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EQUITY RESEARCH
Company Report

May 20, 2015

Actinium Pharmaceuticals (ATNM - $ 2.50)

Healthcare/Biotechnology

Encouraging Actimab-A in First-line Elderly AML Phase I/II Data Update at the ASCO

Ticker:	**ATNM**
Rating:	**Buy**
Price Target:	**$ 17.00**

This morning, ATNM reported that the company will provide an update at the ASCO meeting for the Actimab-A in first-line elderly acute myeloid leukemia (AML) Phase I/II trial.

- **Details.** The presentation will discuss clinical data from the first three dose cohorts. The dose limiting toxicities (DLT) has not been reached in the third cohort (n=3). Further, two out of three Actimab-A treated patients achieved complete remission with different degrees of hematological recovery (CRi). It is noted that one patient achieved CRi of the two earlier lower dose Actimab-A-treated cohorts. The presentation is entitled "Phase I trial of α-particle therapy with actinium-225 (225Ac)-lintuzumab (anti-CD33) and low-dose cytarabine (LDAC) in older patients with untreated acute myeloid leukemia (AML)." ATNM has started the study of the fourth and last cohort (2.0 μCi/kg per dose) of the Phase I portion of the trial. As a reminder, the Phase I/II study is an open-label trial with two study portions: Phase I is a dose-escalating study (with n up to 21) designed to identify the MTD of Actimab-A+ low dose cytarabine (LDAC), while the Phase II portion is to treat AML patients at MTD with Actimab-A+LDAC with n~ 47.

- **Implications.** It is well recognized that the outlook for the elderly AML patients is poor, mainly due to the intolerance to the current therapies and multiple co-morbidities presented by these patients. As such, estimates are that only <30% of the elderly (60+ years old) AML patients undertake standard high intensity chemotherapies, while nearly half of elderly patients seek treatment in various clinical studies. In addition, approximately 20% of patients receive only supportive care. We therefore view the Actimab-A-data to be presented at the ASCO as very encouraging based on its overall satisfactory safety profile. More important is the efficacy signal demonstrated so far even though the number of patients is small. We look forward to more detail to be presented at the ASCO and the outcome from the next dose cohort. Together, we believe today's news bodes well for a positive outlook for Actimab-A treatment for a tough-to-treat patient population.

- **Action.** We are reiterating our Buy rating and $17 target price to reflect the company's continued advancements of the two leading products. Our target price is supported by peer comparable and probability-adjusted-NPV-driven sum-of-the-parts analyses.

Trading Data:

Last Price (05/20/2015)	$ 2.50
52–Week High (6/2/2014)	$ 13.70
52–Week Low (5/18/2015)	$ 2.31
Market Cap. (MM)	$ 90
Shares Out. (MM)	36

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.09A	-0.21	-0.23	-0.23	-0.77	NM
FY-14A	-0.66	0.14	-0.21	-0.18	-0.90	NM
FY-13A	0.02	-0.10	-0.03	-0.25	-0.36	NM
FY-12A	NA	NA	NA	NA	-4.46	NM

Source: Laidlaw & Company estimates

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Abstract: Phase I trial of α-particle therapy with actinium-225 (225Ac)-lintuzumab (anti-CD33) and low-dose cytarabine (LDAC) in older patients with untreated acute myeloid leukemia (AML.

Session: Leukemia, Myelodysplasia, and Transplantation; Sunday May 31, 8:00 AM to 11:30 AM;

Location: S Hall A; Abstract No: 7050; Poster Board Number: Board #39

Joseph G. Jurcic, Farhad Ravandi, John M. Pagel, Jae Hong Park, B. Douglas Smith, Dan Douer, Moshe Yair Levy, Elihu Estey, Hagop M. Kantarjian, Dennis Earle, Dragan Cicic, David A. Scheinberg; Columbia University Medical Center, New York, NY; The University of Texas MD Anderson Cancer Center, Houston, TX; Swedish Cancer Institute, Seattle, WA; Memorial Sloan Kettering Cancer Center, New York, NY; The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD; Texas Oncology-Baylor Charles A. Sammons Cancer Center, Dallas, TX; University of Washington/Seattle, Seattle, WA; Actinium Pharmaceuticals, Inc., New York, NY

Background ^{225}Ac-lintuzumab consists of a radiometal that emits 4 α-particles linked to an anti-CD33 antibody. A phase I trial showed safety and efficacy of ^{225}Ac-lintuzumab in relapsed AML. We are conducting a multicenter, phase I trial to determine the maximum tolerated dose (MTD), toxicity, and activity of fractionated-dose ^{225}Ac-lintuzumab combined with LDAC.

Methods Patients ⩾ 60 yrs with untreated AML not suitable for standard induction were eligible. Patients received LDAC 20 mg BID for 10 d every 4-6 wks for up to 12 cycles. During Cycle 1, 2 doses of ^{225}Ac-lintuzumab were given one week apart, 4-7 d following LDAC. 225Ac doses were escalated using a 3+3 design.

Results Twelve patients (median age, 77 yrs; range, 68-87 yrs) were treated. Eight (67%) had prior myelodysplastic syndrome, for which 6 (75%) received hypomethylating agents (n = 5) or allogeneic stem cell transplant (n = 1). One (8%) had chronic myeloid leukemia in molecular remission prior to AML. Nine patients (75%) had intermediate-risk and 3 (25%) had poor-risk AML. Median CD33 expression was 74% (range, 45-100%). ^{225}Ac-lintuzumab was given at 0.5 (n = 3), 1 (n = 6), or 1.5 (n = 3) μCi/kg/fraction. Up to 4 cycles were given, and 2 patients remain on therapy. DLT was seen in one patient at 1 μCi/kg/fraction who had grade 4 thrombocytopenia and marrow aplasia > 6 wks after therapy. Grade 3/4 toxicities included neutropenia (n = 2), thrombocytopenia (n = 3), febrile neutropenia (n = 6), pneumonia (n = 3), bacteremia (n = 1), cellulitis (n = 1), transient creatinine increase (n = 1), hypokalemia (n = 1), rectal hemorrhage (n = 1), and generalized weakness (n = 1). Six of 8 patients (75%) evaluated after Cycle 1 had bone marrow blast reductions (mean reduction, 68%; range, 34-100%). Five patients (63%) had blast reductions of ⩾ 50%, but no remissions were observed to date. Median progression-free survival (PFS) was 2.4 mos (range, 1.3+-16.9 mos)..

Conclusion Fractionated-dose ^{225}Ac-linutuzmab can be combined safely with LDAC and has antileukemic activity. Accrual continues to define the MTD. Additional patients will be treated at the MTD to determine response rate, PFS, and OS. Clinical trial information: NCI-2014-01360, NCT01756677.

Source: 2015 ASCO Annual Meeting

Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
Iomab-B	Acute Myeloid Leukemia (AML) second line for conditioning for BMT	Potentially file IND for Phase III study	**2H15**	***
		Potentially enroll first patient for Phase III study	**2H15**	***
		Potentially report Phase III study top-line results	**2017**	****
		Potentially file for BLA	**2H17**	***
		Potential FDA decision	**1H18**	****
Actimab-A	Acute Myeloid Leukemia (AML) first line	Potentially complete the Phase I portion of the Phase I/II study	**1H15**	***
		Potentially start the the Phase II portion of the Phase I/II study	**2H15**	***
		Potentially report Phase II study top-line results	**2H16**	****

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

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Major Risks

Risks of clinical study failure could have significant impacts on ATNM share value. Although the prior and ongoing studies have provided encouraging clinical outcomes, risks remain that some current trials might not meet study endpoints. As such, the value of the clinical assets could be significantly impaired and, therefore, ATNM shareholder value could diminish. Such a negative impact could be more pronounced if the clinical program is in very advanced development stages, such as Iomab-B in r/r AML or with high investor expectations. Regulatory risks are part of the clinical risks as even if a drug meets its' endpoints for pivotal studies, regulatory agencies might not grant approval.

Commercial risk even with approval, sales could be substantially below expectations. Even it is approved, the commercial sales of any drug could below expectations, resulting in diminished ATNM shareholder value. Factors that could impact the commercial outlook of a drug could include execution of marketing and sales, competition from other drugs, potential change of the treatment paradigm, and unrealistic expectations or projections.

Future capital raises could potentially dilute value of current shareholders. ATNM is still in the product development stage and additional financial resources maybe needed for further advancement of their product pipeline. The company may need to raise capital from financial markets to support its operations even if the company already has partners to provide milestone and other types of payments and/or product revenue. The company might not always be able to raise capital from financial markets at favorable terms. Share dilution under this scenario could reduce the value of the investment to current shareholders of the company.

Other radiotherapeutics have been approved but failed commercially, and this modality might not be broadly accepted and therefore limit its commercial potential. Although two radiotherapeutic drugs have already been approved and commercialized in the U.S. and other parts of the world, their revenue has been a disappointment. Nevertheless, we believe the market and unmet medical need for ATNM's products is different from that of the two prior radiotherapeutics. It is possible that going forward, radiotherapeutics-based medication could have limited use due to market acceptance. Such a scenario could reduce the market potential of radiotherapeutic drugs and have negative impact on ATNM shareholder value.

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Actinium Pharmaceuticals – Income Statement

($'000)	2013	2014	1Q15	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue												
Product revenue	0	0	-	-	-	-	0	0	0	15,970	53,768	180,276
Other revenue	0	0	-	-	-	-	0	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	0	0	15,970	53,768	180,276
Costs of goods									0	2,555	8,603	28,844
Gross sales									0	13,415	45,165	151,432
Research and development	2,667	12,267	4,049	4,105	4,680	4,867	17,702	25,490	33,137	36,120	39,371	42,520
General and administrative	3,919	10,175	3,806	2,779	2,806	2,835	12,226	12,837	14,635	15,366	16,135	16,941
Marketing and sales	0								7,000	19,600	30,380	31,899
Depreciation and amortization	2	38	10	10	10	10	42	42	42	42	42	42
Loss on disposition of equipment	4	0	-	-	-	-	0	0	0	0	0	0
Total Operating Expenses	3,925	22,481	7,866	6,894	7,497	7,712	29,969	38,369	54,814	71,128	85,927	91,402
Operating Incomes (losses)	(3,925)	(22,481)	(7,866)	(6,894)	(7,497)	(7,712)	(29,969)	(38,369)	(54,814)	(57,713)	(40,761)	60,029
Interest income (expense)	(3)	(1)	(6)	(6)	(6)	(6)	(23)	0	0	0	0	0
Gain on change in fair value of derivative liabilities	(4,179)	(2,206)	4,796	(200)	(200)	(200)	4,196	4,616	5,078	5,585	6,144	6,758
Total Other Income (Expense)	(4,182)	(2,207)	4,791	(206)	(206)	(206)	4,196	4,616	5,078	5,585	6,144	6,758
Net loss and comprehensive loss	(8,107)	(24,688)	(3,075)	(7,100)	(7,703)	(7,918)	(25,773)	(33,753)	(49,736)	(52,127)	(34,617)	66,788
Tax	0	0	-	-	-	-	0	0	0	0	0	(24,711)
Net Income (Loss)	(8,107)	(24,688)	(3,075)	(7,100)	(7,703)	(7,918)	(25,773)	(33,753)	(49,736)	(52,127)	(34,617)	42,076
Net Income (Loss) Applicable to Common Shareholders	(8,107)	(24,688)	(3,075)	(7,100)	(7,703)	(7,918)	(25,773)	(33,753)	(49,736)	(52,127)	(34,617)	42,076
Net Earnings (Losses) Per Share—Basic	($0.36)	($0.90)	($0.09)	($0.21)	($0.23)	($0.23)	($0.77)	($0.95)	($1.36)	($1.39)	($0.90)	$1.06
Net Earnings (Losses) Per Share—Diluted	($0.36)	($0.90)	($0.09)	($0.21)	($0.23)	($0.23)	($0.77)	($0.95)	($1.36)	($1.39)	($0.90)	$1.06
Shares outstanding—basic	22,753	27,364	33,256	33,356	33,656	34,156	33,606	35,606	36,606	37,606	38,606	39,606
Shares outstanding—diluted	22,753	27,364	33,256	33,356	33,656	34,156	33,606	35,606	36,606	37,606	38,606	39,606
Margin Analysis (% of Sales/Revenue)												
Costs of goods										16%	16%	16%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	226%	73%	24%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	96%	30%	9%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-361%	-76%	33%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-326%	-64%	23%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	237%	235%
R&D	-22%	360%	142%	105%	24%	1%	44%	44%	30%	9%	9%	8%
SG&A	-13%	160%	55%	15%	-14%	39%	20%	5%	14%	5%	5%	5%
Marketing and sales										180%	55%	5%
Operating Income (Losses)	-13%	473%	90%	56%	6%	12%	33%	28%	43%	5%	-29%	-247%
Pretax Income	65%	205%	-82%	-302%	27%	46%	4%	31%	47%	5%	-34%	-293%
Net Income	65%	205%	-82%	-302%	27%	46%	4%	31%	47%	5%	-34%	-222%
EPS	-92%	153%	-86%	-256%	7%	28%	-15%	24%	43%	2%	-35%	-218%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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RATINGS INFORMATION

Rating and Price Target Change History

3 Year Rating Change History

Date	Rating	Closing Price ($)
09/17/2013	Buy (B)	4.90

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
09/17/2013	18.00	4.90
02/23/2015	17.00	3.50

Source: Laidlaw & Company **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	73.08%	30.77%	7.69%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.85%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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