (40/40) receiving Iomab-B via crossover from the control arm after failing to achieve a remission accessed BMT and engrafted without delay
- 18% (14/77) of patients randomized to the control arm received a BMT
- Lower rates of 100-day, non-relapse transplant-related mortality were reported in the Iomab-B arm (9%) and the crossover arm (5%) compared to control arm (14%)
- Statistically significant lower rates of sepsis (p=0.002) were reported in patients receiving Iomab-B (5.3%) compared to the control arm (23.7%)
- Iomab-B is the only CD45 targeting drug candidate in Phase 3 clinical development
- Iomab-B has patent protection until 2037, as well as Orphan Drug Designation in the U.S. and Europe
- In April 2022, Actinium licensed the EUMENA commercial rights for Iomab-B to Immedica AB for an upfront payment of $35 million, up to $417 million in potential

regulatory and sales milestones, and mid-twenty percent royalties

Actimab-A: CD33 Targeting Alpha Therapy Program

Actimab-A is the only CD33 targeting radiotherapy in development and utilizes the alpha-emitting radioisotope Actinium-225 (Ac-225), the most potent, medically available, cell-killing isotope. Actinium is developing Actimab-A as a potential backbone therapy for patients with advanced AML using the differentiated mechanism of action of the radioisotope with other therapeutic modalities. Actimab-A is currently being studied in combination with the salvage chemotherapy CLAG-M in patients with r/r AML who are fit for intensive therapy and with the Bcl-2 inhibitor Venetoclax in patients with r/r AML who are unfit for intensive therapy.

- Overall survival data from the Phase 1 Actimab-A + CLAG-M combination trial expected in Q4 2022
- Data from the Phase 1 trial showed 72% MRD negativity rate in patients receiving Actimab-A + CLAG-M, which compares favorably to 39% MRD negativity rate with CLAG-M alone[2]
- 80% overall response rate (CR/CRp/MLFS) in patients receiving less than four lines of prior therapy with 10 complete remissions across all four dose cohorts
- 75% of patients proceeded to a bone marrow transplant, excluding patients with prior transplant experience
- No 30-day mortality

Technology Platform and Research Programs and Collaborations

Actinium is advancing multiple internal research programs and collaborations at the forefront of targeted radiotherapy innovation leveraging its proprietary technology platform, know-how and strong clinical experience. With an intellectual property estate of over 190 patents, Actinium is at the forefront of innovation related to development of Ac-225 based therapies. Actinium has generated and presented the first ever data of CD38 and HER3 targeting Ac-225 therapies as well as the first CD47 immune checkpoint targeted radiotherapy combinations with HER2 in solid tumors and CD33 in blood cancers. This research and differentiated development capabilities have resulted in collaborations focused on solid tumor theranostics with Astellas, HER3 targeting radiotherapies for solid tumors with AVEO Pharmaceuticals and CD47 immune checkpoint targeted radiotherapy combinations with EpicentRx. Actinium is making strong progress with its ongoing research collaborations and internal research programs including its Iomab-ACT program for cell and gene therapy conditioning. Select updates from these programs and collaborations are expected by year-end.

Financial Condition and Outlook

- Cash and cash equivalents of approximately $116.3 million as of June 30, 2022 including $35 million upfront payment from Iomab-B EUMENA licensing agreement with Immedica AB
- Actinium anticipates that its current cash and cash equivalents will be sufficient to fund operations through mid-2025

References:

1. Gyurkocza et al. TCT 2022 Presentation. High Rates of Transplantation in the Phase III SIERRA Trial Utilizing Anti-CD45 Apamistamab with 131-Iodine (Iomab-B) Conditioning with Successful Engraftment and Tolerability in Relapsed/Refractory Acute Myeloid Leukemia Patients after Lack of Response to Conventional Care and Targeted Therapies
2. Abedin et al. ASH 2021 Presentation. Lintuzumab-Ac225 in Combination with CLAG-M Yields High MRD (-) Responses in R/R AML with Adverse Features: Interim Results of a Phase I Study

About Iomab-B and the Pivotal Phase 3 SIERRA Trial

Iomab-B (I-131 apamistamab) targets CD45, an antigen widely expressed on leukemia and lymphoma cancer cells, immune cells and bone marrow stem cells. Monoclonal antibody apamistamab is linked to the radioisotope iodine-131 (I-131), and emits energy against targeted cells, thereby destroying a patient's cancer cells and ablating their bone marrow so they can receive a bone marrow transplant. By targeting the bone marrow with I-131, Iomab-B may reduce the side effects of non-targeted chemotherapy and external radiation on most healthy tissues. Iomab-B has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and has patent protection through 2037.

The pivotal Phase 3 SIERRA trial is a 153-patient, randomized clinical trial, studying Iomab-B compared to physician's choice of salvage therapy in patients with active, relapsed or refractory acute myeloid leukemia (r/r AML) age 55 and above. The SIERRA trial is the only randomized Phase 3 trial with BMT being the intent for this patient population. The control arm of SIERRA included over 20 single agents or combination treatment options based on physician's choice, including salvage chemotherapy and recently approved targeted agents including Bcl-2 inhibitor (Venetoclax), FLT3 inhibitors and IDH 1/2 inhibitors as there is no standard of care for this patient population. The SIERRA trial enrolled patients at 24 leading transplant centers in the United States and Canada. The SIERRA trial completed patient enrollment in 3Q 2021, and topline data is expected to be reported in 4Q 2022.

About Actinium's Technology Platform and Research Programs and Collaborations

Actinium has extensive experience in the development of targeted radiotherapies leveraging its clinical experience in over 600 patients from its Beta and Alpha particle-based programs. Actinium has developed targeted radiotherapies against multiple validated targets (CD45, CD33, CD38, HER2, HER3 and other undisclosed targets) with multiple radioisotopes (Iodine-131, Actinium-225 and Lutetium-177). Actinium is on the leading edge of targeted radiotherapy research and development including collaborations with Astellas focused on solid tumor theranostics, AVEO pharmaceuticals focused on HER3 targeted radiotherapy for solid tumor indications and EpicentRx exploring targeted radiotherapy CD47 immune check point inhibitor combinations. Actinium's patent portfolio has over 190 patents and includes key intellectual property underlying Iomab-B, Actimab-A, gold-standard linker technology, proprietary methods for manufacturing highly pure Ac-225 and multiple novel targeted radiotherapy combinations and applications.

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 radiotherapies 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 bone marrow transplant, gene therapy or adoptive cell therapy, such as CAR-T, to enable engraftment of these transplanted cells with minimal toxicities. For more information about Actinium, please visit 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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