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Actinium appoints Mamata Gokhale as VP, Global Head of Regulatory affairs

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Dr. Gokhale brings to Actinium extensive regulatory knowledge and FDA experience from over 20 years in regulatory positions of increasing responsibility

Actinium Pharmaceuticals announced 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 Iomab-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 Iomab-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 Iomab-B program in multiple hematologic indications. I am also excited to have the opportunity to impact development of the Iomab-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.

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.