



NEW YORK, NY - 03/14/16 - Actinium Pharmaceuticals, Inc. (NYSE MKT: ATNM) ("Actinium" or the "Company"), a biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers provided investors with an update on its business progress following the filing of its 2015 10-K.

Recent Highlights

- Received clearance from the FDA for its lomab-B IND filing in mid-December 2015 enabling the Company to proceed with a pivotal Phase 3 clinical trial.
- Selected Medpace, Inc. as its Contract Research Organization (CRO) for the pivotal Phase 3 lomab-B clinical trial.
- Filed for Orphan Drug Designation for lomab-B in November 2015.
- Significant company presence focused on physician interaction at the February 2016 annual meetings of the Center for International Blood & Marrow Transplant Research (CIBMTR) and American Society of Blood and Marrow Transplantation (ASBMT), referred to as the BMT Tandem Meetings.
- On track to start Phase 2 portion of Actimab-A trial mid-2016.

- Strategically added key senior level professionals to the clinical development team including highly experienced clinical operations and product development professionals, bringing total employee count to 17 as of March 11, 2016.
- Filed two provisional patent applications related to lomab-B to bolster intellectual property portfolio.
- Significantly increased capital markets activity with presentations at 5 investor oriented conferences in Q1 2016 and coverage by 2 equity research analysts in past several months.

lomab-B: Dedication to execution of single, pivotal Phase 3 trial

In the fourth quarter of 2015 Actinium filed and received clearance of the Investigational New Drug (IND) application for lomab-B. This event signaled the elimination of a major risk factor regarding the availability of bioequivalent clinical supplies for lomab-B. The Company is now focused on executing the single, pivotal trial for lomab-B based on which the company believes it will be able to file a Biologics License Application with the US Food and Drug Administration. In anticipation of this trial, Actinium has added experienced staff members in clinical development, clinical operations and product development to meet the increased levels of activity. Also, the Company has engaged Medpace, Inc. as its CRO to help manage the pivotal Phase 3 lomab-B trial. Medpace is a 2,400 person global organization and was selected due to their expertise and experience in hematology and bone marrow transplant. Actinium applied for Orphan Drug Designation for lomab-B in Q4 2015 and is awaiting the FDA's response to its application. Finally, Actinium has initiated the process to obtain EU orphan designation for lomab-B and has engaged a leading regulatory consulting firm to assist the Company with its efforts.

lomab-B is a potentially revolutionary treatment option for refractory and relapsed Acute Myeloid Leukemia (AML) patients over the age of 55. lomab-B is intended to be an induction and conditioning agent prior to a hematopoietic stem cell transplantation (HSCT) or Bone Marrow Transplant (BMT). The pivotal Phase 3 trial size is set at 150 patients, randomized 1:1, with 75 patients per arm. The primary endpoint is durable complete remission, defined as a complete remission lasting at least 6 months, and the secondary endpoint will be overall survival at one year. There are currently no effective treatments approved by the FDA for AML

in this patient population and there is no defined standard of care. In its proof of concept trial, lomab-B results showed that it tripled the rate of survival at one year and twenty percent survived at two years. These results are generating strong support for the trial by many of the leading specialists in the field, as evidenced by strong support from Key Opinion Leaders (KOLs) that was seen at the BMT Tandem Meetings.

Actimab-A: Results from Phase 1 portion of Phase 1/2 trial presented at major medical conference

Data from the fourth and final cohort of the Phase 1 portion of the Actimab-A clinical trial, in which patients were being treated at 2.0 µCi/kg dose level of Actimab-A, up from 0.5, 1.0 and 1.5 µCi/kg per fractionated dose, were presented at the American Society of Hematology 2015 Annual Meeting along with results from previous cohorts. In total, 4 of 14 (29%) evaluable patients had an objective response with 1 complete remission (CR), 2 complete remissions with incomplete platelet count recovery (CRp) and 1 complete remission with incomplete blood count recovery (CRi) reported. Bone marrow blast reductions were seen in 8 of 11 (73%) evaluable patients. The Phase 2 portion of the trial is expected to commence by mid-2016.

Increased capital markets activity

In 2015, the Company presented at 11 investor conferences. In Q1 2016, the Company has presented or will present at a total of 5 investor conferences including:

- Biotech Showcase -- January 11, 2016, San Francisco, CA
- BIO CEO & Investor Conference -- February 9, 2016, New York, NY
- Cowen and Company 36th Annual Healthcare Conference -- March 8, 2016, Boston, MA
- BioCentury Future Leaders in the Biotech Industry Conference -- March 11, 2016, New York,

NY

· 28th Annual ROTH Conference -- Laguna Niguel, CA, March 15, 2016

In addition to increased conference activity, the Company has attracted the attention of equity research analysts and is now covered by:

· Vernon Bernadino -- FBR & Co.

· Andrew Fein -- H.C. Wainwright & Co.

The Company believes that these efforts increase awareness for and raise the profile of Actinium with investors and the capital markets. Management will continue these activities with the goal of increasing shareholder value and liquidity.

Investor oriented events planned for Q2 2016

An investor oriented event will be held in Q2 2016 focused on lomab-B and its upcoming pivotal Phase 3 trial. In addition, the Company will also host other KOL events throughout the year in order to update and educate investors about its progress. Actinium had originally anticipated holding an R&D day in Q1 2016, however, decided not to hold the event heeding the advice of its investor relations advisors. The key driver in deciding to hold a series of KOL throughout 2016 versus hosting a single R&D day was to mitigate the risk that the R&D day could be disregarded by biotech institutional investors given the uncertainty in the biotech capital markets. It is anticipated that an additional KOL day focused on Actimab-A will be held subsequent to the lomab-B KOL day as well as other events in the second half of 2016.

Company on track to transform profile from focus on early-stage to later-stage clinical development during 2016.

Actinium's profile is expected to change significantly in 2016 as the Company transitions to a later stage clinical development enterprise upon the start of the pivotal Phase 3 lomab-B trial and the Phase 2 Actimab-A trial. Several milestones are anticipated for the Company in 2016 including:

- Orphan Drug Designation for lomab-B.
- Clinical trial site and IRB contracts executed with top BMT centers.
- Initiation of pivotal Phase 3 lomab-B clinical.
- Filing of EU Orphan Medicine Designation applications for Actimab-A.
- Progress on EU Orphan Medicine application process for lomab-B.
- Initiation of Phase 2 portion of Actimab-A Phase 1/2 clinical trial.
- Interim data from Actimab-A Phase 2 clinical trial.
- Enrollment updates from lomab-B clinical trial via Data Safety Monitoring Board readouts.
- KOL days focused on lomab-B and Actimab-A, respectively.
- Pipeline and strategic initiative updates.

Actinium entered 2016 with a strong balance sheet with approximately \$25 million cash and has built a team comprised of highly motivated and experienced professionals led by proven pharmaceutical executives. These strengths along with a dedication to improving the lives of Acute Myeloid Leukemia patients and patients suffering from other difficult to treat cancers with targeted payload immunotherapeutics will drive the Company's efforts in 2016.

About Actinium Pharmaceuticals

Actinium Pharmaceuticals, Inc. (www.actiniumpharma.com) is a New York-based biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers. Actinium's targeted radiotherapy products are based on its proprietary delivery platform for the therapeutic utilization of alpha-emitting actinium-225 and bismuth-213 and certain beta emitting radiopharmaceuticals in conjunction with monoclonal antibodies. The Company's lead radiopharmaceutical product candidate lomab-B is designed to be used, upon approval, in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. The Company plans to conduct a single, pivotal, multicenter Phase 3 clinical study of lomab-B in refractory and relapsed AML patients over the age of 55 with a primary endpoint of durable complete remission. The Company's second product candidate, Actimab-A, is continuing its clinical development in a Phase 1/2 trial for newly diagnosed AML patients over the age of 60 in a single-arm multicenter trial.

Forward-Looking Statement for Actinium Pharmaceuticals, Inc.

This news release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause actual results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Actinium Pharmaceuticals undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

Actinium Pharmaceuticals Files Annual Report and Provides Investor Update

Écrit par Actinium Pharmaceuticals

Vendredi, 18 Mars 2016 12:17 - Mis à jour Vendredi, 18 Mars 2016 12:23
