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Actinium Pharmaceuticals, Inc. Announces Clinical Trial Site Expansion in its Multi-Center Phase 1/2 Actimab-A Venetoclax Combination Trial

- Continued site additions to support enrollment and proof of concept results in 2021

NEW YORK, Oct. 6, 2020 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company") today announced that the University of Louisville and the Ochsner Clinic in New Orleans, Louisiana are now active trial sites in its Phase 1/2 Actimab-A venetoclax combination trial for patients with Relapsed or Refractory ("R/R") Acute Myeloid Leukemia ("AML") age 18 and above. These sites join UCLA Medical Center, where the trial is being led by Gary Schiller, MD, Professor, Hematology-Oncology and Director, Hematologic Malignancy/Stem Cell Transplant Program. Both sites participated in Actinium's Phase 2 trial with Actimab-A as a single agent that produced remission rates as high as 69% with minimal non-hematologic toxicities in patients newly diagnosed with AML. The Phase 2 trial results together with a synergistic mechanism of action with venetoclax demonstrated in pre-clinical studies are driving this combination trial with an initial focus on the high unmet needs of R/R patients including those who have relapsed or do not respond to treatment with venetoclax based regimens.



"Venetoclax is now a mainstay in the AML treatment armamentarium, but the lack of durable remissions, particularly in patients with relapsed or refractory disease who may not respond to venetoclax at all, is an area we are committed to addressing. Our pre-clinical data indicate that Actimab-A is synergistic with venetoclax in venetoclax-resistant cell lines and have documented a reduction of Mcl-1 as the mechanism. Our clinical trial seeks to demonstrate improved response rates and response durations without added toxicities with the combination of Actimab-A and venetoclax. Given the preclinical data, the targeted nature of Actimab-A, and the minimal non-hematologic toxicity profile, we think that the combination with venetoclax has great promise" said Dr. Mark Berger, Actinium's Chief Medical Officer. Dr. Berger added, "We are delighted to once again be working with the University of Louisville and the Ochsner Clinic who were among the top enrolling sites in our Phase 2 single-agent Actimab-A trial. We look forward to activating additional sites on this

important trial as we work to advance treatment options for patients with AML."

Actinium recently announced that the first dose cohort in the Phase 1 portion of the Actimab-A venetoclax combination trial has been complete and enrollment of the second dose cohort has been initiated. Actinium expects continued site additions and anticipates proof of concept results from the Phase 1 portion of the trial in 2021.

Rationale for Actimab-A Venetoclax Combination Trial

This Phase 1/2 trial is a multicenter, open label trial of Actimab-A (lintuzumab-Ac225) added to venetoclax for patients with CD33 positive relapsed/refractory (R/R) Acute Myeloid Leukemia. In a poster presentation at the American Association of Cancer Research (AACR) Annual Meeting 2019, Actimab-A was shown to be synergistic with venetoclax in venetoclax resistant cell lines, by depleting MCL-1, a protein shown to mediate resistance to venetoclax. The Phase 1 portion of the study is designed to determine the maximum tolerated dose (MTD) of Actimab-A added to venetoclax for R/R AML. The Phase 2 portion of the trial will assess the percentage of patients with Overall Response (CR + CRh) up to six months after the start of the treatment without receiving other AML therapies. The trial will enroll R/R AML patients who have been treated with venetoclax as well as venetoclax-naïve patients. At the 1.0 uCi/kg dose, Actimab-A is administered on Day 5 of each cycle for four cycles and venetoclax is taken on Days 1-21 of each cycle for up to 4 cycles. Each cycle is 28 days, with a potential to expand to 42 days to allow for full hematologic recovery. Gary Schiller, MD, Professor, Hematology-Oncology and Director, Hematologic Malignancy/Stem Cell Transplant Program at the UCLA Medical Center is the Principal Investigator for this study.

More information on the clinical trial design is available at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03867682) (NCT03867682).

About Actinium Pharmaceuticals, Inc.

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 kill patient's cancer cells and certain immune cells prior to a BMT or Bone Marrow Transplant, CAR-T and other cell therapies or gene therapy 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, 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 fifty percent enrolled and promising single-agent, feasibility and safety data has been highlighted at ASH, TCT, ASCO and SOHO annual meetings. Beyond lomab-B, 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. Underpinning our clinical programs is our proprietary AWE (Antibody Warhead Enabling) technology platform. This is where our intellectual property portfolio of over 120 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.


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, including but not limited to, statements relating to the Company's expectations regarding the intended use of proceeds of the public offering. 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 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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