Seeking Alpha

One Year Later: Lessons Learned In CAR-T

Aug. 14, 2018 7:13 PM ET87 comments | 21 Likes
by: Bill Koski

Summary

- Approaching the one-year anniversary of commercial CAR-T therapy, product sales remain in-line with expectations. Key determinants, including next-gen technology, healthcare policy, and new entrants will affect the competitive landscape.
- Finalized, but imperfect reimbursement policies provide an unhappy medium to facilitate treatment with CAR-T therapy, advancing sales into 2019.
- Next-generation products and sales may be subject to increased competition in 4-7 years with the introduction of newly approved products.
- Watch for flattening YESCARTA sales, penetration of KYMRIAH in B-cell lymphoma, and a 2019/2020 Liso-cel launch for warning signs in CAR-T sales.

Introduction:

With hundreds of ongoing clinical trials and an unprecedented wave of new companies entering the field, chimeric antigen receptor (CAR) T-cell therapy represents one of the most important therapeutic and technological developments in the treatment of Leukemia and Lymphoma in years. Landmark approvals, multi-billion dollar acquisitions, and treatment costs approaching half-a-million dollars have captivated investor imaginations, resulting in billions of dollars in capital trading hands to support research and development for CAR-T.

Eyebrows were raised at the price tags for CAR-T leaders following the $11.9 billion acquisition of Kite Pharma by Gilead (GILD) last fall and the $9 billion acquisition of Juno Therapeutics by Celgene (CELG) in January. With reports that only a handful of patients received treatment following FDA approvals in 2017, many have raised concerns about the commercial prospects of CAR-T therapies in light of these pricey acquisitions, particularly given hefty treatment costs and ongoing reservations about the treatment's side effects. Some have jumped on early sales figures posted by Novartis (NVS) and Gilead to herald the failure of CAR-T.

In this article, I analyze how CAR-T has performed as a commercial product. I report that sales growth is healthy and in-line with expectations, discuss challenges in the competitive environment, and highlight future areas for growth to inform investment strategies in leading CAR-T players.

Competitive landscape for CD19-directed CAR-T therapies

Competitive Profile for CD19-directed CAR-T therapies in r/r Lymphoma and Leukemia

		Kite Pharma / GILEAD	NOVARTIS	JUNO THERAPEUTICS A Celgene COMPANY
Name		Axicaptagene ciloleucel [**YESCARTA**]	Tisagenlecleucel [**KYMRIAH**]	Lisocaptagene maraleucel
Costimulatory Domain		CD28	4-1BB	4-1BB
Manufacturing		No defined cell composition	No defined cell composition	Defined cell composition
DLBCL	Status	Approved (ZUMA-1) [Oct. 2017]	Approved (JULIET) [May. 2018]	Pivotal (TRANSCEND-001) est. 2019 approval
	N	101	81	88
	mF/U	15 months	9 months	6 months
	ORR	84 (82%)	34 (50%)	65 (74%)
	CR	59 (58%)	22 (32%)	46 (52%)
	Gr 3+ CRS	13%	23%	1%
	Gr 3+ NT	31%	18%	12%
ALL	Approval	Ph 1 (ZUMA-3/4)	Approved (ELIANA) [Aug. 2017]	
	N	24	75	-
	ORR	-	81%	-
	CR	17 (71%)	60%	-
	Gr 3+ CRS	28%	46%	-
	Gr 3+ NT	52%	13%	-
Manufacturing failures		1/111 (<1%)	11/117 (~9%)	-
Product Sales	1Q18	$ 40 mn	$ 12 mn	-
	2Q18	$ 68 mn	$ 16 mn	-

Sources: ASCO18, ASH17, New England Journal of Medicine, Quarterly Reports

CD19-directed CAR-T therapies target indications in blood cancers, including Non-Hodgkin's Lymphoma (NHL) and Acute Lymphoblastic Leukemia (ALL).

There are roughly 6,000 new cases of ALL each year vs. 75,000 cases of NHL with relapse rates of 10-15% and 30-40%, respectively. Diffuse Large B-Cell Lymphoma (DLBCL) accounts for ~30-40% of NHL cases.

Indication	Annual new cases	Relapse rates	r/r Population	Citations

DLBCL	~26,000	40-50%	11,700	1, 3
ALL	6,000	10-15%	750	1,2

DLBCL: Diffuse Large B-Cell Lymphoma; ALL: Acute Lymphoblastic Leukemia; r/r: relapsed/refractory.

In DLBCL, standard first-line treatment consists of induction chemotherapy with the R-CHOP regimen. Extended treatment options include salvage chemotherapy with and without stem cell transplant. CAR-T is currently positioned as a treatment option in patients with post-transplant or transplant ineligible relapses. At current prices ($373,000 for KYMRIAH/YESCARTA), this population in DLBCL represents approximately $5 billion in potential sales. While CAR-T therapy is currently approved after 2 or more lines of therapy, ongoing trials such as ZUMA-7 are evaluating the efficacy of CAR-T in second-line therapy.

Thus far, the status quo has been clear. With strong results as the only approved CAR-T in relapsed/refractory (r/r) ALL and minimal competition on the near horizon, Novartis controls the relatively small market in r/r ALL. Similarly, Kite/Gilead's YESCARTA sales remained uncontested in DLBCL until KYMRIAH was approved in May. Juno/Celgene is on track for a 2019 submission for FDA approval.

Celgene has attempted to rally investors behind a best-in-class claim, pointing to numerically lower rates of neurotoxicity (NT) and cytokine release syndrome (CRS) in the TRANSCEND-001 NHL trial. Balancing a best-in-class claim with a late market entry, they will likely price competitively with Kymriah and Yescarta, leaving insurers and health care providers to parse through the results to decide which therapy to cover or prescribe.

Lacking head-to-head data, there will always be ambiguity over the safety and efficacy of different CAR-T products due to fundamental differences across trials. But with numerically lower efficacy in DLBCL, higher rates of CRS, and a track record of manufacturing failures, Kymriah may be at a significant disadvantage in non-Hodgkin's Lymphoma. Novartis has already signaled uncertainty towards CAR-T therapy when they closed their cell therapy division in Summer 2016. It may be that they are content to cling to their market in ALL and leave KYMRIAH as a one-and-done therapy.

Finalized - but imperfect - reimbursement policies provide unhappy medium to facilitate treatment with CAR-T therapy.

The Centers for Medicare and Medicaid Services (CMS) published on August 2nd the final inpatient prospective payment system (IPPS) for 2019, which includes reimbursement for CAR-T therapy. Effective October 1, 2018, CAR-T will be subject to MS-DRG 016, Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy, with a base payment of $36,000 and a maximum NTAP (New Technology Add-On payment) of $186,500.

The American Society of Hematology (ASH) published the following criticism of this policy:

> While this final policy represents an improvement over current CAR-T therapy reimbursement rates, ASH believes patient access to care will be jeopardized as providers and hospitals will not be able to afford to deliver the therapy at this reimbursement rate, particularly as other CAR-T products receive FDA approval.

Although a handful of patients have been treated with CAR-T therapy in an outpatient setting, the vast majority of patients are treated on an inpatient basis, where closer attention may be provided to treatment-related adverse effects. Under CMS guidelines, CAR-T administered on an outpatient basis is reimbursed at 6% above the wholesale acquisition cost.

Further, treatment administered to a patient in the outpatient setting that requires admission to inpatient care within 72 hours will be billed under inpatient care, exposing healthcare providers to reimbursement risk.

Safety then becomes a key consideration in establishing treatment paradigms between analogous T-cell therapies. Juno/Celgene maintains a reasonable claim to an improved safety profile that may enable outpatient treatment and facilitate the adoption of Liso-cel via CMS policy. Maintaining response rates and durability in the final analysis of Liso-cel will be critical for Celgene to grasp a competitive position. It is unlikely that the adverse event profile changes significantly in the final analysis of TRANSCEND-001 NHL as cytokine release syndrome and neurotoxicity manifest symptoms within days/weeks of treatment infusion.

Actual CAR-T sales numbers align with previously published forecasts from Kite, Juno.

Prior to their acquisitions, both Juno Therapeutics and Kite Pharma released sales forecasts conducted by third-party investment banks Morgan Stanley and Centerview Partners, respectively. These forecasts were issued in letters to the shareholders in favor

of the proposed acquisitions.

Revenue forecasts published by Juno Therapeutics and Kite Pharma

	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
JCAR017* Revenue ($mn)	0	199	855	1,504	1,907	2,147	2,323	2,586	2,858	3,030
y/y growth (%)	-	-	330%	76%	27%	13%	8%	11%	11%	6%
Kite Pharma** total revenue ($mn)	285	643	1,468	2,051	2,762	3,755	4,373	4,759	5,047	5,288
y/y growth (%)	-	126%	128%	40%	35%	36%	16%	9%	6%	5%

**risk-adjusted estimate*
***non-risk adjusted estimate, includes all product revenues*

Source: SEC Filings for Kite and Juno

Kite Pharma predicted $285 million in sales for 2018, with ~125% y/y growth in their first two years to generate blockbuster sales of $1-2bn. Meeting their stated expectations of ~125% y/y growth requires initial sales on the order of $40 million and quarterly growth of ~22.5%.

First-year CAR-T sales

Product	Company	1Q18	2Q18	Quarterly growth	est 3Q 2018***	est 4Q 2018***	est FY2018***
JCAR017	Juno/ Celgene	-	-	-	-	-	-
Kymriah	Novartis	$12	$16	33%	$20	$25	$73
Yescarta	Kite/Gilead	$40	$68	70%	$85	$106	$299

****assumes a 25% q/q growth rate, which is conservative given the reported q/q growth for 2Q18.*

Sales for YESCARTA have exceeded that growth rate from 1Q- to 2Q-18. Slower sales for KYMRIAH can be attributed to a smaller market size in ALL (for which KYMRIAH was first approved), among other factors.

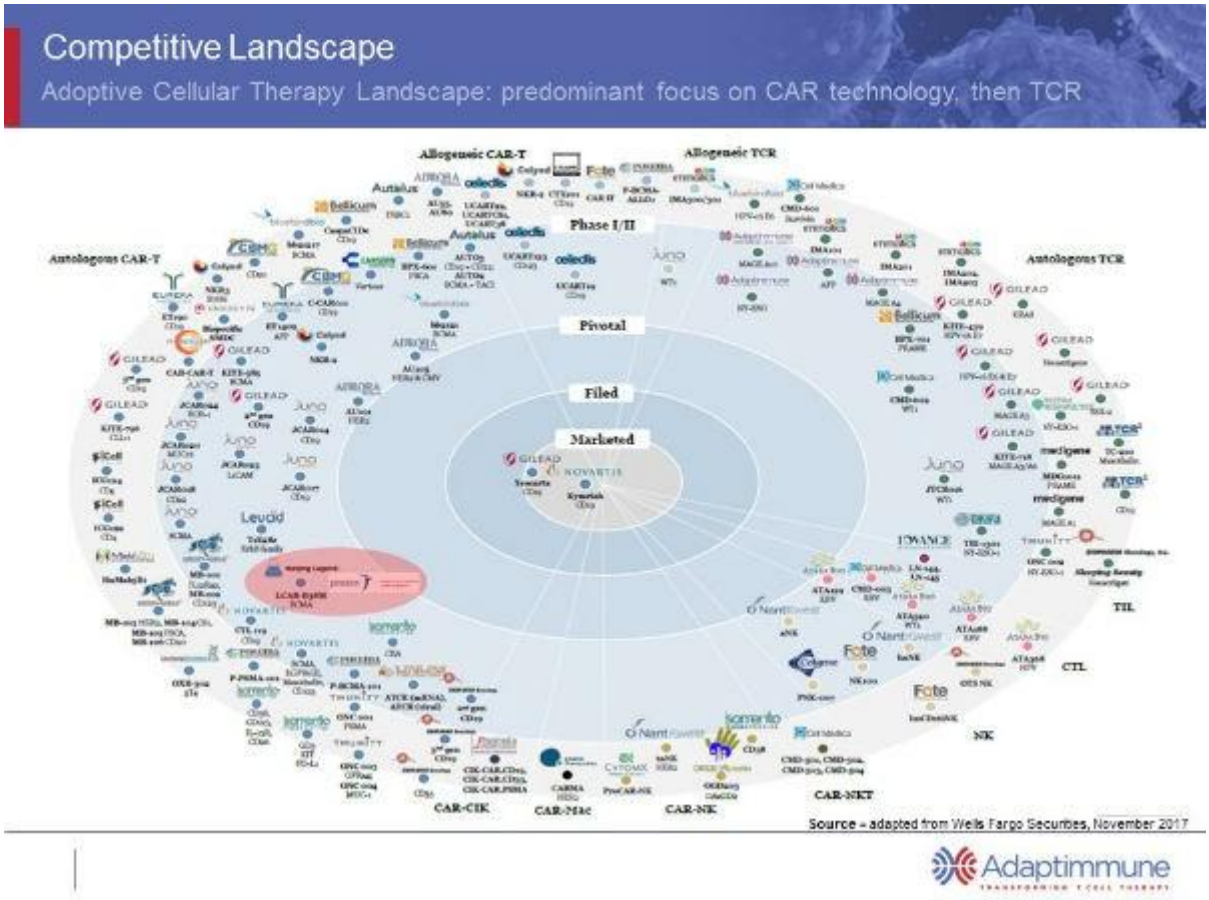
Based on these data, I would argue that YESCARTA sales are at a minimum on track to meet revenue growth modeled by Kite Pharma back in 2017.

The free cash flow predicted by the 15-year Kite model valued Kite Pharma at $11.9 billion at a 7% discount rate, the exact amount paid by Gilead. Of course, with the sheer number of new technologies under development, including next-generation CAR-T therapies, it is

unlikely that these forecasts hold up past 6-7 years.

The landscape for CAR-T therapies remains crowded with next-generation products and sales may be subject to increased competition in 4-7 years with the introduction of newly approved products.

ASH estimates there are some 400 ongoing clinical trials evaluating CAR-T therapies. In addition to novel targets in solid tumors, next-generation CAR-T products include engineered molecular switches, off-the-shelf CAR-T therapies, and synthetic gene circuits which stand to improve safety, efficacy, and manufacturability of CD-19 directed CARs.



Source: Adaptimmune

If they work, allogeneic CAR-Ts may clear the field of first-gen autologous products. A number of companies, including Cellectis/Allogene (CLLS) and Gilead, are developing allogeneic "off-the-shelf" CAR-T products that are engineered using a donor's cells, instead of a patient's. These products benefit from a shorter and more straightforward manufacturing process. A clear signal of safety and efficacy has yet to be established, so

it is difficult to predict the commercial pathway of these products. However, if any of these products report signals of safety/efficacy on par with the first-generation CAR-T therapies, all bets are off.

What should I look for in future earnings?

- **Flattening YESCARTA sales growth:** It goes without saying that a slowdown in YESCARTA sales is a very bad sign. Quarterly growth below 10-20% in the next 2 years for Gilead should ring some bells.
- **Penetration of KYMRIAH in the DLBCL segment:** Significant sales growth of Kymriah in non-Hodgkin's Lymphoma would suggest that healthcare providers do not view evidence as supporting that KYMRIAH efficacy is inferior. This result would lend itself to a more competitive playing field, although Celgene may still differentiate a competitive position on the basis of improved safety.
- **Liso-cel launch and first-year sales:** Celgene needs a strong Liso-cel launch to gain ground on Gilead. Comparing first-year sales with Gilead will provide a benchmark for what to expect in future earnings.

The bottom line:

CAR-T remains an important advance for patients living with leukemia and lymphoma. Healthcare policies have advanced with CMS coverage for CAR-T therapy, but new advances are needed to expand coverage, reduce prices, and decrease manufacturing time.

In the current competitive environment, no individual player is likely to surpass $2-3 billion in annual CAR-T sales. Current sales growth is healthy and in line with expectations, although ongoing uncertainties surrounding cost, manufacturing, and competition, peak sales may yet fall short of expectations.

References:

[1] Cancer Facts and Figures, 2018

[2] Factors Influencing Survival After Relapse From Acute Lymphoblastic Leukemia: A Children's Oncology Group Study

[3] Management of relapsed-refractory diffuse large B cell lymphoma

Disclosure: I/we have no positions in any stocks mentioned, and no plans to initiate any positions within the next 72 hours.

I wrote this article myself, and it expresses my own opinions. I am not receiving compensation for it (other than from Seeking Alpha). I have no business relationship with any company whose stock is mentioned in this article.

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Comments **(87)**

NV_GARY
Thanks
G

14 Aug 2018, 07:32 PM

GreenGrowthGeek, Contributor
Interesting article on a fascinating but risky sector.

15 Aug 2018, 08:26 AM

CSYJ
With a;l due respectBill,

I mist question a lot of your assumptions assmuptions:

1. Under CMS guidelines, CAR-T administered on an outpatient basis is reimbursed at 6% above the wholesale acquisition cost.

So you know for certain? Have you spoken to outpatient treatment centers and verified the 6% figure? What is the say Yescarta WAC anyway? How close is it to the $373K list price?
So the treatment enter would get close to $400K? Really? Have you actually seen an invoicee or two?

2. ***assumes a 25% q/q growth rate, which is conservative given the reported q/q growth for 2Q18.. Why did you decide to be "conservative"? What was your rationale?

3. Yet you estimated YtoY growth of Yescarta from 2018 to 2019 as $126%. That a huge uptick, jump, and leap of faith for your 25% q/q growth, isn't it? What promoted you to change your mind?

In conclusion, IIMHO you are either totally clueless or just speculating!

14 Aug 2018, 07:32 PM

Bill Koski, Contributor
Author’s reply » Hi CSYJ, thank you for reading. Please note a couple things.

Firstly, the first set of forecasts is not mine. They were published by Juno and Kite respectively. The valuations were performed by Centerview Partners and Morgan Stanley. The estimation of 126% growth is not my own.

Secondly, a 25% q/q growth rate equates to a 144% growth rate year over year. This is not an uptick as you describe, it is in fact more than the Y/Y forecast in the investment bank's model. This effect is due to something called compounding interest. Please do the math before issuing a personal attack.

I use a conservative growth rate to illustrate a point--2Q sales growth rate exceeded what is required to outpace the investment banker's valuations.

Finally, I cite references for all of the numbers reported regarding CMS reimbursement. I have not personally contacted treatment centers.

14 Aug 2018, 07:49 PM

BioNoob
CSYJ

The WAC+6% is the standard CMS reimbursement for Part B, no need to contact a facility...that's what it is. That's for the cost of the product only and not any other ancillary services that may be needed and that's why its not used primarily in the outpatient setting. Due to potential complications like cytokine release syndrome (CRS) patients must be monitor in the hospitals.

Bill,

You hit the nail squarely on the head. The ONLY reason the CAR-T technology/therapy has not taken off is REIMBURSEMENT. The hospitals, which are already working with tight margins, are not willing to take the risk that the reimbursement for the product and any services associated with its use will not not cover the cost, especially if complications occurs.

For those what want to know when it may increase utilization...probably in 2 years. Why 2 years? That's the earliest when CMS will come out with a DRG that has factored in the true cost to treat patient with CAR-T. The way CMS works is that it retrospectively analyze the cost to treat a particular disease by the average hospital cost. Once this happens and hospitals are more financially comfortable with the reimbursement...then they will increase the use.

15 Aug 2018, 01:12 AM

SpoiledRottenBrat
Author compares KITE Yescarta revs of $105M in last 2Qs to JUNO forecasted sales, but for GS man, JUNO is not even FDA approved.

I see Yescarta revs over $400M in Q4 2018 compared to JUNO - a big fat zero (no sales) in Q4 2018.

Care to comment?

By EOY 2019 Yescarta will see $800M a quarter to JUNO's what??????

Being first with the mostest is the key in this business. This author missing the boat.

15 Aug 2018, 10:04 AM

Bill Koski, Contributor
Author's reply » @BioNoob -- thanks for reading and for the thoughtful comments. great points across the board.

16 Aug 2018, 01:24 AM

SpoiledRottenBrat
"Watch for flattening YESCARTA sales, penetration of KYMRIAH in B-cell lymphoma, and a 2019/2020 Liso-cel launch for warning signs in CAR-T sales." - Bill Koshi

You are kidding, right Bill?

KYMRIAH couldn't penetrate CAR T even if Yescarta didn't exist. They've already proved that by falling "light years' behind - with miniscule sales over the last year.

16 Aug 2018, 09:26 AM

SpoiledRottenBrat
Yescarta's current website shows 51% CR - better than any other CAR T in or not in the market place!

www.yescarta.com/...

Maybe that's why Yescarta revenues are 5 times KYMRIAH - and will continue to grow exponentially.

16 Aug 2018, 11:26 AM

Bill Koski, Contributor
Author's reply » It appears that this was not made clear which is my mistake as a writer.

I agree with your assessment that Kymriah is unlikely to achieve a significant market share relative to Yescarta. As I state in the article:

"with numerically lower efficacy in DLBCL, higher rates of CRS, and a track record of manufacturing failures, Kymriah may be at a significant disadvantage in non-Hodgkin's Lymphoma."

My statement to watch for Kymriah penetration in NHL is intended to illustrate the following point. As investors, we see higher response rates and lower incidence of adverse events and assume that one treatment is superior to another. There are a number of reasons why you can challenge this assumption as inappropriate. These data are collected in different trials, conducted in different patient settings, at different institutions, with different healthcare providers. As I state, without running a head-to-head trial it is inappropriate to definitely conclude one

I am suggesting that Kymriah sales in DLBCL can provide some indication as to how prescribers/insurers view these results. High Kymriah sales would suggest a conclusion of non-inferiority. Low sales, the opposite.

p.s. As I report in the article, the most recent data, presented by Fred Locke at ASCO suggests a CR rate of 58% at long-term follow up (15 months). This is higher than what we saw at earlier follow-up, understandably so. It is worth considering that complete response rates from TRANSCEND-001 and JULIET trials might also increase.

abstracts.asco.org/...

16 Aug 2018, 05:17 PM

SpoiledRottenBrat
The CR rate you site (58%) is for Yescarta, not Kymriah.

I don't agree that Kymriah CR will necessarily improve. Usually CR fall as time goes on.

Like I said, I'll go with the CR rate of 51% posted on Yescarta/Kite website. www.yescarta.com/...

If kymriah doesn't show improved overall revenues of $28M (over last 12 months), Novartis AG may give up on the drug, and kymriah may not be around in a year or so, IMO.

16 Aug 2018, 07:54 PM

Bill Koski, Contributor
Author's reply » Firstly, you misrepresent my comment. I say that CR rates might increase, not that they will increase. Strictly speaking, the statement that CR rates usually fall over time is inaccurate. ONGOING complete responses decrease over time as patients relapse. We are discussing the percentage of CRs as a best response. If you are following the same cohort of patients, it is by definition not possible for the rate of CRs to decrease, unless it is shown that a patient was previously misclassified as achieving a CR, which will only happen very rarely. The same patients that previously achieved a complete response will still have a best response as CR even if they relapse. To illustrate why CR rates may increase over time, consider patients who have only been on treatment for a few months. A patient with an ongoing partial response may still achieve a CR as best response at a later data point. Tumor remission takes time, and it is absolutely reasonable to predict that the number of patients with CR as the best response will increase over time.

Secondly, yes I am reporting Yescarta data, that was my intention. The data cut-off for the Yescarta label that you cite is from 7 months before the updated ASCO data. I don't understand why you are overlooking the most up-to-date peer-reviewed literature, especially given that it supports your point. In this case, several patients with partial responses achieved complete responses between the 8-month follow-up that you cite, and the 15-month follow-up which reflects the most recently published data.

Finally, I find it inconceivable to suggest that Novartis would consider dropping Kymriah in the near future. They have a complete monopoly in r/r ALL which is a $350 mn market. Novartis will never drop Kymriah as long as it is profitable.

16 Aug 2018, 09:25 PM

SpoiledRottenBrat

"Kymriah Manufacturing Issues Spell Trouble for Commercialization of Novartis CAR-T Therapy"

xtalks.com/...

Much bigger problem than you think. Their "team" is not as good as KITE's.

18 Aug 2018, 11:44 AM

CSYJ

Are yu kidding me about the 2 years' wait? So what would these NHL patients on their alst hopefor treatment who fialed chemos and even stem cell transplants and also their oncologists,hematologists hear from these centers, CMS, and GIlead?

Sorry but you need to wait for two years until we figure out and finazize the reimbursement process? Really?

I actually hear one of the majorreasons for the low Yescarta revenue for GILD in 2Q'18 was due to eating patients dying! I suppose if you duem you didn;t get treated so you dont have to pay?

What happened to the compassionate (or righ to) use legislation? I thought it had bipartisan support for congressioanl enactment ,even with out POTUS favoring it.

18 Aug 2018, 01:36 PM

Bill Koski, Contributor

Author's reply » Novartis has struggled a lot with manufacturing Kymriah in the past. They had much higher manufacturing failure rates on Juliet than Kite/Juno, and a longer turnaround time as of ASH17 if I remember correctly.

20 Aug 2018, 01:18 AM

CSYJ

Bill,

I understand the turnaround time from cell harvesting, re-engineering, growing, and re-injecting i to patients for Yescarta is something like 21 days. Actually also, one of the major stumbling block resulting in less than expected revenue for Yescarta is that some patients die before they can get the cells re-injected. If anyone knows how doe the Yescarta payment work precisely in terms of timing, I would love to know about it! After all, I donlt think any patients should be required to pay up front before the actual treatment is completed. Cell harvesting and re-engineering IMO is just the beginning.

20 Aug 2018, 04:57 PM

SpoiledRottenBrat

CSYJ

I retrieved the info below from Yescarta's webpage.

Go to 14 CLINICAL STUDIES

Of 111 patients who underwent leukapheresis, 101 received YESCARTA. Of the patients treated, the median age was 58 years (range: 23 to 76), 67% were male, and 89% were white. Most (76%) had DLBCL, 16% had transformed follicular lymphoma, and 8% had primary mediastinal large B-cell lymphoma. The median number of prior therapies was 3 (range: 1 to 10), 77% of the patients had refractory disease to a second or greater line of therapy, and 21% had relapsed within 1 year of autologous HSCT.

(JUST) One out of 111 patients did not receive the product due to manufacturing failure.

Nine other patients were not treated, primarily due to progressive disease or serious adverse reactions following leukapheresis. THIS SORT OF ANSWERS YOUR QUESTION = 9%.

www.yescarta.com/...

It is my understanding, that after CR is reached (i.e, about 1/2 that received a one time injection), many of the remaining patients not in CR (PR, etc.) that received Yescarta # die.

At 2 years after injection I would expect as few as 60 of the 101 that actually received a one time injection would still be alive (i.e., 41 died).

My question for you is what is happening now with the $108M (i.e., approximately 270 patients) treated since FDA approval one year ago?

CR %= ?????
PR% = ?
OOR = %??????

20 Aug 2018, 05:50 PM

Bill Koski, Contributor
Author's reply » 59% of patients from ZUMA-1 are alive at 12 months and PFS is abysmal for patients not-achieving a CR. I expect we won't see updated data until ASH in December.

www.ncbi.nlm.nih.gov/...

"The median overall survival was not yet reached (95% CI, 12.0 months to could not be estimated) (Fig. 2C), with overall survival rates of 78% (95% CI, 69 to 85) at 6 months, 59% (95% CI, 49 to 68) at 12 months, and 52% (95% CI, 41 to 62) at 18 months."

CSYJ-- that is a really good question. I wasn't able to find any info on CMS policy with regard to payment at infusion or apheresis. It looks like Primera reimburses at infusion (www.premera.com/...)

You are right, the turnaround time is about 3 weeks. I remember seeing some data at ASH that suggested there might be a discrepancy in manufacturing times. Things looked especially ugly for Novartis with all the early manufacturing failures on JULIET. All that data is old anyway. We may only see commercial data if it is good.

20 Aug 2018, 08:26 PM

BioNoob

I didn't say 2 year wait.

I said it may take up to 2 years to get a more realistic cost of therapy based on the way the DRG is currently calculated.

The quarterly report reflects the sentiment of the facilities. They will not take the financial risk with treating patients if it adversely impacts their financial well being. And, if a facility takes that risk...they could be attracting patients and further exacerbating the financials

22 Aug 2018, 05:46 PM

BioNoob
CAR-T reimbursement is based on a similar structure as stem cell transplant. There are certain milestones that must be met with each being reimbursed at a different rate:

I'm overly simplifying the process, but hopefully it illustrates the point.
1) Stage 1: Qualification: Does the patient meet clinical criteria. Patient physical assessment and history. This is usually conducted by a expert nurse or provider. If patient qualifies, enrolled with coordinated care usually with family, clinical team, social worker, etc.

2) Stage 2: Cell proliferation and harvesting. Treatment to boost targeted cell production, and cell re-engineering.

3) Stage 3: Infuse engineered cells into patient. Patients are prepared for re-infusion. First need to ablate (remove) all of the cancerous cells with chemotherapy. Then engineered cells are reintroduced to the body

4) 30 days follow up

5) 6 months follow up

6) 12 month follow up.

22 Aug 2018, 05:59 PM

CSYJ
OK BN,

Care to break down the Yescarta $373K listr pcrie to the six stages as you described? equal amount payment at each stage? Milestone? Full payment only after 12 months follow up assessment? Really?

22 Aug 2018, 11:34 PM

SpoiledRottenBrat
KITE/GILD hasn't updated the # of treatment centers since June 30th - when it stood at 61 (end of Q2 2018).

So, Q3 2018 revenues should exceed last Quarter's $68M (up from $40M Q1 2108); and, I would think $100M + as a minimum.

While I believe there are now more than 61 yescarta treatment centers, KITE does not want to provide the public with any increase for some reason.

For this reason revenues could be above $120 in Q 3 2018 IMO.

More importantly, apparently there have been no deaths from CRS since FDA approval. There have been approximately 270 patients treated with Yescarta since FDA approval.

In ZUMA 1 (101 patients), CRS deaths (4) occured within the first month of injection. ZUMA 1 trials (with results CR, PR, ORR) are now almost 2 years old.

FDA would shut Yescarta down (like they did JUNO 4/6 deaths) with even one death - IMO.

So CSYJ , what do you have to say about Yescarta safety record with the 270 patients treated since FDA approval?

Any deaths?

23 Aug 2018, 06:23 AM

BioNoob

The payment schedule is based on stem cell transplant and each milestone has it's associated reimbursement. The stages that involve follow up and assessments will be based on provider contracted rate. However, the bulk of the cost associated with the CAR-T treatment will be with hospital stay, mainly the cell infusion stage.

Interesting, CMS groups the cost of Stage 2 plus cost of the product under their reimbursement schedule at cap of $186,500. Any additional medical services due to complications and hospital stay are not covered by this cost.

Hopefully that explains the financial risk with the treatment of these drugs.

Again this is CMS' reimbursement so Medicare and Medicaid, and not so much commercial/private insurance. Commercial/private insurance have their own reimbursement structure; HOWEVER, since reimbursement is largely based on CMS numbers, commercial/private insurance is indirectly impacted.

23 Aug 2018, 11:50 AM

Bill Koski, Contributor

Author's reply » Thanks for the comments @BioNoob this is really helpful. Do you have a primary reference I could use for my own research here?

23 Aug 2018, 04:53 PM

BioNoob

Is there something specific that you're referring? I stated a lot, some of that verbiage are experiential and some are pulled from various sources.
It may be very difficult to cite many since a lot it overlaps...and if this comments make people uncomfortable...IT SHOULD. You should always vet the info yourself.

With most of my posts, I try to attach a source of reference so that readers can come to their own conclusion or at least educate themselves.

27 Aug 2018, 02:11 PM

Bill Koski, Contributor
Author's reply » With respect to CMS policy: "The payment schedule is based on stem cell transplant and each milestone has it's associated reimbursement".

I have had a hard time finding useful primary source material from CMS. Especially w/ regards to a payment schedule. Was curious if you had found any interesting reading.

27 Aug 2018, 07:15 PM

BioNoob
I have had a hard time finding useful primary source material from CMS. Especially w/ regards to a payment schedule. Was curious if you had found any interesting reading.

That's a rabbit hole that is going to be difficult to find in one spot. It's really difficult to understand and navigate CMS fee schedule. I had to reach out to experts to get an understanding and that's at a high level.

You found the article published with the CAR-T payment, that's one. Not a direct citation, but below is a link and it describes a little bit of the process if you can read between the services. www.bluecrossnc.com/...

I can tell you that Novartis and Gilead probably didn't really understand the reimbursement process either when they launched their respective product. Now trying to adjust and develop their strategies for patient access.

28 Aug 2018, 09:56 AM

CSYJ
SRB,

Sorry, but No deaths means nothing unless and until GILD consistently gets the full (or close to) the list price! When do you think that would happen? Maybe 2020?

28 Aug 2018, 11:15 PM

SpoiledRottenBrat
No deaths from CRS means everything CSYJ. The list price will be cut in 1/2 in a few months and the profits will boom. Right now the very rich just pay for the $400,000 treatment out of pocket (with full coverage). If you got's $100M in the family, $1M for your life means little.

GILD has 1000 scientists MDs and PHDs in the labs that know much more than the people that just left - that you and others "glorify" as immortals. Get serious. The discoveries happen the "test tubes" and their labs!

You gots $100M in centrifuges and other equipment (electron microscopes that cost $1M each - ever use one?), etc., like in GiLead labs and manufacturing facilities in your kitchen?

"I'm really lucky, really lucky," she told CBS Boston medical Dr. Mallika Marshall. "They gave me my life back." - Yescsarta

Check out the video. www.cbsnews.com/...

29 Aug 2018, 08:43 AM

CSYJ
SRB,

Drug pricing is one of the most closely held confidential information within GILD. SO tell me how could you possibly know " the list price will be cut in 1/2 in a few months"? Please....

Are you just speculating based on Harvoni price? Did you predict the list price now is about $23K for VA and mid to low teens for MediCal (I live in California)? Really? Base on what information.

My mother was seen by one of the topp three in the US and the top hepatologist in the West Coast two weeks ago (Dr. Nora Terrault).

profiles.ucsf.edu/...

She agreed to initiate Harvoni treatment. SHe asked me whether ai hadany concerns. I told her as a former GILD employes. I wondered how would California;s Medicaid pay for it and how did she decide on Harvoni and not Mavyret? She told me not to to worry about the cost since GILD is now matching ABBV $ for $ and that the mid to mid-teen Mavyret list prcie is being matched by GILD. She also said that I should know better after attendingmany of her presentations myelf (yes she remembered me), since my mother's advanced Allzheimer's Disease would make compliance of Mavyret 3X per day difficult to comply with.

So with all due respect as you can see from the above, I rely on direct relevant information from genuine experts rather than just providing a convenient link as you did which anyone can do!

BTW yes i had many virologists as my colleagues at GILD and visited their negative pressure labs often and actually have seen them using electono micresocpe and even peeped into it and say the enalrged HIV on a monitor as well. So please refrain from what I know and whom I knew at Gilead.

Finally, you have absolutely no idea as to what does Andrew Cheng mean to Gilead specifically for HIV R&D. These so callled glorified immortals still require a leader. Without Andrew after September, Gilead would not have any and nobody can step up IMO! Would GILD hire someone from outside to replace Andrew? I do'n't think so. Got it?

Furthermore, GILD screwed up i letting Norbert go. John McHutch is not at the same level. They also screed up in letting ROy Baynes go (few years ago) David CHang (Kite) go (a few months ago). Alessandro simply does not measure up.

Last one SRB,

As a tax expert. have you ever used an electron microscope yourself????

29 Aug 2018, 10:25 AM

SpoiledRottenBrat
Electron Microsoft:

No. but the university I attended had one of the first and it was over $100,000 cost. Remember them telling us that.

Drug price of Yescarta Confidential or not , as soon as the big money is finished paying and patients flying in (with cash) from around the world to get Yescarta .. prices will drop off.

Yes... Harvoni and rest of HCV is already at their price lows. Remember when it was $100,000 for 12 weeks? People paid that amount, you know.

Andrew Cheng don't mean "jack" to GILD HIV. They got 1000nds of Andrew Chengs on the payroll already. Thousands - phds under the microscope daily … at the manufacturing for Yescarta… technicians with 3.8GPAs in chemistry … MD's at the hospitals.. nurses ...

You brainwashing (fool) yourself - CSYJ.

You need to open your own lab, and get off this cheap SA waste of time BS...

No offense CSYJ intended.

29 Aug 2018, 10:37 AM

SpoiledRottenBrat
CSYJ.. before I got into "tax" you asked about.
Check out this link: Trump's two attorneys are going to end up with felony convictions and million dollar fines for one of the charges they pled guilty to (or were convicted of).

Guess they didn't teach them any tax in law school!

www.linkedin.com/...

They'll both be disbarred when it's all said and done IMO.

29 Aug 2018, 11:04 AM

CSYJ
SRB,

I interacted with Andrew personally many times when was at GILD. I also have heard his presentations on HIV topics many times. The minions of PhD's in the labs are just soldiers. Without an effective leader/general, you cannot win a war. You htink hundred of CPA" would automatically guarantee a successful and profitable CPA firm? Really?

BTW, I did work in a lab soon after I graduated with my advanced degree in microbiology and molecular biology. Not my cup of tea. Mere academic degree does not guarantee promotion nor big compensation. One must be able to show some leadership quality (meaning being able to inspire others and execute a project).

Lastly, I stand by my claim and observation after more than three decades in this industry with the last decade at Gilead. I am retired thus not interested nor motivated to have my own lab.

30 Aug 2018, 05:42 AM

Dan Schmeidler, Contributor
Excellent article. No doubt this is a one tough sector.

14 Aug 2018, 07:50 PM

Bill Koski, Contributor
Author's reply » Thank you for reading, Dan! Glad that you enjoyed the article.

14 Aug 2018, 11:07 PM

GeorgeFF
CELG. The effect on stock price is ZERO

14 Aug 2018, 08:29 PM

Idancer44
I have no idea what your point is. Does it pay to keep Gild or sell? I have it for too long thanks to several Seeking Alpha contributors and all I want to know is if you think it is worthwhile to hold.
I'm tired or metaphors and poetic language. I don't mean to insult you, just want to know what you think about the investment I made three years ago.

14 Aug 2018, 08:44 PM

RussMc
Idancer, I'm not a contributor. Just someone in your shoes, that is owning Gild for many years. It's been a hell of a ride! But I feel that the company is worth the ride. And with the Div. that it pays, it's worth holding onto. I've also owned Celgene, but that doesn't pay a div. But thinking of buying some back, as I still like the company to. Do your own home work on the companies that you maybe interested in. Good luck! Russ

14 Aug 2018, 10:16 PM

Bill Koski, Contributor
Author's reply » Hi @Idancer44 and @Boss_302. Thank you for reading. I am sorry that you didn't find what you were looking for in my article.

I do not provide explicit recommendations to buy or sell stocks. My personal belief is that every investor that makes investments in individual stocks owes it to themself to fully understand the company they invest in, inside and out. Especially in biotech, where the technology underlying a company's valuation is exceedingly complex.

My intention in writing this article is not to value Gilead or any of the companies mentioned. The commercial challenges of CAR-T are unprecedented and my point is to educate the reader about factors affecting competition in the market for CD19-directed CAR-T therapies and discuss who is best prepared to compete for market share.

As @RussMc mentions, do your own homework. This article is a tool to help you. If you are not willing to do that, dump the stock. Don't take recommendations from strangers at face value.

14 Aug 2018, 11:34 PM

Knowledge helps !

Why don’t you do your own homework, instead of reading SA writers and blaming them when things don’t work? For me, healthcare is way too difficult. If you don’t have the time, don’t invest in individual namens. Good luck.

14 Aug 2018, 11:41 PM

Knowledge helps !

That’s a very kind reply to these pretty frustrated readers (most GILD investors react aggressively when you make some critical remarks on capital allocation the last few years is my experience). CELG is very risky. One huge blockbuster, with patent expiration a few years out. After that, hardly any revenues left.

14 Aug 2018, 11:50 PM

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yeti786

Whether 'worthwhile to hold' or not is function of time and expectations. As also safety/stability when the market dips.

Perhaps you can look at some other companies where the stock price appreciation will outpace GILD's growth and offset its dividend - which anyway is no big deal in absolute terms.

You could try reading or subscribing to Bret Jensen; he has a fine reputation for selecting bio-tech stocks and helping with advice; another with medical background is Bio Sci Capital Partners. As also Taylor Dart but in the non biotech field and with a different approach to investing/trading and securing ROI.

I'd say there are many other companies that will likely offer better returns than GILD in coming yrs. Based on this understanding I got out of GILD about 2 yrs back and so far have been proved correct.

The best!

15 Aug 2018, 12:08 AM

Tambo210

Its how you view their pipeline.

One concern I've not fully grasped or waived is the Juno acquisition. What Juno brings is interesting, just may not be in time when patents expire

15 Aug 2018, 03:55 AM

Tambo210

Good to have your opinion on the drug impact side of the business rather than if a stock is a buy or not.....too many day traders and MM's on these boards looking for others to do their homework.

Your insight into the deployment of these therapies is very educational. Must say, the more I read comments like your's, the more immoral it feels to invest in companies like CELG and GILD. More than just a scratch/graze. There pressure on the nation to deliver affordable treatment, which implies tight margins, yet companies need margins to plough that money back in to R & D

15 Aug 2018, 04:00 AM

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ldancer44
RussMc, thanks for taking the time to address my semi-meltdown. I've been chastising myself for keeping Gild when I could have used the money elsewhere. I broke my own rules and kept Gild after more than a 20% drop. I believed in the company and still do, just know how long I should wait. Thanks again.

15 Aug 2018, 08:59 AM

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ldancer44
I do subscribe to Bret Jensen which in a combination with my own research, despite the presumption by some repliers that I don't do, I like the company. Thank you for your sharing your own thoughts and experience with Gild. I sincerely appreciate it. It's become a different market this year as the thread moves higher and thinner. Good luck also.

15 Aug 2018, 09:09 AM

Mr. Wacker
Educational, yes
$2Bb to &3bb per CART is an interesting data point
So if analysts are projecting more
Time for a reality check.
Thanks, food for thought

15 Aug 2018, 10:23 AM

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jade mid
I wouldn’t base my decision on Car-T therapy with Gild. They bought Kite on a flyer and worse case scenario they will recover their money over the next decade, best case they will succeed wildly. Either way Car-T is not going to break this company, now HIV and Nash will be the drivers.

15 Aug 2018, 04:56 PM

13th Floor Investments
Agree with you comments on CAR-T. That wasnt the smartest decision. They dont have a good handle on the side effects which makes this only a salvage therapy drug.

GILD is an HIV company. I read there is a once a week injectible coming to the market that could replace HAART. Not sure if its true but that would be a game changer. There are competitive threats from JNJ's 2 drug combination pill. If the virus doesn't mutate then this is going to destroy Bikarvy.

15 Aug 2018, 06:59 PM

egga
What do you think of GSKs two drug injections that just made news today? Gets me worried about GILD

15 Aug 2018, 07:07 PM

yeti786
Another angle to consider: You now also have an unexpected change in CEO and CMO. Maybe more of the top management will change in foreseeable future... ?

16 Aug 2018, 08:12 AM

jondoeuk
They are working on improving the safety and efficacy of the CAR and TCR constructs www.gilead.com/... www.gilead.com/...

23 Aug 2018, 05:07 PM

RussMc
My pleasure! If you are not sure in your investment, be smart and spread it out into Apple. At least you keep making money, even if it goes a bit lower. Russ

29 Aug 2018, 10:40 PM

BOSS_302
I agree with Idancer44.

What kind of investment is GILD or NVS or CELG.

Anybody can just rip parts off of GILD or NVS or CELG.websites and sound like they know what they're talking about without making an estimation where these stocks are going.

14 Aug 2018, 09:23 PM

biogenius
I think both GILD and CELG overpaid for their CART. It is hard to imagine a peak sale of 2 bil for complicated therapies like CART. It is hard to pick individual big biotech/pharm stocks because there are so many moving parts. You are better off buying the index (IBB).

14 Aug 2018, 10:04 PM

Jimghad

Competition will bring this area to $100,000 to $150,000 a patient
This is when I see No. of patients exploding. Sales shooting up.
Not till then..

14 Aug 2018, 11:43 PM

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ray69
We are at the start of a revolution in cancer therapy and time will bring some clarity.

Right now too difficult for experts to assess with confidence so how would investors know what to do. That's the opportunity in biotech - spread your bets and hopefully you will hit a 10 bagger.

15 Aug 2018, 05:52 AM

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ukpdam
Thanks for the article. I've been following/investing in a few of the development firms and watching clinicals progress. Seems there are a lot of positive developments in the pipelines but very difficult to understand the technology proposals. It is interesting to dig into the literature and watch cancer finally meet it's match, but damn difficult to pick winners and losers. Well, actually in retrospect it has been easy to pick losers (in my case). However, even the losers I hold still look promising enough to hang onto as they continue thru the later trial phases toward potential commercialization. So I stay in the game.

15 Aug 2018, 08:56 AM

> **Bill Koski, Contributor**
> Author's reply » Thanks, @ukpdam! I share your sentiment here. Background in biomedical engineering and it still took me over a year to get a solid grasp on CAR-T. It's always difficult to pick winners. Hindsight is 20/20 and nothing is ever usually obvious in the moment.
>
> 16 Aug 2018, 01:29 AM

Dieter Hovekamp
Thank you for a great summary after 1st year of CAR-T approval.
As you've used the Adaptimmune 'Competitive Landscape' slide I would love to see a follow-on about the emerging trend to TCR T-cell therapies after armed and a few non-CD19 CAR-T are progressing toward pivotals.
Also a note on Amgen 40% growth for BiTE CD19 targeting Blincyto and its upcoming competition of new generation BiSpec as a potential safer and more economical treatment thread to CAR-T peek market sales in early lines of therapies would deserve a mention with any update next year.

15 Aug 2018, 09:17 AM

> **Bill Koski, Contributor**
> Author's reply » Thanks for reading! I have valued reading your perspectives on Twitter and it means a lot that you liked the article. It sounds like I owe you a follow-up.
>
> 16 Aug 2018, 01:36 AM

kenberthiaume
wow stock getting hammered today. Chief medical officer resigning, not sure why. Guess all their irons in the fire are pretty bad if he's leaving.

15 Aug 2018, 09:36 AM

jade mid
Maybe he is retiring or just got a better offer. Your just jumping to conclusions

15 Aug 2018, 03:38 PM

CSYJ
KB & JM,

Andrew was a key lieutenant of Norbert. With Norber gone, there is really no compelling reason for Andrew to stick around especially with the new CSO focusing almost exclusively on immuninflammatory and NASH, and also oncology.

I wish all the luck in the world and hope he would be much more appreciated and valued at say VIIV and come up with a genuine HIV cure.

28 Aug 2018, 11:24 PM

Doyle3000
Very informative article - thank you. I feel that all cutting edge technologies must go through these growing pains. But progress is inevitable in the fight vs. our most common cancers. There is both utility and money in the endeavor; a win-win for sure.

Thank you

15 Aug 2018, 09:46 AM

Jolene5689
Any ideas on blcm

15 Aug 2018, 10:49 AM

Bill Koski, Contributor
Author's reply » BLCM had a much stronger value proposition a year ago when there was greater uncertainty surrounding treatment safety. With physician experience and safer expansion profiles (i.e JCAR017) serious adverse events have become rarer and CRS starts to look more manageable.

Management has struggled a lot to advance products in the past. BPX-501 is also a whole different ballpark and I haven't sat down to value 501.

Interestingly, I have seen some of the synthetic biology elements underlying BLCM's tech popping up more in literature,

16 Aug 2018, 01:43 AM

Jolene5689
Thanks Bill

16 Aug 2018, 11:27 AM

BOSS_302
We also need to recognize that Kite and Novartis approaches are completely different. Kite re-engineers the CAR-t cell itself, replicates it, and sends it back into the body. Novartis has a drug that stimulates the CAR-T cells to do their job better.

15 Aug 2018, 11:54 AM

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kenberthiaume
Gilead needs to expand Kite to other cancers. WHen is that going to happen?

15 Aug 2018, 12:06 PM

13th Floor Investments
The biggest issue effecting sales are the side effect of the Cytokine Release Syndrome (CRS). This really should have gotten a mention in the article.

15 Aug 2018, 02:41 PM

Bill Koski, Contributor
Author's reply » Thanks for reading. I mention cytokine release and neurotoxicity multiple times. I have included the relevant commentary from my article below. I assume that the reader has a basic understanding of adverse events related to CAR-T therapy.

To be explicit, I think Celgene (pending approval) is positioned to gain market share lost due to a later approval due to lower rates of CRS which enable outpatient treatment.

"Celgene has attempted to rally investors behind a best-in-class claim, pointing to numerically lower rates of neurotoxicity (NT) and cytokine release syndrome (CRS) in the TRANSCEND-001 NHL trial. "

"But with numerically lower efficacy in DLBCL, higher rates of CRS, and a track record of manufacturing failures, Kymriah may be at a significant disadvantage in non-Hodgkin's Lymphoma."

"Juno/Celgene maintains a reasonable claim to an improved safety profile that may enable outpatient treatment and facilitate the adoption of Liso-cel via CMS policy. Maintaining response rates and durability in the final analysis of Liso-cel will be critical for Celgene to grasp a competitive position. It is unlikely that the adverse event profile changes significantly in the final analysis of TRANSCEND-001 NHL as cytokine release syndrome and neurotoxicity manifest symptoms within days/weeks of treatment infusion."

16 Aug 2018, 01:50 AM

ukpdam
Bill, just curious whether you've ever researched Celyad (CYAD) and their technology as they seem to have the global IP ownership for natural killer cell approaches which look promising in trials. Not a lot of info available as they are in Belgium.

16 Aug 2018, 11:05 AM

Bill Koski, Contributor
Author's reply » I haven't heard much! I will take a closer look next time I have a lazy afternoon.

Where most CAR's are engineered to express a murine or human SCFv (antibody fragment) that binds to a single target (CD19, BCMA, CEA, etc.), it looks like they are using an endogenous NK-receptor that binds to a class of ligands. Interestingly this includes targets in the vasculature. There is a strong rationale for adoptive cell therapy with NK cells, but most groups I have seen are approaching things the other way around--expressing a chimeric receptor in NK cells, not NK-receptors in T-cells

Its a really intriguing idea and it looks like they had a CR in AML.

16 Aug 2018, 02:05 PM

ukpdam
Yes - on their Investors page there is a really good presentation describing their approach, results to-date, and pipeline progress. They are doing work with both autologous and allogeneic as well as solid tumor. I listened to one of their quarterly results phone conferences and definitely heard one of their management state that they own the IP for what they are working with - which is significant in my view.

16 Aug 2018, 02:30 PM

ukpdam
link to the Celyad CYAD presentation materials www.celyad.com/...

16 Aug 2018, 02:31 PM

Bill Koski, Contributor
Author's reply » Thanks!

16 Aug 2018, 05:05 PM

kenberthiaume
God what an utter dog this stock is. Pile of garbage. Down every day. Relentless selling.

17 Aug 2018, 09:57 AM

kenberthiaume

Company is absolutely disgusting. Sits of 35B of cash and watches their stock burn down every day. Basically telling the market they think it's overvalued.

17 Aug 2018, 10:10 AM

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pro8
Look in the mirror , you bought high evidently, maybe you should stick with index funds or CD's as your stock prowess seems to be lacking....

17 Aug 2018, 10:16 AM

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kenberthiaume
Somehow I thought a company at 10x earnings and a decent pipeline with 1/3 of its value in cash would buy back stock etc.

So GFY. My prowess is fine with other stocks. So again, GFY.

17 Aug 2018, 10:51 AM

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cvnt
Great analysis! Any data about reimbursement policy of private insurance?

17 Aug 2018, 02:53 PM

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me66
Good article on a very promising segment of medicine, difficult to predict individual winners, but I hold a position in GILD still. Sold about 70%, took a loss, but redeployed the capital elsewhere. I will hold what I have, watch, & increase my position when things are a little more clear.....

Individual BioTech companies are not for the faint of heart... The gains have outweighed the losses, but it has been a pretty wild ride these last 4 years, for me.

17 Aug 2018, 10:09 PM

NDHT
Very interesting to know the sales performance of these two CAR T pioneers.

If Celgene's product comes to the market, is it possible for the MCOs/PBMs to reimburse only one out of the three, if they are kind of interchangable?

You stated, "Safety then becomes a key consideration in establishing treatment paradigms between analogous T-cell therapies."

Do you mean autologous, not analogous, here?

19 Aug 2018, 05:15 PM

Bill Koski, Contributor

Author's reply » Thanks for reading! I did actually intend that to read "analagous" not "autologous", although I see how that could come up as a typo. The idea was, given two (or three) comparable CAR-T products, I think the key driver at this point will be a signal of superior safety, rather than a signal of superior efficacy.

As for your question on reimbursement, I honestly have no idea what the precedent is here. My gut tells me that they wouldn't consider selective reimbursement until (or if) we see any type of head-to-head, but the honest answer is that I really don't know. I would be really curious if someone can weign-in with an intelligent comment here.

20 Aug 2018, 01:13 AM

CSYJ

All,

Can someone answer this question? Regardless of NVS's Kymriah or GILD's Yescarta, when is the payment for these exorbitantly costly drugs made, in patient or outpatient, to the centers, by the insurance companies and eventually to the manufacturers?

20 Aug 2018, 11:58 PM

RussMc

CSYJ

No one in there right mind would give you a time line!

29 Aug 2018, 11:09 PM