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MorphoSys' (MOR) tafasitamab (MOR208) – an effective treatment option in r/r DLBCL

TABLE 1: MorphoSys (MOR) – Key Valuation Metrics

Mkt. Cap (US$)	Symbol	Company	Mkt. Price 02/07/20	P/S	YTD	Viola Advisory Rating	Viola Advisory PT	Upside Potential 52-Week High	Upside Potential PT
4.0B	MOR	MorphoSys	31.38	49.5	-12.9%	Buy	40.00	21%	27%

Source: Yahoo Finance, Ycharts.com, Viola Advisory LLC

Summary: **Frontline therapy can cure around two thirds of patients with diffuse large B-cell lymphoma (DLBCL). However, there is still a large number of patients who experience relapse or refractory disease. We believe tafasitamab, which is being explored as a new option in the r/r DLBCL setting in combination with lenalidomide (Revlimid) is on track for an FDA approval possibly in the latter half of 2020. The BLA was submitted on December 30, 2019 based on the results of the L-MIND clinical trial. The trial examined the combined therapy of tafasitamab with lenalidomide in r/r DLBCL and produced impressive response rates (ORR: 60%, CR: 43%) and a median PFS of 12 months. Moreover, the results also showed the combination treatment to have a very good safety profile. We are optimistic tafasitamab can achieve and surpass the consensus FY2024 sales forecast of $661M. Tafasitamab's main competitor in the r/r DLBCL space is polatuzumab vedotin (Polivy). Clinical trial comparisons show tafasitamab as having a longer remission and a better safety profile.**

Summary of Contents

I. Overview of Tafasitamab (MOR208)

A. Treatment Sequence for DLBCL and Tafasitamab (MOR208)

The L-MIND trial specifically looked at patients with relapsed large cell lymphoma. This is a patient population with a high unmet clinical need. Many of the patients had 2 or 3 lines of prior therapy and nearly all of them were not eligible for autologous stem cell transplant (ASCT).

The most common first line therapy currently used In the U.S. is a regimen called R-CHOP (rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, prednisone). This is rituximab with a combination of chemotherapy drugs that is usually used every 3 weeks for a total of 6 cycles. The cure rate or the long-term remission rate for first-line therapy is around 50% to 70%. That means that about 30% to 50% of

patients will at some time relapse following frontline therapy. The relapses usually occur somewhere between 6 months and 2 years. If patients go beyond 2 years, the odds of a relapse drop significantly.

If the patient relapses either after frontline therapy or after ASCT, then they generally fall into two main groups. The first group is patients with a high performance status – those whose blood counts and organ function are good. They would be suitable for an aggressive approach like combination chemotherapy using different drugs from the ones used in either the transplant or in the frontline setting.

The second group of patients are those that are either too old or who have poor performance status, i.e., are bed-bound, their kidney function is poor, and they may have difficulties with heart function. These are patients that even if they achieve remission are probably not going to tolerate a stem cell transplant. Patients in this category need a treatment that is not too toxic and that will provide a long progression-free survival.

This patient group has shown to have high clinical benefit for tafasitamab. The L-MIND trial results show that patients were able to tolerate the combined tafasitamab/lenalidomide therapy. Moreover, treatment did not affect organ function and provided a long progression-free survival. For these patients that cannot be given aggressive chemotherapy, clinicians are looking for a treatment that is mild and is capable of controlling the disease for as long as possible.

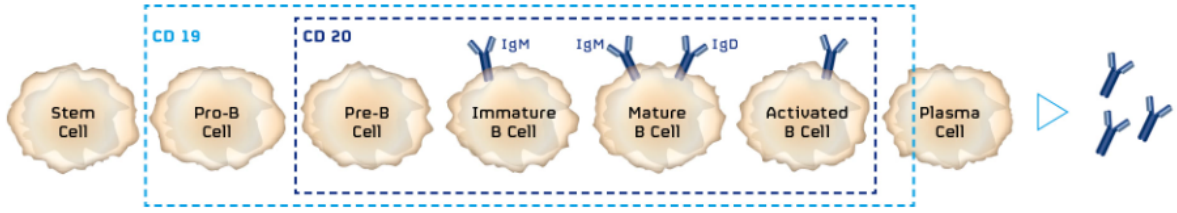
B. Tafasitamab's Anti-CD19 is an Attractive Target

For the past two decades, researchers have been exploring B-cell specific antigens in hopes of developing a new anti-cancer target that would mirror the success of the CD20-targeting rituximab (Rituxan). Currently, strategies that are aimed at CD19 look particularly promising.

CD19 makes an attractive target for cancer therapy since its expression on normal cells is limited to those of B-cell lineage. Furthermore, it is expressed on most B-cell malignancies, including 80% of acute lymphoblastic leukemias (ALLs), 88% of B-cell lymphomas, and 100% of B-cell leukemias.

Therefore, CD19 is a suitable tumor-associated antigen (TAA) against which to target anti-cancer agents. In contrast to CD20, the CD19 protein is expressed throughout B-cell development, from B-cell precursors through mature B-cells, before expression is lost when they become plasma cells (see Figure 1).

FIGURE 1: CD-19 Expression on B-cells



Source: MorphoSys website

This wider range of expression potentially gives CD19-targeted agents an advantage over their CD20 counterparts, since they could be more useful in treating early B-cell neoplasms like ALL, which cannot be treated with rituximab.

Furthermore, the L-MIND trial combined tafasitamab with lenalidomide. Lenalidomide is a drug that has been shown to change the tumor microenvironment by potentially increasing antibody dependent cellular cytotoxicity (ADCC). Clinical trials have shown that when a monoclonal antibody is combined with lenalidomide, there is an increased activation of certain benign cells within the tumor microenvironment that can potentially increase the activity of monoclonal antibodies. The goal of the L-MIND trial was to combine a drug like lenalidomide with tafasitamab to potentially increase the treatment response from just either the single therapy tafasitamab or lenalidomide alone.

II. Clinical Trial Comparison: Tafasitamab vs. Polatuzumab Vedotin (Polivy)

A. Tafasitamab vs. Polatuzumab Vedotin (Polivy)

We believe tafasitamab's main competitor in the r/r DLBCL space is polatuzumab vedotin-piiq (Polivy), a CD79b directed antibody drug conjugate manufactured by Genentech/Roche. Polatuzumab vedotin was FDA approved on June 10, 2019 and is indicated for adult patients with r/r DLBCL.

Target Patient Group: Tafasitamab + lenalidomide is intended for patients with r/r DLBCL who are not eligible for high-dose chemotherapy and autologous stem cell transplantation. Polatuzumab vedotin + bendamustine and rituximab (BR) is also intended for adult patients with r/r DLBCL who have undergone at least two prior therapies. Table 2 summarizes the results of both clinical trials.

TABLE 2: Clinical Trial Comparisons: Tafasitamab vs. Polatuzumab Vedotin (Polivy)

Clinical Trial:	L-MIND (tafasitamab + lenalidomide)	Study GO29365 (polatuzumab vedotin + BR)
Primary Endpoint:	Best ORR	Best ORR
ORR:	60%	63%
CR:	43%	40%
mPFS:	12.1 months	12 months
mDoR:	21.7 months	6 months (64%), 12 months (48%)
Adverse Events:	IRRs (1%, grade 1), neutropenia (48%), thrombocytopenia (17%), anemia (7%)	Neutropenia, thrombocytopenia, anemia, peripheral neuropathy, fatigue, diarrhea, pyrexia, decreased appetite and pneumonia; cytopenia (18% – most common reason for treatment discontinuation)

Note: BR – bendamustine and rituximab, IRRs – infusion-related reactions, ORR – objective response rate, CR – complete response, mPFS – median progression free survival, mDoR – median duration of response.

Source: Company press release

Efficacy results for both the L-MIND and Study GO29365 studies show similarities in responsiveness for both tafasitamab + lenalidomide relative to polatuzumab + BR. The objective response rates were at 60% and 63% for tafasitamab and polatuzumab vedotin respectively. Complete response rates at 43% and 40% were also similar for tafasitamab and polatuzumab respectively.

We believe key differences between tafasitamab and polatuzumab vedotin can be found in the durability of response and the safety profile of each drug.

Durability of Response: Progression free survival was roughly 12 months each for both tafasitamab and polatuzumab vedotin. However, median duration of response showed that tafasitamab had a deeper remission of around 22 months, almost 2x that of polatuzumab vedotin, which showed a 6-month duration for 64% of patients and a 12-month response duration for 48% of patients (see Table 2).

Safety Profile: The safety profile showed that tafasitamab had less adverse events (AEs) occurring relative to polatuzumab vedotin (see Table 2). Tafasitamab showed 4 AEs – infusion related reactions (IRRs), neutropenia, thrombocytopenia and anemia. In addition, 43% of patients required a dose reduction with lenalidomide while 78% of patients were able to stay on a daily lenalidomide dose of 20 mg or higher.

In contrast, there were 10 AEs in the polatuzumab vedotin study. For polatuzumab vedotin + BR, the most common adverse reactions with at least 20% of incidence included neutropenia, thrombocytopenia, anemia, peripheral neuropathy, fatigue, diarrhea, pyrexia, decreased appetite, and pneumonia. Moreover, serious adverse reactions occurred in 64% of patients, most often from infection, while cytopenia was the most common reason for treatment discontinuation in 18% of all patients.

B. Potential Label Expansion

Tafasitamab is being positioned for an earlier line of therapy for adult patients with newly diagnosed, previously untreated DLBCL (First-MIND study). Tafasitamab is also being studied for a potential new indication in adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (COSMOS STUDY).

First-MIND STUDY: First-MIND is an open-label, randomized Phase 1b study to evaluate the safety and efficacy of tafasitamab in addition to R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) as well as tafasitamab and lenalidomide in addition to R-CHOP in adult patients with newly diagnosed, previously untreated DLBCL. Patients enrolled in each arm will receive six cycles of treatment. The primary endpoint is the incidence and severity of treatment-emergent adverse events (AEs); key secondary endpoints are objective response rate (ORR) and PET-negative complete response (CR) rate at the end of treatment.

COSMOS STUDY: The COSMOS-Study is a single-arm, open-label, multicenter Phase 2 combination trial of tafasitamab with either idelalisib or venetoclax in adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Patient enrolled must have been refractory or have shown relapse or intolerance to a prior, most recent therapy with a Bruton's Tyrosine Kinase (BTK) inhibitor (e.g. ibrutinib). The study will evaluate the safety of the drug combinations. Data of the primary analysis of the COSMOS trial was presented at ASH in 2019.

III. Key Opinion Leaders on Tafasitamab (MOR208)

KOL #1: Nathan H. Fowler, MD
Associate Professor, The University of Texas MD Anderson Cancer Center
Department of Lymphoma and Myeloma, Division of Cancer Medicine
Source: "Anti-CD19 Monoclonal Antibody Therapy in DLBCL," Targeted Oncology, December 19, 2019

"With large cell lymphoma there are limited treatment options for patients, especially patients who are ineligible for transplant or have failed standard chemotherapy. In the past, we many times would give these patients chemotherapy again. Unfortunately, many of them would not respond. So the nice thing about this non-chemotherapy-based regimen is we have another bullet in our gun that could potentially knock out large

cell lymphoma. I think this regimen may eventually be combined with other therapies to hopefully achieve cures in many of these patients. But with an overall response rate of over 50%, and a duration of remission that's over a year, it's a great option for patients who really don't have a lot of treatment options with available therapy."

KOL #2: John M. Burke, MD

Associate Chair, Hematology Research Program, US Oncology Network
Rocky Mountain Cancer Centers
Source: "Phase Ib Clinical Trial Enrolling to Evaluate Tafasitamab in Treatment-Naive DLBCL," Targeted Oncology, January 17, 2020

"Tafasitamab as a monotherapy has demonstrated clinical activity as well as safety in patients with relapsed/refractory chronic lymphocytic leukemia and small lymphocytic, as well as in relapsed/refractory non-Hodgkin lymphoma (NHL). The agent demonstrated promising responses in a phase IIa clinical trial (NCT01685008), which indicated an objective response rate in relapsed/refractory patients of 26% with DLBCL, 29% with follicular lymphoma, and 27% with other indolent NHLs. Patients received tafasitamab intravenously weekly for 8 weeks. In terms of safety, the most common toxicities of any grade included infusion-related reactions (12%) and neutropenia (12%). Grade 3/4 neutropenia was observed in 8 patients (9%), and 1 patient experienced a grade 4 infusion-related reaction."

"After this first safety-finding study [First-MIND trial], we would have to go to a randomized phase III trial. If that trial were positive, it would change the standard of care for how to treat patients with large cell lymphoma initially. The original study that has been proposed that will be conducted first won't be practice-changing immediately by itself."

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