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# Actinium Pharmaceuticals, Inc. and Immedica Announce Commercialization Agreement for Iomab-B (131I apamistamab) in Europe, the Middle East and North Africa

*-Potential for up to \$452 million in milestone payments with royalties in the mid-twenty percent range*

*-Actinium receives \$35 million upfront payment*

*-Immedica obtains exclusive rights to Iomab-B in Europe, the Middle East and North Africa*

NEW YORK and STOCKHOLM , April 12, 2022 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (Actinium or the Company) a leader in the development of targeted radiotherapies for patients with unmet needs, and Immedica Pharma AB ("Immedica") today announced entering a license and supply agreement for Iomab-B, an Antibody Radiation Conjugate comprised of apamistamab, a CD45 targeting antibody, and the radioisotope iodine-131 that is being developed for targeted conditioning to facilitate bone marrow transplant (BMT) and other cell and gene therapies. A pivotal Phase 3 trial, **Study of Iomab-B versus Conventional Care in Elderly, Relapsed or Refractory Acute Myeloid Leukemia (SIERRA)**, of Iomab-B completed patient enrollment in the third quarter of 2021 with topline data expected in the third quarter of 2022. BMT is the only potentially curative treatment option for patients with active, relapsed or refractory acute myeloid leukemia (AML).



Sandesh Seth, Actinium's Chairman and CEO, said, "Immedica has established a strong team and impressive capabilities to commercialize specialty products in Europe, the Middle East and North Africa. Europe and the MENA countries are key commercial markets for Iomab-B, with a large addressable AML patient population and access to a strong BMT community that is highly concentrated with select leading centers performing a majority of the BMT procedures. Despite multiple drug approvals for patients with AML in recent years, curative outcomes and access to potentially curative BMT are severely lacking, particularly

for patients with active, relapsed or refractory disease. We are excited to partner with Immedica to work to bring lomab-B to patients with AML in Europe, the Middle East and North Africa who may benefit from a potentially curative transplant."

"We are excited about the opportunity to make lomab-B accessible for patients in Europe, the Middle East and North Africa. It is clear there is a large medical need for these AML patients, which we believe will be addressed by this new innovative treatment. We also look forward to deepening our collaboration with Actinium to bring the best possible support to AML treatment centers and health care professionals in Europe, the Middle East and North Africa", says Anders Edvell, CEO at Immedica.

Under the terms of the agreement, Actinium will receive an upfront payment of \$35 million and will be eligible to receive an additional \$417 million in regulatory and commercial milestones as well as royalties in the mid-twenty percent range on net sales. Immedica receives commercialization rights in Europe and MENA countries. Actinium retains all rights related to lomab-B in the United States and the rest of the world, and will be responsible for certain clinical and regulatory activities and the manufacturing of lomab-B.

Shadow Lake Group (SLG) served as the advisor to Immedica.

### **About lomab-B**

lomab-B (I-131 apamistamab), via the monoclonal antibody apamistamab, targets CD45, an antigen widely expressed on leukemia and lymphoma cancer cells, immune cells and bone marrow stem cells. Apamistamab is linked to the radioisotope iodine-131 (I-131) and once attached to its target cells emits energy that travels about 100 cell lengths, destroying a patient's cancer cells and ablating their bone marrow. By carrying iodine-131 directly to the bone marrow in a targeted manner, lomab-B may avoid the side effects of non-targeted chemotherapy and external radiation on most healthy tissues while effectively killing the patient's cancer (induction) and marrow cells (myeloablation) including those in bone marrow niches due to the "crossfire" effect enabled by the I-131 radioisotope.

lomab-B was licensed from the Fred Hutchinson Cancer Research Center where it was studied in nearly 300 patients, in multiple clinical trials in 6 blood cancer indications. lomab-B is being studied in the pivotal Phase 3 SIERRA (Study of lomab-B in Relapsed or Refractory AML) trial, a 150-patient, randomized controlled clinical trial in patients with active, relapsed or refractory Acute Myeloid Leukemia (AML) who are age 55 and above. If granted approval, lomab-B is intended to prepare and condition patients for a bone marrow transplant, also referred to as a hematopoietic stem cell transplant, in a potentially more efficacious manner and with a more beneficial safety profile than the non-targeted intensive chemotherapy conditioning that is the current standard of care in bone marrow transplant conditioning. A bone marrow transplant is often considered the only potential cure for patients with certain blood-borne cancers and blood disorders. lomab-B has been granted Orphan Drug Designation from the U.S. FDA and the European Medicines Agency (EMA). lomab-B also has patent terms extending to at least 2036/2037 in the US and EU. In addition, Actinium received positive Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the EMA indicating that the Phase 3 SIERRA trial design, primary endpoint and planned statistical analysis are acceptable as the basis for a Marketing Authorization Application.

### **About the SIERRA Phase 3 Trial**

The SIERRA trial is a 150-patient, randomized clinical trial, studying lomab-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 completed enrollment in the third quarter of 2021 with the last patient receiving a BMT in the fourth quarter of 2021. Topline data from the SIERRA trial is expected in the third quarter of 2022. In SIERRA, patients receiving lomab-B, those achieving a remission after salvage therapy or those patients not achieving remission after salvage therapy that crossed over to receive lomab-B were offered a BMT, which is the only treatment option with curative potential for patients with active r/r AML. The SIERRA trial is the only randomized Phase 3 trial to offer BMT to 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.

### **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 (lomab-B) has been studied in over four hundred patients including the pivotal Phase 3 Study of lomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning that complete patient enrollment in the third quarter of 2021. Topline data from the SIERRA trial is expected in the third quarter of 2022. lomab-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 170 patents and patent applications, know-how, collective research and expertise in the field are leveraged to design and study novel targeted radiotherapies and combinations to strategically bolster our pipeline. Our AWE technology platform is currently being utilized in collaborative research partnerships with Astellas Pharma, Inc. for solid tumor theranostics, with AVEO Oncology to create an Actinium-225 HER3 targeting radiotherapy for solid tumors, and with EpicentRx, Inc. to create targeted radiotherapy combinations with their novel, clinical stage small molecule CD47-SIRPα inhibitor. Website: <https://www.actiniumpharma.com/>

### **About Immedica AB**

Immedica is a fast-growing private niche pharma group with its headquarter in Stockholm,

Sweden, and commercial coverage across Europe and the Middle East. Immedica has significant know-how and experience in commercialization of specialty care products across Europe and the Middle East, and the company's management team has an outstanding track record of operating niche pharma products internationally. Immedica has capabilities to provide optimal access of specialty care medicines to patients with significant medical needs, including key areas such as regulatory affairs, pharmacovigilance, medical affairs, pricing & reimbursement, quality assurance and product distribution.

More information is available at [www.immedica.com](http://www.immedica.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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