William Blair

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Autolus Therapeutics plc

Obe-Cel Continuing to Show Durability and Persistence; Takeaways From ASCO and Management Dinner

Over the weekend, Autolus presented updated results from the FELIX study of obe-cel at the American Society of Clinical Oncology (ASCO) annual meeting and hosted an investor call to discuss the update. Overall, we are encouraged by the continued durable responses seen with obe-cel, adding to its differentiated profile for the treatment of relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL). In addition, we hosted a dinner with management and investors where we discussed the FELIX update; commercial launch preparation underway for obe-cel; and the Autolus pipeline, including the opportunity in autoimmune disease. In this note, we provide takeaways from the data update at the conference and our discussions with management.

FELIX Data Update

Autolus presented updated results from the Phase Ib/II FELIX study of obe-cel in r/r B-ALL (exhibit 1). The focus of the ASCO presentation was updated survival data with longer follow-up, as well as analyses of the impact of consolidative stem cell transplant (SCT) and CAR-T persistence on survival outcomes in the study.

With an updated median follow-up of 21.5 months as of the February 7, 2024, data cutoff date (up from 16.6 months at the previous update at ASH 2023), the median event-free survival (EFS) was 11.9 months, in line with Tecartus's 11.6 months, and with a plateau in relapses forming in the long-term data. As previously reported, the CR/CRi rate was 78%. The update shows durability of remission in the majority of patients, with 40% of responders in ongoing remission without subsequent therapy, and 18% of responders in remission who had subsequent SCT. The remaining 41% of patients had relapsed or died (36%) or started new anti-cancer therapy (5%). As the FELIX data has matured, it has started to show a long-term stabilization of responses, as was seen in the Phase Ib ALLCAR trial, and we are encouraged by the durability of remission and the plateau in relapses achieved with obe-cel treatment, which has not been observed with Tecartus.

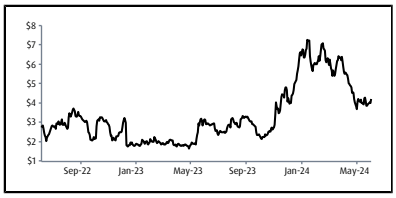
A sub-analysis of the updated results was conducted to evaluate the impact of consolidative SCT on survival outcomes. Interestingly, in the FELIX study, consolidative SCT did not improve either EFS or OS. The 12-month EFS rate was 49.5% with censoring for patients that received SCT, but without censoring for SCT, the 12-month EFS rate was lower at 44.0%, suggesting that patients who had consolidative SCT actually had worse survival outcomes. Similarly, the 12-month OS rate was 63.7% with SCT censoring, and slightly lower at 61.1% without SCT censoring. These results differ from the general paradigm and assumption that all patients should benefit from SCT.

Stock Rating:				**Outperform**
Symbol:				AUTL (NASDAQ)
Price:				$4.19 (52-Wk.: $2-$7)
Market Value (M):				$1,115
Dividend/Yield:				$0.00/0.00%
Fiscal Year End:				December
		2023A	**2024E**	**2025E**
Estimates				
EPS	Q1	$(0.23)	$(0.24)	$(0.23)
	Q2	$(0.26)	$(0.23)	$(0.23)
	Q3	$(0.26)	$(0.25)	$(0.20)
	Q4	$(0.44)	$(0.27)	$(0.16)
	FY	$(1.20)	$(0.98)	$(0.82)
Sales (M) FY		$1.7	$12.7	$47.9
Valuation				
FY P/E		NM	NM	NM

Trading Data (FactSet)	
Shares Outstanding (M):	266.0
Float (M):	236.6
Avg. Daily Volume (90-day):	1,672,008

Financial Data (FactSet)	
Book Value Per Share (MRQ):	$1.64
Return on Equity (TTM):	(52.1)%
Enterprise Value (M):	$584

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

Autolus, based in London, England, is developing next-generation CAR-T therapies, with lead program obe-cel showing best-in-class potential in adult leukemia.

The update also assessed the impact of CAR-T cell persistence on outcomes, which showed that the predicted EFS was higher in the subset of patients with ongoing persistence as compared to those who lost persistence. In a six-month landmark analysis among patients in ongoing remission, median EFS was not reached for patients with ongoing persistence, whereas median EFS was 15.1 months in patients that lost persistence by six months. A similar trend was observed for patients with ongoing B-cell aplasia, who had higher predicted EFS versus those with B-cell recovery by month 6 or month 12.

In discussing these results, management commented that the lack of benefit (and negative impact) of consolidative SCT in the FELIX study could be related to the persistence of the CAR-T. In those patients who received SCT, it is possible that the conditioning therapy ablated the obe-cel CAR-T and led to worse responses, consistent with the observation that ongoing CAR-T persistence correlated with better long-term EFS. This could be a clear differentiating aspect of obe-cel versus other therapies in adult ALL, where consolidation therapy is often necessary for long-term benefit.

In the ASCO presentation and on the company's investor call, physicians involved in the study expressed a clear enthusiasm for obe-cel. The lead investigator in the study stated that obe-cel would be the preferred choice over Tecartus in most, if not all, cases.

Exhibit 1
Clinical Data With CD19 CAR-T Therapy in Adult ALL

	Tecartus		AUTO1	Obe-Cel - ASH 2023	Obe-Cel - ASCO 2024
Clinical Trial	ZUMA-3	FDA Package insert	FELIX (NCT04404660)	FELIX (NCT04404660)	FELIX (NCT04404660)
Baseline Characteristics	Median age: 40 years ECOG 1: 71% Median prior therapies: 2 (1-8) Prior Blincyto: 45% Prior Besponsa: 22% Primary refractory: 33% Median blast count: 65% Prior alloSCT: 42% EMD: 11%	Median age: 40 years Median prior therapies: 2 (1-8) Prior Blincyto: 46% Prior Besponsa: 22% Primary refractory: 26% Ph chromosome +: 26% Prior alloSCT: 43%	Median age: 42 years Median Prior line: 3 (2-5) ≥50% blasts : 50% Median blast count: 57% Prior alloSCT: 65%	Median age: 47 years Median prior lines: 2 (1-6) Prior Blincyto: 42% Prior Besponsa: 31% Median blast count: 36% Prior alloSCT: 44% Extramedullary disease: 23%	Median age: 47 years Median prior lines: 2 (1-6) Prior Blincyto: 42% Prior Besponsa: 31% Median blast count: 40% Prior alloSCT: 44% Extramedullary disease: 23%
Treated Patients	55 patients	54 patients	16 patients	127 patients	127 patients
Overall Complete Remission (Evaluable)	71% CR/CRi 56% CR/15% CRi 20% subsequent alloSCT	64.8% CR/CRi 51.9% CR	75%	Morphologic Disease: 74% CR/CRi (95% MRD-) All pts: 80% CR/CRi	78%
Overall Complete Remission (Leukaphresed)		50.7% CR/CRi 40.9% CR		65% CR/CRi	65% CR/CRi
Median DoR	14.6 months CR: 20 months CRi: 8.7 months	13.6 months CR: NR CRi: 8.7 months	NR		
Landmark RFS/EFS	12 month: 45% 18 month: 35%			12 month: 50% 18 month: ~45%	12 month: 50% 18 month: ~45%
Median OS	26 months CR/CRi: 38.9 months	NR	NR		23.8 months
Severe CRS	24%	26%	0%	2%	2%
Grade 3+ Neurotoxicity	25%	35%	6%	7%	7%
Tocilizumab Administration	80%				
Reference	ASCO 2022; EHA CAR-T 2023	Tecartus Package Insert	ASH 2021	ASH 2023	ASCO 2024

Source: Company reports and William Blair Equity Research

Management Dinner Discussion Points

- **Regulatory progress.** The target PDUFA date for the obe-cel BLA is November 16, 2024, and management expressed confidence in the progress made up to this point with the review. The review process for obe-cel includes an analysis of the clinical data and differentiation of the product, CMC assessment, and label discussions. Management noted that the midcycle review point has passed.

- **Commercial launch.** Much of the conversation focused on the strategy and dynamics around the upcoming commercial launch for obe-cel. Autolus is focused on preparing for the U.S. launch, where it has a target number of 60 sites, which are expected to support the majority of obe-cel's addressable U.S. r/r B-ALL market. The company plans to roll out the launch in waves, with roughly 36 centers onboarded at first, and the second wave of centers shortly after (by the first year of launch). The process to onboard a center and enable the site to administer obe-cel is involved and incorporates various requirements, including commercial agreements, FDA requirements, preparation for order and reimbursement processes, as well as training for handling of the cell therapy product and for management of adverse events associated with CAR-Ts. Management noted that the majority of the onboarding process (about 80%) can be done ahead of the approved label, with the final steps to activate a center expected to be completed fairly quickly, within weeks to months following obe-cel approval and launch.
    - **Pricing.** The current pricing for Tecartus is roughly $460,000, and around $580,000 for Kymriah. When asked about potential price for obe-cel, management noted that while it will not be priced lower than Tecartus, as expected given obe-cel's favorable safety and efficacy profile, it will likely not be priced as high as Kymriah given its use in the adult rather than pediatric setting, which supports higher price points. We currently estimate an initial price of $450,000 in the U.S. in our model, roughly in line with Tecartus pricing.
    - **NTAP payment.** Management shared that it is likely to seek a New Technology Add-On Payment (NTAP) designation for obe-cel, which enables an additional CMS payment to sites as compensation for administering a new product. Autolus estimates that a hospital could receive an additional $80,000 payment for obe-cel administration if obe-cel receives the designation, and the designation would last a few years post-approval (typically three years). Certain CAR-T products have received NTAP designation including Tecartus, Abecma, and Carvykti, which have designations expiring in 2024. A potential NTAP designation for obe-cel would be another favorable factor supporting strong uptake in hospitals that receive the payment.
    - **Manufacturing.** Management reiterated the reliable manufacturing process for obe-cel enabled by the company's Nucleus facility. Management expects obe-cel's vein-to-delivery time to be about 16 days, which could be reduced further with additional efficiencies. Autolus has a collaboration agreement with Cardinal Health, which allows Autolus to ship the product to regional depots after manufacturing and initial safety testing, with the product quarantined at the depot until final sterility testing is complete. This approach will help facilitate delivery to treatment centers and shorten vein to delivery times.
- **Market competition in r/r B-ALL.** Management estimates that there are 3,000 addressable r/r B-ALL patients in the U.S. and EU, of which about two-thirds are treated with Blincyto currently. Blincyto is currently under regulatory review for the treatment of early-stage B-ALL (with a June 21 PDUFA date), and management noted that if approved, this could change the market in the relapsed/refractory setting, resulting in a larger market opportunity for CAR-Ts like obe-cel as Blincyto moves into earlier lines. However, it was pointed out that in ZUMA-3, a sub-analysis showed that patients previously treated with Blincyto have lower responses to Tecartus compared to those that did not have prior Blincyto use. In FELIX, management noted that the same trend was observed for obe-cel, and hypothesized that one potential reason for this observation is simply that disease is more aggressive in patients that have progressed on more lines of therapy, which may have included Blincyto.
- **Autoimmune disease.** Our discussion touched on the opportunity for Autolus in autoimmune disease, where the company is exploring the potential for obe-cel in systemic lupus erythematosus (SLE) in a Phase I study. As previously disclosed, two patients have been enrolled in the study and management did not provide any additional details around patient enrollment or treatment status compared to the recent first-quarter earnings update. We discussed the evolving competitive landscape for CD19-targeting agents in autoimmune disease, and specifically competition from bispecific T-cell engagers (TCEs). Management highlighted that despite promising case reports for Blincyto in autoimmune indications, there has been very little, if any, follow-up in these case studies to date. Unlike CD19-targeted CAR-T, at this point TCEs have not demonstrated complete B-cell compartment depletion, which management views as a critical feature to be able to drive deep and durable remission. Management highlighted that the lack of clinical data at this point makes it difficult to truly understand the utility for the TCE class in autoimmune disease treatment. However, it was noted that in theory, a TCE with a convenient dosing profile, single-agent activity, and a good safety profile could have a place in the treatment landscape, with a potential use-case in patients with less severe autoimmune disease.
- **AUTO8.** Our conversation also touched on Autolus's AUTO8, the dual BCMA/CD19 CAR-T that is being evaluated in a Phase I study in multiple myeloma. Autolus does not plan to independently pursue late-stage development of AUTO8 in multiple myeloma given the resources that would be required, so partnership may be possible for the program. Interestingly, management noted that there could also be a potential application of a dual BCMA/CD19 CAR-T product like AUTO8 in the autoimmune setting. While Schett's studies have demonstrated that depletion of CD19-positive B cells clearly can drive deep durable remission in a set of autoimmune indications (SLE, myositis, and systemic sclerosis), this type of result may not be the case across all autoimmune indications. Targeting B cells more broadly with BCMA or dual BCMA/CD19 may be an alternative strategy, particularly in cases where mature plasma cells are key drivers of disease.

Valuation. We remain encouraged by the profile of Autolus's lead programs and its ability to differentiate from currently available CAR-T therapies. We believe that obe-cel has a clear development path in adult ALL that should provide Autolus's first commercial product with a PDUFA date of November 16, and significant upside can come from additional indications like autoimmune indications and the company's pipeline, including AUTO8, AUTO1/22, AUTO6NG, and AUTO4/5. We assume peak sales of obe-cel in adult ALL of roughly $300 million in the United States. We reiterate our Outperform rating.

Risks. Investment in Autolus shares carries the risk of clinical setbacks and the highly competitive landscape in engineered cellular therapies for cancer treatment. In particular, Autolus is attempting to develop therapies with greater efficacy than products recently approved by the FDA or in late stages of clinical development, and the inability to show a clearly differentiated profile may limit the ability to garner market share from the approved assets. Development of cell therapies is capital intensive and current market conditions add capital risk for biotechnology companies**.**

Autolus Therapeutics plc
Company Rating: Outperform
5/30/2024

Income Statement

(dollars in thousands except EPS and shares in thousands)

	2023A	Q1A	Q2E	Q3E	Q4E	2024E	2025E	2026E	2027E
Revenues									
Obe-cel	0	0	0	0	2,591	2,591	47,864	137,618	221,388
AUTO8	0	0	0	0	0	0	0	0	27,580
AUTO4/5	0	0	0	0	0	0	0	0	36,884
AUTO6	0	0	0	0	0	0	0	0	0
Product Revenue	0	0	0	0	2,591	2,591	47,864	137,618	285,853
License Revenue	1,698	10,091				10,091	0	0	
Grant Income	0	0	0	0	0	0	0	0	0
Total revenues	**$1,698**	**$10,091**	**$0**	**$0**	**$2,591**	**$12,682**	**$47,864**	**$137,618**	**$285,853**
COGS	0	0	0	0	596	596	11,009	31,652	65,746
R&D	130,481	30,671	34,658	39,857	45,836	151,022	187,267	172,401	181,287
SG&A	46,745	18,177	19,995	21,994	24,194	84,359	107,655	122,503	146,248
Other operating expenses	382								
Total Operating Expenses	181,399	48,848	54,653	61,851	70,625	235,977	305,931	326,557	393,282
Income (loss) from operations	(179,701)	(38,757)	(54,653)	(61,851)	(68,034)	(223,295)	(258,067)	(188,938)	(107,429)
Interest and other income, net	0		0	0	0	0	0	0	0
Net income/loss before income taxes	**($208,402)**	**($52,698)**	**($68,594)**	**($75,792)**	**($81,975)**	**($279,059)**	**($258,107)**	**($188,978)**	**($107,469)**
Income tax expense (benefit)	(19)	(8)	(6,859)	(7,579)	(8,198)	(22,644)	(25,811)	(18,898)	(10,747)
Net income/loss to ordinary shareholders	**($208,383)**	**($52,690)**	**($61,735)**	**($68,213)**	**($73,778)**	**($256,415)**	**($232,296)**	**($170,080)**	**($96,722)**
Net income/loss per common share, diluted	**($1.20)**	**($0.24)**	**($0.23)**	**($0.25)**	**($0.27)**	**($0.98)**	**($0.82)**	**($0.58)**	**($0.32)**
Weighted average number of shares, diluted	173,942	222,171	271,048	273,759	276,496	260,869	283,478	294,618	301,666

Sources: Autolus reports and William Blair estimates

Please consult the following link for disclosures: https://williamblair.bluematrix.com/sellside/Disclosures.action?ajax&page=ajax/williamblairDisclosures.jsp&firmId=18877&companySymbol=AUTL

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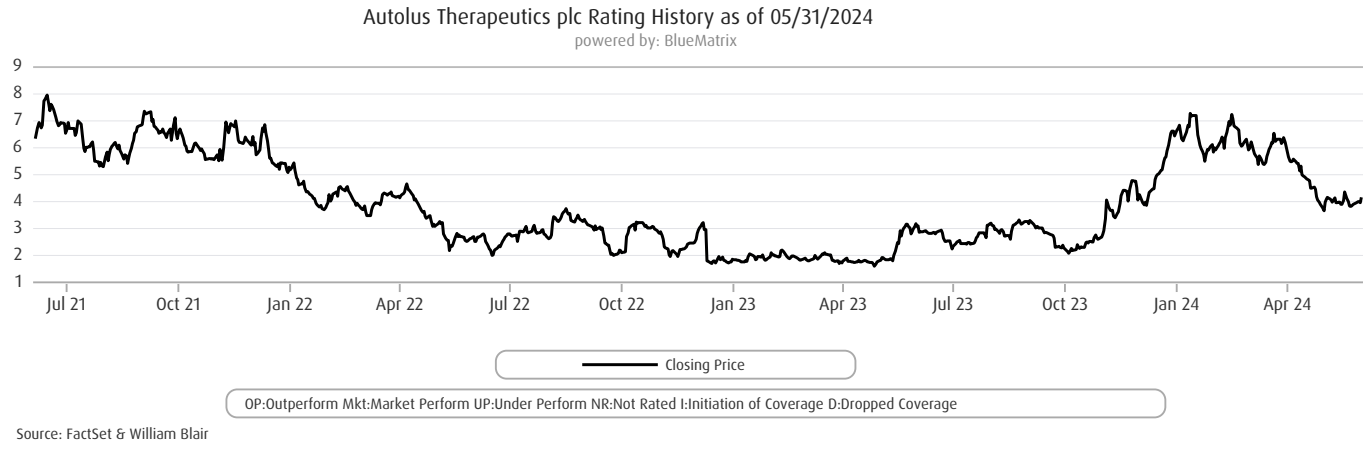
DOW JONES: 38686.30
S&P 500: 5277.51
NASDAQ: 16735.00



Source: FactSet & William Blair

Additional information is available upon request.

Current Rating Distribution (as of June 2, 2024):

Coverage Universe	Percent	Inv. Banking Relationships *	Percent
Outperform (Buy)	72	Outperform (Buy)	8
Market Perform (Hold)	28	Market Perform (Hold)	2
Underperform (Sell)	1	Underperform (Sell)	0

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