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BELANTAMAB MAFODOTIN FOR RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM)

Keywords: GSK2857916, anti-cancer, anti-BCMA, biologics, monoclonal antibody

SUMMARY OF TECHNOLOGY

Belantamab mafodotin (previously known as GSK2857916) is an anti-cancer drug developed by GlaxoSmithKline (GSK). It is first-in-class, investigational monocloncal antibody consist of humanised immunoconjugate against B-cell maturation antigen (BCMA). It binds to BCMA and kills multiple myeloma (MM) cells via a multimodal mechanism as shown in Figure 1:

- delivery of mono-methyl auristatin F (MMAF) to BCMA-expressing MM cells, thereby inducing apoptosis
- enhancing antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis
- inducing immunogenic cell death

The proposed dosage is 2.5 mg/kg via intravenous infusion every three weeks on day 1 of each cycle in patients with relapsed or refractory multiple myeloma with disease progression after three or more lines of therapy and who were:

- refractory to immunomodulatory drugs and proteasome inhibitors
- refractory or intolerant (or both) to an anti-CD38 monoclonal antibody.

In 2017, belantamab mafodotin was granted Breakthrough Therapy designation from the US Food and Drug Administration (FDA) and Priority Medicines (PRIME) designation from the European Medicines Agency. In January 2020, US FDA granted Priority Review for belantamab mafodotin for their Biologics License Application. On 5th August 2020, US FDA granted accelerated approval to belantamab mafodotin indicated for RRMM based on results from the pivotal DREAMM-2 study.[1]

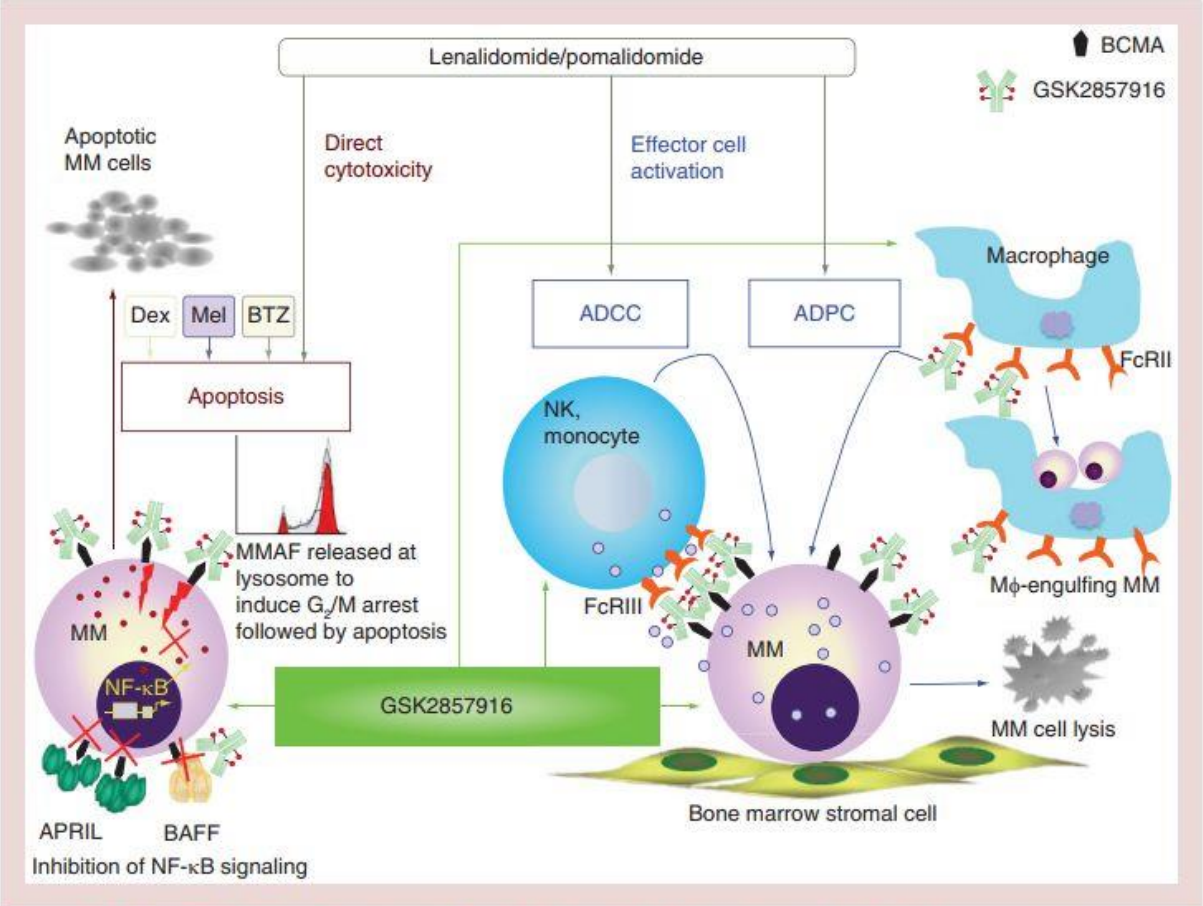

Figure 1: **GSK2857916 induces direct and indirect killing of multiple myeloma cells in the bone marrow microenvironment.** GSK2857916 specifically binds to BCMA on the MM cell membrane, and MMAF is then released inside MM cells by lysosome to induce G2-M growth arrest, followed by caspase 3/7-dependent apoptosis. It inhibits binding of APRIL and/or BAFF to BCMA, thereby blocking NF-κB signaling cascades critical for MM cell growth and survival. It has been Fc-engineered to enhance its binding to effector cells (i.e., NK cells, monocytes, macrophages), leading to significantly increased antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). ADCC and ADCP is induced via binding of FcγRs on NK cells and macrophages (myeloid effector cells) by tumor cell-bound GSK2857916. These three key anti-MM activities of GSK2857916 are further enhanced by lenalidomide or pomalidomide, triggering both direct and indirect killing of MM cells. Dexamethasone (Dex)/predonisolone, melphalan (Mel), or bortezomib (BTZ) also augment direct toxicity induced by GSK2857916.
BCMA: B-cell maturation antigen; MM: Multiple myeloma.

INNOVATIVENESS

Novel, completely new	√
Incremental improvement of the existing technology	
New indication of an existing technology	

DISEASE BURDEN

MM is a clonal plasma cell neoplasm with substantial morbidity and mortality, characterised by end organ damages such as renal impairment, hypercalcaemia, lytic bony lesions and anaemia.[2]

According to International Myeloma Working Group (IMWG), active myeloma is defined as clonal bone marrow plasma cells >10% or biopsy-proven plasmacytoma (bony or extramedullary) and any one or more of the following features and myeloma-defining events as shown in Table 1.[3]

Table 1: Definition of active myeloma clonal bone marrow plasma cells >10% or biopsy-proven bony or extramedullary plasmacytoma and any one or more of the following features and myeloma-defining events.

EVIDENCE OF END ORGAN DAMAGE THAT CAN BE ATTRIBUTED TO THE UNDERLYING PLASMA CELL PROLIFERATIVE DISORDER
Hypercalcaemia: serum calcium >0.25 mmol/L (>1 mg/dL) higher than the upper limit of normal or >2.75 mmol/L (>11 mg/dL)
Renal insufficiency: creatinine clearance < 40 mL per min or serum creatinine > 177 µmol/L (>2 mg/dL)
Anaemia: haemoglobin value of >20 g/L below the lower limit of normal, or a haemoglobin value <100 g/L
Bone lesions: one or more osteolytic lesions on skeletal radiography, computed tomography scan (CT-scan) or Positron Emission Tomography/Computed Tomography (PET/CT)
ANY ONE OR MORE OF THE FOLLOWING BIOMARKERS OF MALIGNANCY
60% or greater clonal plasma cells on bone marrow examination
Serum involved/uninvolved free light chain ratio of 100 or greater, provided the absolute level of the involved light chain is at least 100mg/L (a patient's involved free light chain either kappa or lambda is the one that is above the normal reference range; the uninvolved free light chain is the one that is typically in, or below, the normal range)
More than one focal lesion on magnetic resonance imaging (MRI) that is at least 5 mm or greater in size.

Progressive MM is defined as a 25% increase from baseline in the serum monoclonal protein (M-protein; absolute increase >0.5g/dL), urine M-protein (absolute increase >200 mg/dL), percentage of bone marrow plasma cells (absolute percentage increase >10%), and/or the difference between involved and uninvolved free light chain levels (absolute increase must be >10 mg/dL). Progressive disease can also

be established based on the presence of definite new bone lesions and/or soft tissue plasmacytomas, with a clear increase in the size of existing plasmacytomas or hypercalcaemia that cannot be attributed to another cause. Disease that meets these criteria for progression is defined as relapsed disease.[4]

Relapsed/refractory multiple myeloma (RRMM) is defined as a disease which becomes non-responsive or progressive on therapy or within 60 days of the last treatment in patients who have achieved a minimal response or better on prior therapy. Indication of treatment at relapse is shown in Table 2.[3]

Table 2: Indication of treatment at relapse.

Clinical Relapse
Development of new soft-tissue plasmacytomas or bone lesions
Definite increase (≥50%) in size of existing plasmacytomas or bone lesions
Hypercalcaemia (≥11.5 mg/dL; 2.875 mmol/L)
Decrease in haemoglobin of ≥2 g/dL (1.25 mmol/L) or to <10 g/dL because of myeloma
Rise in serum creatinine by ≥2 mg/dL or more (≥177 mmol/L) due to myeloma
Hyperviscosity requiring therapeutic intervention
Significant biochemical relapse in patients without clinical relapse
Doubling of the M-component in two consecutive measurements separated by two months with the reference value of 5 g/L or in two consecutive measurements of any from the following increases: • the absolute levels of serum M protein by ≥10 g/L • an increase of urine M protein by ≥500 mg per 24 hours • an increase of involved FLC level by ≥20 mg/dL (plus an abnormal FLC ratio) or 25% increase (whichever is greater)

Multiple myeloma (MM) is the second most common haematological cancer worldwide. It is more likely to occur in people with African descent.

A study on global burden of MM done in 2016 showed that there were 138,509 incident cases with an age-standardized incidence rate (ASIR) of 2.1 per 100,000 persons (95% uncertainty interval (UI) 1.8 to 2.3). The disease was also responsible for 98,437 (95% UI 87,383 to 109,815) deaths globally with an age-standardized death rate (ASDR) of 1.5 per 100,000 persons (95% UI 1.3 to 1.7).

MM was responsible for 2.1 million (95% UI 1.9 to 2.3 million) Disability-Adjusted Life Year (DALYs) at the global level in 2016, with an age-standardized rate of 30.5 (95% UI 27.4 to 33.9) DALYs per 100 000 person-years. From 1990 to 2016, MM incident cases increased by 126% and deaths increased by 94%.[5]

In Malaysia, MM ranked 23rd among all cancer incidence with incidence rate of 0.53% and the death rate of 0.70%.[6]

Based on the data above, MM is a relatively uncommon cancer. Despite many novel groups of drug emerged to treat MM, the disease remains incurable with most patients experiencing relapse and requiring additional therapy. In general, the disease has very short survival rate (three to five months) in heavily pretreated patients.[7] Patients who are refractory to both proteasome inhibitors (PI) and immunomodulatory drugs (IMiD) have an estimated survival of only 13 months.[8]

CURRENT OPTIONS FOR PATIENTS

The treatment strategy and outcome depend substantially on the burden, prognosis of the disease and fitness of the patient, therefore a thorough work-up to determine the disease stage, risk group and vital organ functions is mandatory.[9]

According to IMWG, for newly diagnosed MM, the standard induction regimens include thalidomide, lenalidomide, and/or bortezomib. Eligible patients may undergo autologous stem cell transplantation (ASCT), which deepens and prolongs the therapeutic response and improve outcomes especially when integrated with novel agents. Consolidation/maintenance post-ASCT does not only upgrades but also deepens the response which translates into improved progression-free survival.[4]

Treatment options in patients with relapsed MM, who were refractory to bortezomib and refractory to or ineligible to receive treatment with an IMiD (thalidomide or lenalidomide) are limited. Carfilzomib and pomalidomide, in conjunction with dexamethasone, have shown some efficacy in patients refractory to bortezomib and lenalidomide respectively.[4]

IMWG recommends a regimen containing carfilzomib or pomalidomide be considered for patients with MM relapsed and refractory to lenalidomide and bortezomib. Carfilzomib should preferably be used in combination with lenalidomide and low dose Dexamethasone consistent with the results of the ASPIRE trial. Similarly, pomalidomide is preferably used in combination with low dose dexamethasone, and can be combined with other agents, including bortezomib. Besides these regimens, there is no specific preference between other regimens that contain pomalidomide,

carfilzomib, or both drugs in this setting; the choice of regimen should be based on response and tolerability to immediate prior therapy, current clinical status and co-morbidities of the patient, as well as access and availability of agents. Panobinostat in combination with bortezomib and dexamethasone can be considered for patients with other limited treatment options and who have good performance status.[4] Table 3 below shows the drug class for the treatment of MM.[10]

Table 3: Classes of Drug for the treatment of MM.

Drug Class	Drug name
Chemotherapy	Melphalan Vincristine (Oncovin) Cyclophosphamide (Cytoxan) Etoposide (VP-16) Doxorubicin (Adriamycin) Liposomal doxorubicin (Doxil) Bendamustine (Treanda)
Corticosteroids (steroids)	Dexamethasone Prednisone
Immunomodulating agents	Thalidomide (Thalomid) Lenalidomide (Revlimid) Pomalidomide (Pomalyst)
Proteasome inhibitors	Bortezomib (Velcade) Carfilzomib (Kyprolis) Ixazomib (Ninlaro)
Histone deacetylase (HDAC) inhibitors	Panobinostat (Farydak)
Monoclonal antibodies	Daratumumab (Darzalex) Elotuzumab (Empliciti)
Nuclear export inhibitor	Selinexor (Xpovio)

POTENTIAL IMPACT OF TECHNOLOGY

Systematic search from MEDLINE, Embase, Cochrane Library and EUROScan databases identified two published papers and several on-going clinical trials on belantamab mafodotin as shown in Table 4.

DREAMM-1 (NCT02064387) was a phase 1 international, multicentre, open-label, dose escalation study to investigate the safety, pharmacokinetics, pharmacodynamics, immunogenicity and clinical activity of the antibody drug conjugate gsk2857916 in subjects with RRMM and other advanced haematologic malignancies expressing BCMA such as lymphoma. The study consisted of two parts. In part 1, patients received GSK2857916 (0.03 – 4.60 mg/kg) through one hour intravenous infusions once every three weeks. In part 2, patients received the selected recommended phase 2 dose of GSK2857916 (3.40 mg/kg) once every three

weeks. Primary endpoints were maximum tolerated dose and recommended phase 2 dose. Secondary endpoints for part 2 included preliminary anti-cancer clinical activity. The trial recruited 73 patients (38 patients in the dose-escalation part 1 and 35 patients in the dose-expansion part 2) who had prior therapy with alkylators, immunomodulatory drugs and proteasome inhibitors, had undergone stem cell transplant (if eligible) and refractory to the last line of treatment (defined as progressive disease on or within 60 days of completion of the last therapy) that included stem cell transplant.[8]

DREAMM-2 (NCT03525678) was an on-going randomised, open label, phase 2 study done at 58 multiple myeloma centers in eight countries. The trial recruited patients (196 patients were included in the intention-to-treat population) with RRMM with disease progression after three or more lines of therapy and who were refractory to immunomodulatory drugs and proteasome inhibitors, and refractory or intolerant or both to an anti-CD38 monoclonal antibody. Patients were randomised to two arms either receiving 2.5 mg/kg or 3.4 mg/kg belantamab mafodotin via intravenous infusion every three weeks on day one of each cycle until disease progression or unacceptable toxicity. The primary outcome was overall response rate.[11]

Table 4 Several on-going and planned clinical trials on belantamab mafodotin.

Name of the studies	Phase	Brief description of the studies
DREAMM-3 (ClinicalTrials.gov Identifier: NCT04162210)	3	Open-Label, Randomised Study to Evaluate the Efficacy and Safety of Single Agent Belantamab Mafodotin Compared to Pomalidomide Plus Low Dose Dexamethasone (Pom/Dex)
Bortezomib, Lenalidomide and Dexamethasone (VRd) with Belantamab Mafodotin versus VRd Alone in Transplant Ineligible Multiple Myeloma (ClinicalTrials.gov Identifier: NCT04091126)	3	Randomised, Open-Label Study of Belantamab Mafodotin Administered in Combination With Bortezomib, Lenalidomide and Dexamethasone versus Bortezomib, Lenalidomide and Dexamethasone Alone in Participants With Newly Diagnosed MM Who Are Ineligible for Autologous Stem Cell Transplantation
DREAMM 5	1/2	Randomised, Open-label Platform Study

(ClinicalTrials.gov Identifier: NCT04091126)		Utilising a Master Protocol to Study Belantamab Mafodotin (GSK2857916) as Monotherapy and in Combination with Anti-Cancer Treatments in Participants with RRMM
DREAMM 7 (ClinicalTrials.gov Identifier: NCT04246047)	3	A Multicentre, Open-Label, Randomised Study to Evaluate the Efficacy and Safety of the Combination of Belantamab Mafodotin, Bortezomib and Dexamethasone (B-Vd) Compared with the Combination of Daratumumab, Bortezomib and Dexamethasone (D-Vd) in Participants with RRMM
A Study of Belantamab Mafodotin to Investigate Safety, Tolerability, Pharmacokinetics, Immunogenicity and Clinical Activity in Participants With Relapsed/Refractory Multiple Myeloma (RRMM) (ClinicalTrials.gov Identifier: NCT04177823)	1	Open-label, Dose Escalation Study to Investigate the Safety, Tolerability, Pharmacokinetics, Immunogenicity and Clinical Activity of the Antibody Drug Conjugate GSK2857916 in Chinese Participants With RRMM who have failed at least Two Lines of Previous Treatment, Containing an Alkylator, a Proteasome Inhibitor and an Immunomodulatory Agent

Effectiveness

In DREAMM-1 study, the confirmed overall response rate (ORR) was 60% (95% CI; 42.1,76.1) with one (3%) patient had stringent complete response (sCR), two patients (6%) had complete response (CR), 15 patients (43%) had very good partial response (VGPR) and three patients (9%) had partial response (PR).[8]

In DREAMM-2 study, 30 patients (97.5% CI: 20.8, 42.6) of 97 patients in the 2.5 mg/kg cohort and 34 (97.5% CI: 23.9, 46.0) of 99 patients in the 3.4 mg/kg cohort achieved an overall response.[11]

Safety

In DREAMM-1 study, the most common adverse events (AE) occurring in ≥25% of patients were corneal events, thrombocytopaenia, anaemia, increased aspartate aminotransferase and cough. Blurred vision was the most common AE that led to

dose reduction, in 11/35 (31%) of patients, followed by thrombocytopaenia (4/35; 11%) and keratitis (3/35; 9%). There were three deaths in Part 2, all of which were attributed to progressive MM and not deemed treatment-related.[8]

According to DREAMM-2 study, the most common grade 3 – 4 AE in the safety population were keratopathy (27% in the 2.5 mg/kg cohort and 21% patients in the 3.4 mg/kg cohort), thrombocytopaenia (20% and 33% in respective group), and anaemia (20% and 25%, respectively). About 40% of patients in the 2.5 mg/kg cohort and 47% in the 3.4 mg/kg cohort had serious AE. Two deaths were potentially treatment-related (one case of sepsis in the 2.5 mg/kg cohort and one case of haemophagocytic lymphohistiocytosis in the 3.4 mg/kg cohort).[11]

Cost

The price of belantamab mafodotin is $8,277 per vial (~MYR 33,844) , with estimated monthly cost of $23,900 (~MYR 97,727) based on average weight of the patient.[12] However, there is no retrievable evidence on its cost effectiveness. Comparatively, the prices of each drug are shown in Table 5.

Table 5: Prices of MM drugs.

Drug Class	Drug name	Unit	Price USD	Price MYR
Chemotherapy	Melphalan Vincristine (Oncovin) Cyclophosphamide (Cytoxan) Etoposide (VP-16) Doxorubicin (Adriamycin) Liposomal doxorubicin (Doxil) Bendamustine (Treanda)	50mg (IV) 1 mg/mL 1g (IV) 20 mg/mL 2 mg/mL 2 mg/mL	$257.30[13] $14 per mL[14] $231 per injection[15] $14 per 5 mL[16] $17 per 5 mL[17] $823 per 10 mL[18] $4320[19]	1087.09 59.15 975.97 59.15 71.82 3477.17 18252.00
Corticosteroids (steroids)	Dexamethasone Prednisone		$7.59 $4.83	32.07 20.41
Immunomodulating agents	Thalidomide (Thalomid) Lenalidomide (Revlimid) Pomalidomide (Pomalyst)	50mg (oral) 1 mg/cap	$1,972 (10cap)[20] $22,313.77 (28cap)[21] $19,051.05 (21cap)[22]	8331.70 94275.68 80490.69
Proteasome inhibitors	Bortezomib (Velcade) Carfilzomib (Kyprolis) Ixazomib (Ninlaro)	3.5 mg (IV)	$1,356[23] $10,000 (28days)[24] $8,670 (28days)[25]	5729.10 42250.00 36630.75
Histone deacetylase (HDAC) inhibitors	Panobinostat (Farydak)		$8,800 (per cycle)[26]	37180.00
Monoclonal antibodies	Daratumumab (Darzalex) Elotuzumab (Empliciti)	- 300mg (IV)	$23,400 monthly[27] $2,037[28]	98865.00 8606.32
Nuclear export inhibitor	Selinexor (Xpovio)		$22,000 monthly[29]	92950.00

Otherwise, there was no organisational, societal or ethical issue identified on this technology.

In conclusion, belantamab mafodotin had shown potential efficacy for patients with RRMM with manageable safety profile. The medication is expensive therefore further cost-effectiveness analysis is recommended.

EVIDENCE

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