

Karyopharm Therapeutics Inc. (KPTI)

KPTI Outlines Registration Strategy in DLBCL, AML, and Richter's

MARKET DATA	
Price	\$26.48
52-Week Range:	\$15.50 - \$47.87
Shares Out. (M):	29.8
Market Cap (\$M):	\$789.1
Average Daily Vol. (000):	235.0
Cash (M):	\$156
Cash/Share:	\$5.24
Enterprise Value (M):	\$785
Float (M):	14.6
LT Debt (M):	\$0
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2013A	2014E	2015E	
Revenue (\$M)) 1Q		\$0.2A	\$0.0	
	2Q	\$0.4	\$0.0	\$0.0	
	3Q	\$0.0	\$0.0	\$0.0	
	4Q	\$0.0	\$0.0	\$0.0	
	FY	\$0.0	\$0.0	\$0.0	
EPS	1Q		(\$0.46)A		
	2Q	(\$5.39)	(\$0.44)		
	3Q	(\$3.66)	(\$0.46)		
	4Q	(\$0.47)	(\$0.53)		
	FY	(\$5.59)	(\$1.89)	(\$5.18)	
Source: Company reports and JMP Securities LLC					



MARKET OUTPERFORM | Price: \$26.48 | Target Price: \$50.00

INVESTMENT HIGHLIGHTS

We reiterate our Market Outperform rating and \$50 price target after Karyopharm details selinexor heme malignancy registration strategy with selinexor at an investor event in conjunction with ASCO. On the heels of compelling activity signals in DLBCL (29% ORR, with responses in 'double hit' patients), AML (16% ORR in a heavily pretreated population), and Richter's syndrome (100% disease control), registration trials in each of these indications were outlined: 1) SOPRA – a 150-patient, randomized Phase II trial in R/R elderly AML not suitable for intensive chemotherapy versus physicians' choice (LDAC, HMA therapy or BSC). Primary endpoint of overall survival by ITT, with 80% power to show median OS improvement of three to 5.4 months; 2) SADAL – a 150-patient, single–arm Phase II trial of selinexor plus low dose dexamethasone in \geq 3L R/R DLBCL, in all subsets. Primary endpoints of ORR and duration of response, with a lower bound confidence limit of 20%; and 3) SIRRT – a 50 patient, single-arm Phase II study in CLL patients transforming to Richter's syndrome (10-20% of CLL patients) and relapsing after chemotherapy. Primary endpoint of ORR (targeting \geq 20% with DOR of \geq 4 months).

We note that while the DLBCL registration strategy reflects a shift from prior guidancegoing from a randomized to single-arm study design- we believe it retains the capacity to support accelerated approval, which can subsequently be secured by a confirmatory trial in combination with standard therapy. Our valuation is derived through DCF and SOTP valuation methodologies.

In our view, the modified registration strategy for DLBCL is better suited for patient enrollment and fits a paradigm established by other drugs in the heme space. Moving SADAL from a randomized trial versus physician's choice chemotherapy to a single-arm design was based upon physician feedback indicating a reluctance to randomize patients to an ineffective, poorly tolerated chemo regimen. Pending additional feedback from regulators, Karyopharm anticipates being able to file for accelerated approval on the basis of meaningful single-arm ORR, to be confirmed by a randomized study (potentially chemoimmunotherapy +/- selinexor). While in the contrast to prior expectations, we note there are multiple successful precedents to this approach, in particular Pomalyst (CELG, MO, \$205 PT), Velcade (Takeda and JNJ, NC), and Kyprolis (AMGN, NC) in multiple myeloma. Based on the objective response and clinical benefit rates seen to date in DLBCL (29% and 70%, respectively) at a suboptimal mean drug exposure, we maintain a high degree of confidence in selinexor's potential to satisfy regulators' threshold for meaningful activity in a single-arm ≥ third-line study (in the neighborhood of ~30%, in our view).

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Company Description

Karyopharm Therapeutics (KPTI) is a Natick, MA-based, clinical-stage biopharmaceutical company focused on the discovery and development of novel first-in-class drugs directed against nuclear transport targets for the treatment of cancer and other major diseases. Karyopharm's Selective Inhibitors of Nuclear Export (SINE) compounds function by preventing the export of tumor suppressor proteins from the nucleus, driving accumulation and restoration of function. The company's lead pipeline candidate, selinexor (KPT-330), is a Phase I orally available small molecule inhibitor of XPO1, set to initiate pivotal Phase II/III evaluation in various hematologic malignancies in 2014. Karyopharm is also developing selinexor and SINE as potential therapies for autoimmune and inflammatory disease, viral infections, and wound healing.

Investment Risks

Clinical. Drug development is an inherently risky business. Clinical trials always carry a risk of failure and Karyopharm's assets (Selinexor (KPT330), KPT-350, PAK4 inhibitor, verdinexor or future drug candidates) may fail to demonstrate meaningful enough levels of efficacy in current or future clinical trials.

Regulatory and commercial. The ability of Karyopharm to market its drugs depends upon the drugs obtaining approval from the FDA and foreign regulatory agencies. Failure to achieve approval or delays in the timelines to approval could negatively impact the company's share price.

Competitive. Hematologic malignancies including multiple myeloma, indolent non-Hodgkin lymphoma and acute myeloid leukemia represent increasingly competitive fields and Karyopharm faces competition from both commercial and development-stage companies with product(s) or product candidates addressing similar clinical indications. Some of these companies may possess substantially greater R&D and commercial resources than Karyopharm. As such, there is no assurance Karyopharm will be competitive or differentiated from other drug products.

Financial. Following its IPO, Karyopharm ended 1Q14 with approximately \$156MM in cash and cash equivalents. We anticipate the company is likely to seek additional equity financing in the form of a secondary offering in order to complete the development of its drug candidates, creating dilution risk for existing shareholders.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

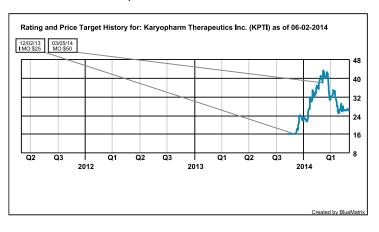
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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							# Co's	
							Receiving	
							IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
	_			_				
MARKET OUTPERFORM	Buy	259	58.73%	Buy	259	58.73%	99	38.22%
MARKET PERFORM	Hold	134	30.39%	Hold	134	30.39%	16	11.94%
MARKET UNDERPERFORM	Sell	5	1.13%	Sell	5	1.13%	0	0%
COVERAGE IN TRANSITION		43	9.75%		43	9.75%	0	0%
TOTAL:		441	100%		441	100%	115	26.08%

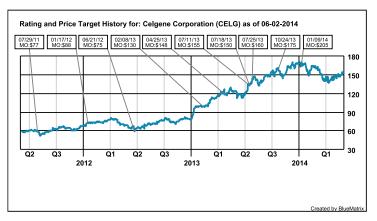
Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar guarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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