

# Chimerix, Inc.

# **Encouraging Data Presentation From Phase II AdV HALT Study at ICAAC**

On Tuesday, September 10, at the 2013 Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) annual meeting (Denver, September 10-13), final results from the Phase II HALT study of brincidofovir in adenovirus (AdV)-infected hematopoietic stem cell transplantation (HSCT) patients were presented (Grimley et al., late breaker T-351a).

Chimerix announced top-line data from the Phase II AdV preemption study back in August, noting that the cohort who received brincidofovir dosed twice weekly (BIW) had decreased levels of AdV viremia and demonstrated numerical benefit in reducing both progression to AdV disease and all-cause mortality, as compared with the brincidofovir cohort dosed once weekly (QW) and the placebo cohort. We summarize the incremental data presented at the ICAAC meeting below.

- Phase II HALT study (Study 202) design (exhibit 1, on page 3). Study 202 is a multicenter, randomized, placebo-controlled study evaluating brincidofovir in 48 adult and pediatric HSCT recipients. HSCT patients with asymptomatic AdV viremia were enrolled and randomized to receive brincidofovir BIW, QW, or placebo for 12 weeks as preemptive therapy, followed by a four-week follow-up period. Adult patients received 100 mg BIW, 200 mg QW, or placebo; pediatric patients received 2mg/kg BIW, 4mg/kg QW, or placebo. The primary endpoint is treatment failure rate, a composite of 1) progression to probable or definitive AdV disease and 2) increasing AdV viremia during randomized therapy that requires discontinuation from randomized therapy, brincidofovir versus placebo. Secondary endpoints include the incidence and time to mortality, and the proportion of patients with undetectable plasma AdV.
- Safety was adequate (exhibit 2, on page 3); in particular, no patients discontinued because of diarrhea, a result from the successful implementation of SMMP, which bodes well for SUPPRESS, in our opinion. No new safety issues were identified with brincidofovir BIW in the HALT study. No renal or hematological toxicities were observed, and incidences of serious adverse events (SAEs) were balanced among the arms. The Safety Monitoring and Management Plan (SMMP) was implemented in the study, resulting in no discontinuation because of diarrhea from the BIW arm, although the incidence of diarrhea was higher in the BIW arm (57% in the BIW arm, versus 38% in the QW arm and 28% in placebo arm). We note that diarrhea was the major adverse event of brincidofovir that resulted in high incidence of discontinuation in previous Phase II studies. The successful implantation of SMMP in the HALT study bodes well for the Phase III SUPPRESS study for cytomegalovirus (CMV) prevention, in our opinion. We note that SUPPRESS just dosed the first patient, and SMMP is to be implemented in the study as well.

Chimerix, Inc., a biopharmaceutical company based in Durham, North Carolina, focuses its research-and-development efforts on antiviral therapies.

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Please consult the last page of this report for all disclosures.

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### September 11, 2013

Stock Rating:

Company Profile:	Aggressive Growth
Price Target:	\$28.00
Symbol:	CMRX (NASDAQ)

Outperform

Price: \$19.03 (52-Wk.: \$15-\$27)
Market Value (mil.): \$491
Fiscal Year End: December
Long-Term EPS Growth Rate:

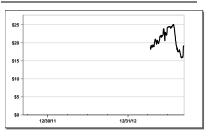
Dividend/Yield: None

	2012A	2013E	2014E
Estimates			
EPS FY	\$-5.71	\$-4.08	\$-1.91
CY		\$-4.08	\$-1.91
Sales (mil.)	NA	5	3
Valuation			
FY P/E	NM	NM	NM
CY P/F		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	23
Float (mil.)	12
Average Daily Volume	72,124

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.1
Book Value Per Share (MRQ)	4.3
Enterprise Value (mil.)	328.6
EBITDA (TTM)	0.0
Enterprise Value/EBITDA (TTM)	0.0x
Return on Equity (TTM)	-7.5

# Two-Year Price Performance Chart

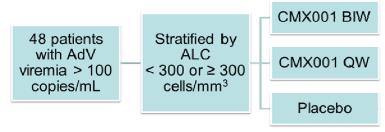


Sources: FactSet, William Blair & Company estimates

- On the primary endpoint (exhibit 3, on page 3), 21% of patients in the BIW arm were treatment failures, versus 38% in the QW arm and 33% in the placebo arm (p=0.45 for BIW arm versus placebo). Treatment failure was defined as progression to definitive or probable AdV disease, or confirmed increase of viral load by one log from baseline.
- On the secondary endpoint of all-cause mortality (exhibit 4, on page 4), there is clear separation of the BIW arm from the QW and placebo arms, although statistical significance was not reached.
- Clinical efficacy correlates well with viral kinetics (exhibit 5, on page 4). The BIW arm suppressed most of the AdV viremia, while QW and placebo arms were much less effective in suppressing AdV. The anti-viral activity correlated well with the clinical efficacy in treatment failure and all-cause mortality.
- **Potential reasons for the study not reaching statistical significance**. The first potential reason is the small size of the study. There were only 48 patients in the study, and they were randomized into three arms. Second, Study 202 assumed 50% treatment failure rate for the placebo arm; however, only 33% of the placebo arm failed treatment in the study. The lower treatment failure rate in the placebo arm was the result of several patients having low levels of AdV at baseline, which subsequently spontaneously cleared. The lower-than-expected treatment failure rate on placebo rendered it harder for the brincidofovir arm to demonstrate a statistically significant reduction in the study.
- There were no apparent differences observed between pediatric and adults in this study; however, based on literature, mortality rate related to AdV viremia and disease is much higher in pediatric patients than in adult patients. This is again likely due to the small size of the study.
- Other dsDNA viruses including CMV and BK viruses are reduced or cleared as well; we might see data on these endpoints at the analyst event on September 17 in New York City.
- Implications in brincidofovir development plan: maybe go for the high-risk pediatric patients where a clear benefit could be demonstrated. Chimerix intends to review the HALT study with the Food & Drug Administration (FDA) during fourth quarter 2013 and discuss the results of the study in the context of a pediatric plan that would support the further development of brincidofovir in pediatric and high-risk patients. We expect an update on this issue at the analyst event on September 17.

We maintain our Outperform rating and \$28 price target (exhibit 6, on page 5). In our probability-adjusted NPV model, we expect brincidofovir to reach the market by early 2016 and become the market leader in the prevention setting. We assume brincidofovir achieves peak sales of roughly \$530 million in the United States and \$410 million in Europe; for Europe, we project that Chimerix will license the commercial rights to brincidofovir to a partner and receive 30% royalties on EU sales. We assign an 80% probability of success to brincidofovir in the HSCT setting. Chimerix's second asset, CMX157, has been licensed to Merck (MRK \$47.98) for development of novel HIV combo therapies that could have certain advantages over Gilead's (GILD \$62.86; Outperform) industry-leading regimens. We assign \$4 per share to the program, which is in Phase I development. We estimate a 35% probability for the CMX157-containing combo to reach the market in 2019, \$1.1 billion in peak worldwide sales, and 15% royalties to Chimerix. Adding net cash of approximately \$2 per share to our valuation of brincidofovir and CMX157, we derive our 12-month price target of \$28 per share.

Exhibit 1 Chimerix, Inc. Phase II-ADV HALT Trial Design



ALC =absolute lymphocyte count

Sources: Chimerix, Inc. and William Blair & Company, L.L.C.

Exhibit 2 Chimerix, Inc. Summary of Phase II Adverse Events

	CMX001 BIW n=14	CMX001 QW n=16	Placebo n=18		
Grade 3, 4, or 5 AE	10 (71%)	9 (56%)	11 (61%)		
Drug-related Grade 3, 4, or 5	2 (14%)	4 (25%)	2 (11%)		
SAE	6 (43%)	7 (44%)	6 (33%)		
AE leading to dose change or interruption	5 (36%)	1 (6%)	1 (6%)		
AE leading to study drug discontinuation	2 (14%)	2 (13%)	1 (6%)		
Abdominal pain	1 (7%)	0	0		
Diarrhea	0	1 (6%)	0		
Lower GI hemorrhage	1 (7%)	0	0		
Toxic epidermal necrosis	0	0	1 (6%)		
Neutrophil decrease, anorexia, fatigue	0	1 (6%)	0		

AE = adverse event, WBC = white blood cell

Sources: Chimerix, Inc. and William Blair & Company, L.L.C. estimates

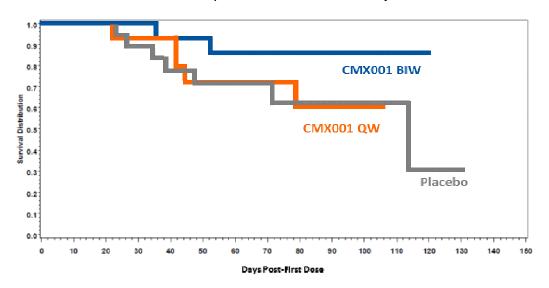
Exhibit 3 Chimerix, Inc. Treatment Failure (Primary Endpoint)

	CMX001 BIW n=14	CMX001 QW n=16	Placebo n=18
Subjects with treatment failure	3 (21%)	6 (38%)	6 (33%)
Increase in viremia only	1	1	1
Evidence of end-organ disease +/- increasing viremia	2	5	5
p-value (versus placebo) <sup>a</sup>	0.450	0.779	N/A

 <sup>&</sup>lt;sup>a</sup> Based on a logistic regression model adjusted for randomization stratum (absolute lymphocyte < 300 vs.</li>
 ≥ 300 cells/mm³).

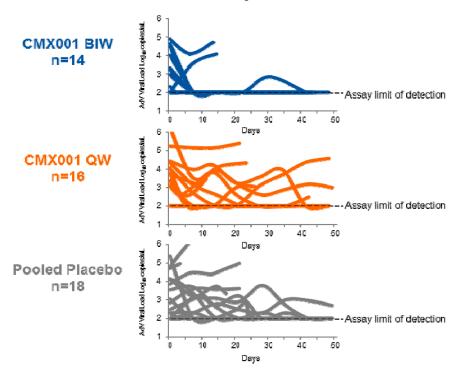
Sources: Chimerix, Inc. and William Blair & Company, L.L.C.

Exhibit 4 Chimerix, Inc. Kaplan Meier Curves: All Cause Mortality



Sources: Chimerix, Inc. and William Blair & Company, L.L.C.

Exhibit 5
Chimerix, Inc.
Adenovirus Viremia During Blinded Treatment Period



Sources: Chimerix, Inc. and William Blair & Company, L.L.C.

# Exhibit 6 Chimerix, Inc. Sum-of-the-Parts Fair Value (dollars in thousands)

Drug Candidate	Peak Sales	Stage of Development	Estimated Launch Date	Probability of Commercialization	Percentage of Sales to Company	Probability- Adjusted NPV	Value Per Share	Percentage of Fair Value
Brincidofovir— United States	\$526,017	Phase III start mid-2013	H1:2016	80%	100%	\$445,114	\$17.23	60.7%
Brincidofovir— European Union	\$413,065	Phase III start mid-2013	H1:2017	80%	30%	\$114,102	\$4.42	15.6%
CMX157— HIV	\$1,074,060	Phase I	H1:2019	35%	15%	\$112,361	\$4.35	15.3%
Subtotal						\$671,576	\$25.99	91.6%
Net Cash at mid-2014 Net Present Value of additional Gain (Loss)*					\$73,279 (\$11,364)	\$2.84 (\$0.44)	10.0% (1.5%)	
Sum-of-Parts Fair Value				\$733,492	\$28.39	100.0%		

\*Includes costs not directly related to programs above Sources: Company reports and William Blair & Company, L.L.C. estimates

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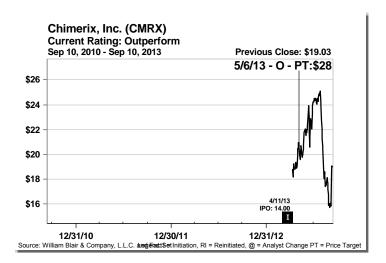
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DOW JONES: 15,191.06 S&P 500: 1,683.99 NASDAQ: 3,729.02



## Current Rating Distribution (as of 08/31/13)

0411 0110 1140 115							
Coverage Universe	Percent	Inv. Banking Relationships*	Percent				
	62		10				
Outperform (Buy)	62	Outperform (Buy)	10				
Market Perform (Hold)	33	Market Perform (Hold)	1				
Underperform (Sell)	1	Underperform (Sell)	0				

<sup>\*</sup>Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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