

March 19, 2019



## **Actinium Appoints Accomplished FDA and Industry Professional Mamata Gokhale, Ph.D., RAC as Vice President, Global Head of Regulatory Affairs**

- Dr. Gokhale brings to Actinium extensive regulatory knowledge and FDA experience from over 20 years in regulatory positions of increasing responsibility**
- Recent Cell & Gene Therapy experiences align with Actinium's targeted conditioning portfolio for Bone Marrow Transplant, CAR-T and Adoptive Cell Therapies**

NEW YORK, March 19, 2019 /PRNewswire/ -- Actinium Pharmaceuticals, Inc. (NYSE American: ATNM), announced today the appointment of Mamata Gokhale, Ph.D., RAC as Vice President, Global Head of Regulatory Affairs. In this role, Dr. Gokhale will be responsible for developing and implementing a comprehensive clinical regulatory strategy across Actinium's portfolio of ARC or Antibody Radiation-Conjugate product candidates for targeted conditioning. These include the pivotal Phase 3 trial for Actinium's lead candidate lomab-B, therapeutic and combination trials of Actimab-A, as well as potential next-generation ARC's resulting from its AWE or Antibody Warhead Enabling technology platform. Dr. Gokhale brings over 20 years of regulatory affairs experience to Actinium that began at the U.S. Food and Drug Administration or FDA as a reviewer before transitioning to industry where she worked at biotechnology and pharma companies including Amgen, Watson Pharma, Neumedicines Inc. and global Contract Research Organizations including Voisin Consulting Life Sciences and Paraxel International. At Amgen Dr. Gokhale successfully contributed to approvals and expansion of Prolia®, Xgeva®, Vectibix® and Sensipar®.

Dr. Gokhale, said, "I am particularly excited that I will be able to apply my skills most immediately to lomab-B given it is in a pivotal Phase 3 trial. Throughout my career, I have been passionate about ushering novel candidates to approvals and where possible by using regulatory strategy to affect a better development plan and/or label. Actinium's portfolio of ARC's can represent opportunities to apply my regulatory strategy in multiple ways by leveraging the extensive clinical history of the lomab-B program in multiple hematologic indications. I am also excited to have the opportunity to impact development of the lomab-ACT program, which represents an exciting opportunity in CAR-T and cell therapy, and also Actinium's combination trials."

Familiarity with all phases of drug development allows Dr. Gokhale to align nonclinical and clinical development with regulatory strategies and implementing them at regional and global levels and seamlessly transition between INDs, NDAs/BLAs (United States) and CTAs/IMPDs, MAAs (EU). Dr. Gokhale's regulatory experience includes developing regulatory strategies for small molecules, monoclonal antibodies, cell and gene therapies, leading and managing regulatory interactions, requesting orphan drug, breakthrough therapy and fast track designations and pediatric vouchers, resolution of clinical hold issues, developing target product profiles, core data sheets and conducting labeling negotiations.

Sandesh Seth said, "Dr. Gokhale's experience at the FDA, her extensive FDA interactions while in industry and her cell and gene therapy experience are invaluable as we begin to undertake preparations for potential regulatory submissions for the lomab-B Phase 3 SIERRA trial and progress several first in class or novel programs including Actimab-MDS, lomab-ACT and other combination trials. With two pivotal programs now in our rapidly expanding pipeline given the broad applicability of ARC's and investigator interest, I am excited to have Dr. Gokhale join the Actinium team to lead and shape our regulatory strategies and to enable us to achieve our vision of being a leading specialty oncology company developing ARC therapies for patients with unmet or underserved needs."

Dr. Gokhale also has highly complementary and relevant clinical experience that includes developing study concept documents and protocols, interacting with Key Opinion Leaders and data safety monitoring committees, drafting and reviewing Protocols and Investigator Brochures, compiling and reviewing clinical study reports, project management, conducting study feasibility, evaluating budgets for clinical trials, pharmacovigilance and resolution of audit findings.

Dr. Gokhale earned her Ph.D. from the University of Bombay (accredited in United States), trained as postdoctoral fellow at Johns Hopkins University (School of Medicine and Johns Hopkins Bloomberg School of public Health) and as a staff fellow at the FDA. Dr. Gokhale has the RAC certification from RAPS and Associate training in the ISO 9001:2000 Quality Management System. Dr. Gokhale maintains academic ties with the University of Southern California by lecturing at its International Center for Regulatory Science.

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

Actinium Pharmaceuticals Inc. is focused on improving patient access and outcomes to cellular therapies such as BMT or Bone Marrow Transplant and CAR-T with its proprietary, chemotherapy free, targeted conditioning technology. Actinium is the only company with a multi-disease, multi-target, drug development pipeline focused on targeted conditioning. Its targeted conditioning technology is enabled by ARC's or Antibody Radiation-Conjugates that combine the targeting ability of monoclonal antibodies with the cell killing ability of radioisotopes. Actinium's pipeline of clinical-stage targeted conditioning ARC's are designed to target the antigens CD45 and CD33 for patients with a broad range of hematologic malignancies including AML or Acute Myeloid Leukemia, MDS or Myelodysplastic Syndrome and MM or Multiple Myeloma.

lomab-B, Actinium's lead targeted conditioning product candidate, is currently enrolling patients in the pivotal Phase 3 SIERRA trial in patients age 55 and older, with active, relapsed or refractory AML. lomab-B (Iodine-131 apamistamab), combines the anti-CD45 monoclonal antibody labeled with iodine-131 for myeloablation prior to a bone marrow transplant. CD45 is expressed on leukemia, lymphoma and normal immune cells. lomab-B

has been studied in over 300 patients in 10 clinical trials in numerous hematologic diseases. Actinium's lomab-ACT program is an expansion of its CD45 program that is intended to be a universal, chemotherapy-free solution for targeted lymphodepletion prior to CAR-T. Through targeted lymphodepletion, the lomab-ACT program is expected to improve CAR-T cell expansion, reduce CAR-T related toxicities and expand patient access to CAR-T treatment and potentially other adoptive cell therapies. Due to its lower payload dose, lymphodepletion with the lomab-ACT program may be accomplished through a single outpatient infusion. Actinium intends to advance its lomab-ACT program with CAR-T focused collaborators from academia and industry.

Actinium's pipeline also includes a potentially best-in-class CD33 program with its ARC comprised of the anti-CD33 antibody lintuzumab labeled with the alpha-particle emitter actinium-225. Its CD33 program is currently being studied in multiple Phase 1 clinical trials for targeting conditioning, in combinations and as a therapeutic in multiple diseases and indications including AML, MDS and MM. Notable trials include the planned pivotal trial for Actimab-MDS for targeted conditioning prior to a BMT for patients with high-risk MDS, that is expected to initiate in 2019, and two Actimab-A venetoclax combination trials including the initiated Phase 1 doublet trial and the planned triplet trial with a hypomethylating agent.

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 cancers. The AWE technology 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 110 patents covering composition of matter, formulations, methods of use and also methods of manufacturing the radioisotope Actinium-225 in a cyclotron.

More information is available at [www.actiniumpharma.com](http://www.actiniumpharma.com) and our Twitter feed @ActiniumPharma, [www.twitter.com/actiniumpharma](https://twitter.com/actiniumpharma).

#### **Forward-Looking Statements for Actinium Pharmaceuticals, Inc.**


This press release contains "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 performance of Actinium which Actinium 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, including without limitation its most recent annual report on Form 10-K for the period ended December 31, 2018, subsequent quarterly reports on Form 10-Q and Form 8-K, each as amended and supplemented from time to time.

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