

Accelerating our oncology pipeline: belantamab mafodotin (GSK'916) DREAMM-2 data

17 December 2019

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A number of adjusted measures are used to report the performance of our business, which are non-IFRS measures. These measures are defined and reconciliations to the nearest IFRS measure are available in our third quarter 2019 earnings release and Annual Report on Form 20-F for FY 2018.

All expectations and targets regarding future performance and the dividend should be read together with "Assumptions related to 2019 guidance and 2016-2020 outlook" on page 59 of our third quarter 2019 earnings release.

Accelerating our oncology pipeline

Dr Hal Barron
Chief Scientific Officer, President R&D



Results of DREAMM-2

Dr Peter Voorhees
Director of Outreach for Hematologic Malignancies, Levine Cancer Institute



Putting DREAMM-2 in context

Dr Axel Hoos
SVP, Oncology R&D



Commercial ambitions in multiple myeloma

Luke Miels
President, Global Pharmaceuticals



Q&A:

Christine Roth, SVP Global Oncology Therapy Area Head

Ira Gupta, Medicine Development Lead belantamab mafodotin (GSK'916)

Science

x

Technology

x

Culture



Strengthening our R&D pipeline through a focus on science related to the immune system, the use of human genetics, and advanced technologies

Accelerating our oncology pipeline



16 assets in development with 3 potential launches in 2020



PARP inhibitor (<i>ZeJula</i> , niraparib)*	First line maintenance ovarian, other solid tumors under investigation
Anti-BCMA immunoconjugate (<i>belantamab mafodotin</i>) [†]	Multiple myeloma
TGF-beta trap/PD-L1 antagonist (<i>bintrafusp alfa</i>) [‡]	NSCLC, BTC, breast cancer, other solid tumors
PD-1 antagonist (<i>dostarlimab</i>) [*]	Solid tumours (including endometrial, ovarian, NSCLC, Cervical, other MSI-H tumors)
ICOS receptor agonist (GSK3359609) ^{†‡}	NSCLC, HNSCC, other solid tumors
NY-ESO-1 TCR T cells (GSK3377794) [†]	Sarcoma, NSCLC, multiple myeloma
BET inhibitor (<i>molibresib</i> , GSK525762)	Breast, prostate, other solid tumors and heme malignancies
PRMT5 inhibitor (GSK3326595) [†]	Solid tumors, heme malignancies
TIM-3 antagonist (TSR-022) [*]	Solid tumors
PI3K beta inhibitor (GSK2636771)	Solid tumors
NY-ESO-1 ImmTAC® (GSK3537142) [‡]	Solid tumors
OX40 agonist (GSK3174998) ^{†‡}	Solid tumors
TLR4 agonist (GSK1795091)	Solid tumors
LAG-3 antagonist (TSR-033) [*]	Solid tumors
Type 1 PRMT inhibitor (GSK3368715) [†]	Solid tumors, DLBCL
STING agonist (GSK3745417)	Solid tumors

* Tesaro acquisition

[†] In-license or other partnership with third party

[‡] ICOS HNSCC Phase 2/3 study with registrational potential

[‡] Option based alliance with Immunocore Ltd. ImmTAC is a registered trademark of Immunocore Ltd.

[‡] Being developed in a strategic global alliance between GSK and Merck KGaA, Darmstadt, Germany

[^] Re-categorised from phase II to I following refinement of phase definitions

FTIH = first time in human; NSCLC = non small cell lung cancer; HNSCC = Head and neck squamous cell carcinoma; BTC = biliary tract cancer

Belantamab mafodotin (GSK'916): accelerated development plan advancing rapidly in multiple myeloma (MM)



July 2018

- Initiated DREAMM-2 4L monotherapy pivotal study
 - 1st subject dosed early July
 - Planned to recruit 130 patients
- Announced broad development plan of DREAMM studies 1 to 10:
 - 4/3L in mono and combo
 - 2L in combo with SoC
 - 1L in combo with novel and SoC agents

83 patients treated on belantamab mafodotin at end July 2018

December 2019

- DREAMM-2 pivotal data readout
 - Both doses show positive benefit risk in heavily pre-treated relapsed/ refractory MM
 - BLA filed December 2019
 - Study results published in the Lancet Oncology
- Initiated DREAMM-4 pilot study in combination with pembrolizumab
- Initiated DREAMM-5 platform study evaluating novel combinations

478 patients treated on belantamab mafodotin at end Nov 2019



Results of DREAMM-2

Dr Peter Voorhees

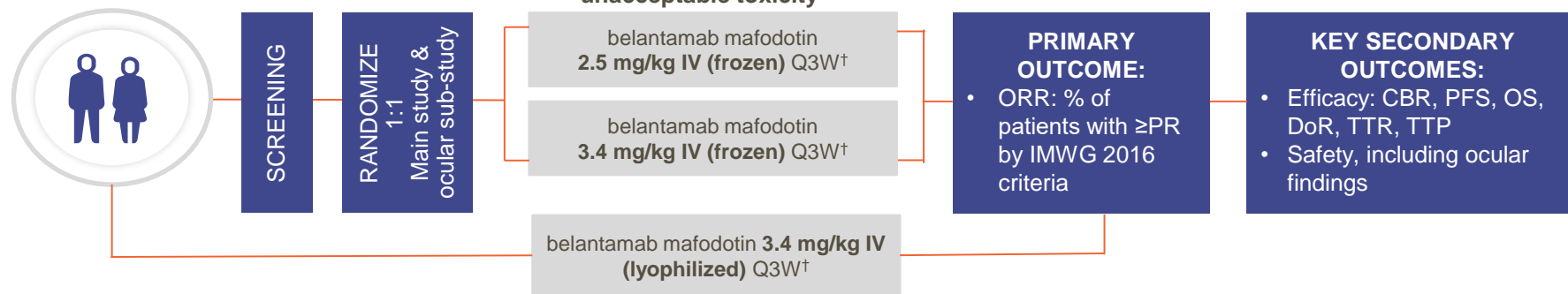
Director of Clinical Operations and Outreach for the Department of Hematologic Oncology
and Blood Disorders

Member, Plasma Cell Disorders Division

Levine Cancer Institute, Atrium Health

Patients: 3L+ RRMM

Treatment until disease progression or unacceptable toxicity



ELIGIBILITY CRITERIA:

- ✓ Measurable disease**
- ✓ ECOG PS 0–2
- ✓ ≥ 3 prior lines of therapy
- ✓ *Refractory to proteasome inhibitor, immunomodulatory agent, and refractory/intolerant to anti-CD38 mAb
- ✓ Patients with mild/moderate renal impairment and grade 2 cytopenias were permitted
- ✓ Prior BCMA-targeted therapy excluded
- ✓ Prior auto-SCT allowed, allo-SCT excluded

NCT03525678 and EudraCT: 2017-004810-25. †Actual enrolment N=223. N=24 enrolled in the independent lyophilized presentation cohort (3.4 mg/kg); Data for the frozen presentation cohorts (2.5 mg/kg and 3.4 mg/kg) are presented. **Serum M-protein ≥0.5 g/dL (≥5 g/L); urine M-protein ≥200 mg/24h; serum FLC assay: involved FLC level ≥10 mg/dL (≥100 mg/L) and an abnormal serum FLC ratio (<0.26 or >1.65). allo-SCT, allogeneic stem-cell transplant; auto-SCT, autologous stem-cell transplant; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free-light chain; IMWG, International Myeloma Working Group; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks; TTR, time to recurrence; TTP, time to progression. All information is available on ClinicalTrials.gov.

Baseline demographic and disease characteristics



Characteristic	belantamab mafodotin 2.5 mg/kg (N=97)	belantamab mafodotin 3.4 mg/kg (N=99)
Age, median (IQR), years	65 (60–70)	67 (61–72)
Sex, n (%)		
Male	51 (53)	56 (57)
Female	46 (47)	43 (43)
ISS stage at screening, n (%)		
I	21 (22)	18 (18)
II	33 (34)	51 (52)
III	42 (43)	30 (30)
Unknown/ missing	1 (1)	0
Cytogenetics risk, n (%)		
High risk*	41 (42)	47 (47)
Other	56 (58)	52 (52)
Number of prior lines of therapy, median (range)	7 (3–21)	6 (3–21)
Refractory to prior immunomodulatory agent, proteasome inhibitor and an anti-CD38 antibody, n (%)	97 (100)	99 (100)

*High-risk cytogenetics defined as having any of the following cytogenetic features: t(4;14), t(14;16), 17p13del, or 1q21+.

IQR, interquartile range; ISS, International Staging System

Lonial S et al. Lancet Oncology, 2019, epub ahead of print

Primary endpoint, meaningful ORR with deep responses in both dose groups



IRC-assessed response*	belantamab mafodotin 2.5 mg/kg (N=97)	belantamab mafodotin 3.4 mg/kg (N=99)
ORR [†] , n (%) (97.5% CI)	30 (31) (20.8–42.6)	34 (34) (23.9–46.0)
sCR, n (%)	2 (2)	3 (3)
CR, n (%)	1 (1)	0
VGPR, n (%)	15 (15)	17 (17)
PR, n (%)	12 (12)	14 (14)
CBR [‡] , n (%) (97.5% CI)	33 (34) (23.5–45.8)	39 (39) (28.5–51.1)

Intent-to-treat population. *As assessed using 2016 IMWG criteria (Kumar S et al. *Lancet Oncol* 2016; 17: e328–346.). [†]defined as PR or better. [‡]defined as MR or better.

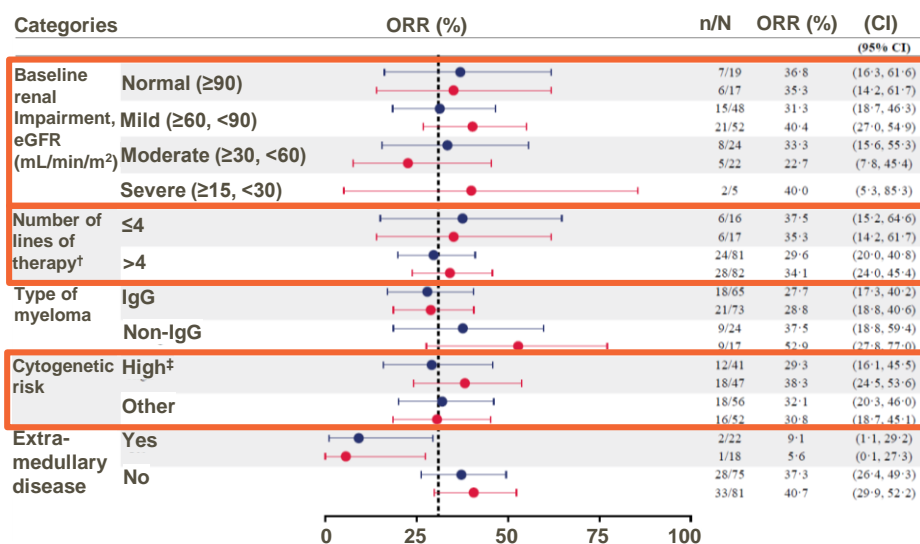
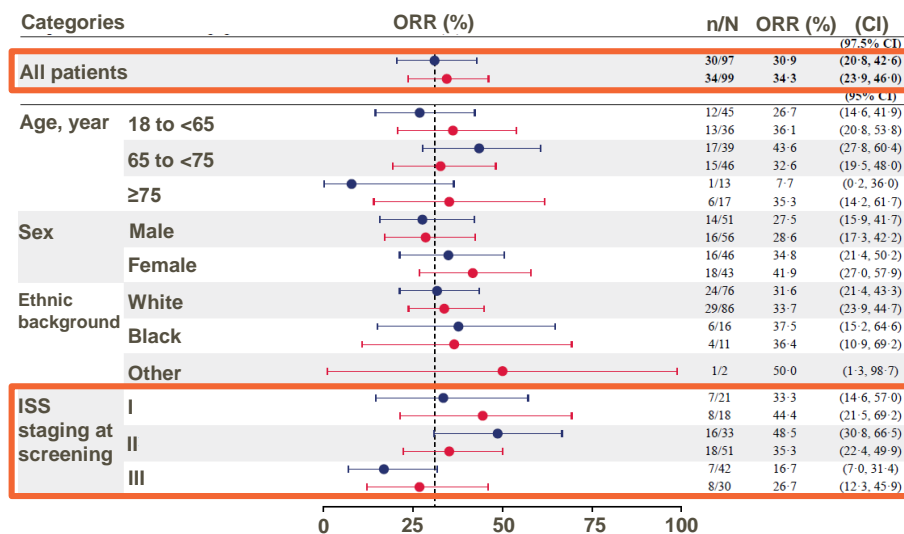
CBR, clinical benefit rate; CI, confidence interval; CR, complete response; IMWG, International Myeloma Working Group; IRC, independent review committee; MR, minimal response; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

Lonial S et al. *Lancet Oncology*, 2019, epub ahead of print

Response rates in high-risk patient cohorts were comparable to the overall patient population



- 2.5 mg/kg belantamab mafodotin
- 3.4 mg/kg belantamab mafodotin



Intent-to-treat population. Responses as assessed by IRC according to 2016 IMWG criteria (Kumar S et al. *Lancet Oncol* 2016;17:e328–346).

†Number of prior anti-cancer regimens as reported on electronic case report form; combination therapies containing multiple components counted as one regimen.

‡High-risk cytogenetics defined as having any of the following features: t(4:14), t(14:16), 17p13del, or 1q21+.

§Post-hoc analysis.

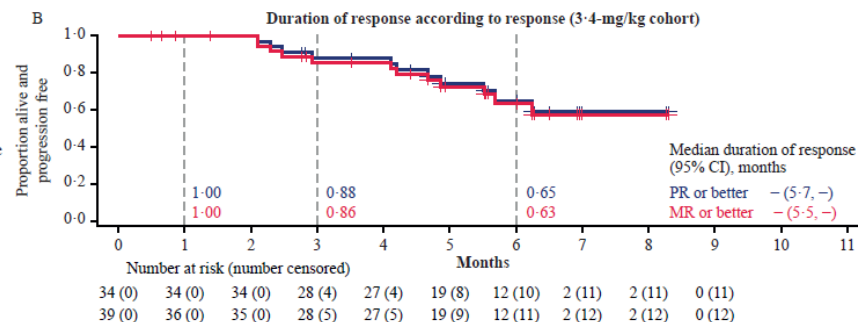
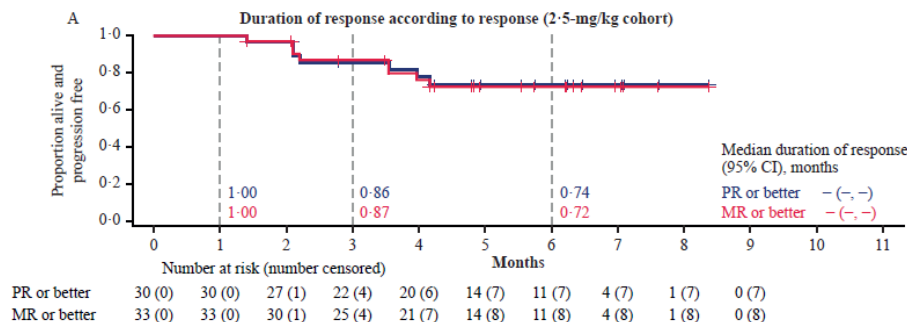
CI, confidence interval; eGFR, estimated glomerular filtration rate; IgG, immunoglobulin G; ISS, international staging system; ORR, overall response rate.

Lonial S et al. *Lancet Oncology*, 2019, epub ahead of print

Median DoR and OS were not reached for responders in either cohort*



IRC-assessed outcome (median)	belantamab mafodotin 2.5 mg/kg (N=97)	belantamab mafodotin 3.4 mg/kg (N=99)
OS, months	NR‡	NR‡
PFS, months (95% CI)	2.9 (2.1–3.7)†	4.9 (2.3–6.2)†
DoR, months	NR‡	NR‡
Patients with DoR ≥4 months (% [95% CI])*	78 (57–89)	87 (69–95)



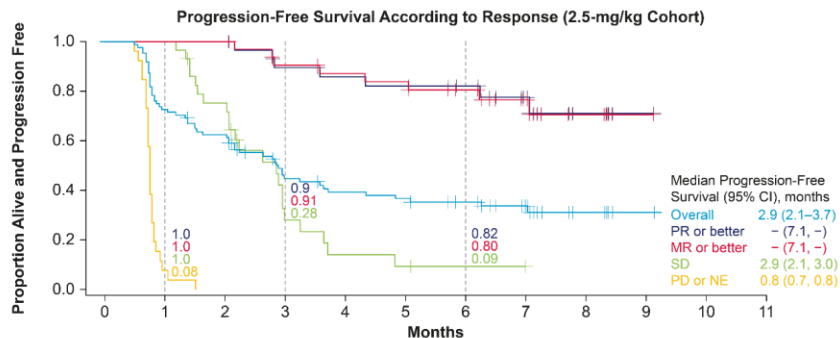
Follow up is ongoing to confirm durability

Median PFS was not reached for responders in either cohort



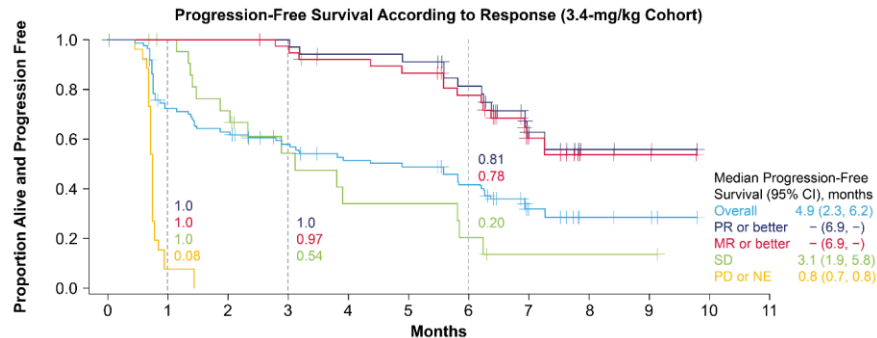
mPFS was 2.9 and 4.9 mos in the 2.5-mg/kg and 3.4-mg/kg groups, not reached in patients with MR or better

A. PFS survival by response (belantamab mafodotin 2.5-mg/kg)



Number at risk (number of events)	0	1	2	3	4	5	6	7	8	9	10	11
All patients	97 (0)	64 (24)	54 (33)	34 (47)	29 (51)	27 (53)	22 (54)	14 (55)	5 (56)	1 (56)	0 (56)	
PR or better	30 (0)	30 (0)	30 (0)	25 (3)	23 (4)	22 (5)	19 (5)	13 (6)	4 (7)	1 (7)	0 (7)	
MR or better	33 (0)	33 (0)	33 (0)	28 (3)	26 (4)	25 (5)	21 (6)	14 (7)	5 (8)	1 (8)	0 (8)	
SD	30 (0)	29 (0)	21 (7)	6 (18)	3 (21)	2 (22)	1 (22)	0 (22)				
PD or NE	34 (0)	2 (24)	0 (26)									

B. PFS survival by response (belantamab mafodotin 3.4-mg/kg)



Number at risk (number of events)	0	1	2	3	4	5	6	7	8	9	10	11
All patients	99 (0)	62 (24)	54 (32)	45 (36)	38 (41)	36 (43)	29 (48)	10 (54)	4 (55)	3 (55)	0 (55)	
PR or better	34 (0)	34 (0)	34 (0)	34 (0)	31 (2)	30 (3)	25 (6)	9 (11)	3 (12)	2 (12)	0 (12)	
MR or better	39 (0)	39 (0)	39 (0)	37 (1)	33 (3)	31 (5)	26 (8)	9 (13)	3 (14)	2 (14)	0 (14)	
SD	23 (0)	21 (0)	15 (6)	8 (9)	5 (12)	5 (12)	3 (14)	1 (15)	1 (15)	1 (15)	0 (15)	
PD or NE	37 (0)	2 (24)	0 (26)									

Post-hoc analysis. Responses in intent-to-treat population as assessed by IRC according to 2016 IMWG criteria (Kumar S et al. *Lancet Oncol* 2016;17:e328–346).

IMWG, International Myeloma Working Group; IRC, independent review committee; MR, minimal response; NE, not evaluable; PD, progressive disease; PFS, progression-free survival; PR, partial response; SD, stable disease.

Lonial S et al. *Lancet Oncology*, 2019, epub ahead of print

Safety overview



All AE's of interest and any AE's >20% in either cohort

Number of patients with event (safety population), n (%) [*]	Belantamab mafodotin 2.5 mg/kg (N=95)				Belantamab mafodotin 3.4 mg/kg (N=99)			
	Grade 1-2	Grade 3	Grade 4	Grade 5	Grade 1-2	Grade 3	Grade 4	Grade 5
Keratopathy or corneal epithelium changes [†]	41 (43)	26 (27)	0	0	53 (54)	20 (20)	1 (1)	0
Thrombocytopenia [‡]	14 (15)	8 (8)	11 (12)	0	24 (24)	11 (11)	22 (22)	1 (1)
Anemia	4 (4)	19 (20)	0	0	12 (12)	22 (22)	3 (3)	0
Nausea	23 (24)	0	0	0	31 (31)	1 (1)	0	0
Pyrexia	18 (19)	2 (2)	1 (1)	0	21 (21)	4 (4)	0	0
Blurred vision [§]	17 (18)	4 (4)	0	0	28 (28)	2 (2)	0	0
Infusion-related reactions [¶]	17 (18)	3 (3)	0	0	15 (15)	1 (1)	0	0
Increased aspartate aminotransferase	17 (18)	2 (2)	0	0	18 (18)	6 (6)	0	0
Fatigue	13 (14)	2 (2)	0	0	21 (21)	5 (5)	0	0
Dry eye ^{**}	12 (13)	1 (1)	0	0	23 (23)	0	0	0
Neutropenia ^{††}	4 (4)	5 (5)	4 (4)	0	12 (12)	12 (12)	3 (3)	0

Listed in order of decreasing frequency of Any Grade events in the 2.5-mg/kg cohort. ^{*}Events reported based on Common Terminology Criteria for Adverse Events criteria v4.03 in the safety population (including all patients who received at least one dose of trial treatment). [†]Keratopathy or corneal epithelium changes (considered an adverse event of special interest [AESI]) were observed by ophthalmic examination. [‡]Thrombocytopenia (considered an AESI) includes preferred terms thrombocytopenia, decreased platelet count, and cerebral hemorrhage. [§] Blurred vision includes preferred terms vision blurred, diplopia, visual acuity reduced and visual impairment. [¶]Infusion-related reactions (considered an AESI) includes preferred terms infusion-related reaction, pyrexia, chills, diarrhea, nausea, asthenia, hypertension, lethargy, tachycardia, vomiting, cough and hypotension occurring within 24 hours of infusion. ^{**}Dry eye includes preferred terms dry eye, ocular discomfort, eye pruritus and foreign body sensation in eye. ^{††}Neutropenia includes neutropenia, febrile neutropenia and neutrophil count decreased. Lonial S et al. Lancet Oncology, 2019, epub ahead of print.

Adverse event-related dose reductions and delays were less frequent in 2.5 mg/kg vs 3.4 mg/kg group



Number of patients with event (%) (safety population)	belantamab mafodotin 2.5 mg/kg (N=95)	belantamab mafodotin 3.4 mg/kg (N=99)
Any adverse event (AE)	93 (98)	99 (100)
AEs leading to permanent treatment discontinuation	8 (8)	10 (10)
AEs leading to dose reduction	28 (29)	41 (41)
AEs leading to dose delay	51 (54)	61 (62)
Any serious adverse event (SAE)	38 (40)	47 (47)
Fatal SAEs related to study treatment	1 (1)	1 (1)

Keratopathy though common, led to few discontinuations



Number of patients with event (safety population), n (%)	Belantamab mafodotin 2.5 mg/kg (N=95)				Belantamab mafodotin 3.4 mg/kg (N=99)			
	Grade 1-2	Grade 3	Grade 4	Grade 5	Grade 1-2	Grade 3	Grade 4	Grade 5
Keratopathy or corneal epithelium changes [†]	41 (43)	26 (27)	0	0	53 (54)	20 (20)	1 (1)	0

- Keratopathy led to dose reduction in 23% and 27% of patients and dose delays in 47% and 48% of the patients in the 2.5-mg/kg and 3.4-mg/kg groups, respectively.
 - Among patients with treatment delays due to keratopathy in the 2.5-mg/kg and 3.4-mg/kg groups median time to re-initiation 83 and 63 days, respectively
 - Only 4 patients (1 and 3 patients in the 2.5-mg/kg and 3.4-mg/kg groups) permanently discontinued treatment due to keratopathy
- Among patients with keratopathy worse than baseline at the end of treatment, the median time to resolution was 71 days (IQR: 57 to 99) and 96 days (IQR: 70 to 127) in the 2.5 mg/kg and 3.4-mg/kg groups, respectively
- Three patients experienced transient worsening of vision ($\geq 20/200$) in both eyes
 - All three patients saw an improvement in best-corrected visual acuity (i.e. returned to baseline during follow-up)
- Most common patient-reported corneal symptoms were blurred vision (22% and 30%; [Grade 3/4: 4% and 2%]) and dry eye (14% and 23%; [Grade 3/4: 1% and 0%])

Corneal event management protocol



- The nature of corneal events reported in DREAMM-2 is not uncommon for immunoconjugates, which use MMAF or other microtubule-targeting cytotoxins.
 - Exact mechanism for onset of these events is unknown, might be related to non-specific uptake of ADC into actively dividing epithelial cells residing in the basal epithelial layer of cornea.
- Keratopathy observed by ophthalmic examination were common and mostly restricted to the corneal epithelium.
- Initial results of the ocular sub-study suggest that corticosteroid eye drops were an ineffective prophylaxis for the development of changes to the corneal epithelium.
- Dose reductions and delays with concomitant use of preservative-free artificial tears were useful.

If patients experience corneal adverse reactions or changes in visual acuity of Grade 2 or higher, the following steps are advised:

- Consult an eye care professional if corneal adverse reactions occur
- For Grade 2 events, reduce dose by 25% and continue treatment
- For Grade 3 or 4 events, withhold treatment until symptoms improve to Grade 2 or better and resume treatment at 25% lower dose

In DREAMM-2 belantamab mafodotin provided a clinically meaningful response rate for heavily pretreated patients with RRMM with limited treatment options

Single-agent belantamab mafodotin (2.5 mg/kg and 3.4 mg/kg Q3W) demonstrated:

- Deep and durable responses
- A manageable safety profile – novel corneal events will require education

The response rates seen in DREAMM-2 compare favourably with other approved combination treatments for RRMM

Articles

Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM-2): a two-arm, randomised, open-label, phase 2 study



Sagar Lonial, Hans C Lee, Ashraf Badros, Suzanne Trudel, Ajay K Nooka, Ajai Chari, Al-Ola Abdallah, Natalie Callander, Nikoletta Lendvai, Douglas Sborov, Attaya Suvannasankha, Katja Weisel, Lionel Karlin, Edward Libby, Bertrand Amulf, Thierry Facon, Cyrille Hulin, K Martin Kortüm, Paula Rodriguez-Otero, Saad Z Usmani, Parameswaran Hari, Rachid Baz, Hang Quach, Philippe Moreau, Peter M Voorhees, Ira Gupta, Axel Hoos, Eric Zhi, January Baron, Trisha Piontek, Eric Lewis, Roxanne C Jewell, Elisha J Dettman, Rakesh Popat, Simona Degli Esposti, Joanna Opalinska, Paul Richardson, Adam D Cohen

Summary

Background Belantamab mafodotin (GSK2857916), an immunoconjugate targeting B-cell maturation antigen, showed single-agent activity in the phase 1 DREAMM-1 study in heavily pre-treated patients with relapsed or refractory multiple myeloma. We further investigated the safety and activity of belantamab mafodotin in the DREAMM-2 study.

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Putting DREAMM-2 in context

Dr Axel Hoos, SVP Oncology R&D

Belantamab mafodotin: critical features



- First BCMA-targeted agent in multiple myeloma
- DREAMM-2 demonstrated deep and durable responses in a heavily pre-treated patient population including those who were refractory to an anti-CD38 antibody
- Treatment-related corneal events were manageable with use of artificial tear drops along with recommended dose modifications
- Easy administration (30 minute infusion every 3 weeks)
- Scalable manufacturing
- Potential for synergistic combinations in earlier lines (SoC and novel/novel)

Monotherapy BLA filed in December 2019 for RRMM

DREAMM-2 results in-line with expectations based on DREAMM-1 subpopulation



Prior treatment	DREAMM-1 overall population: Refractory to immunomodulatory drugs, proteasome inhibitors, and an alkylator ^{1,2}		DREAMM-1 subpopulation Refractory to immunomodulatory drugs, proteasome inhibitors, and exposed to anti-CD38 monoclonal antibodies ^{1,2}		DREAMM-2 overall population: Refractory to immunomodulatory drugs, proteasome inhibitors, and exposed to anti-CD38 monoclonal antibodies	
	2.5 mg/kg N=8	3.4 mg/kg N=35	2.5 mg/kg N=4	3.4 mg/kg N=13	2.5 mg/kg N=97	3.4 mg/kg N=99
Median age, years (range)	61 years (48–79)	60 years (46–75)	61 years (56–79)	59 years (47–70)	65 years (60–70)*	67 years (61–72)
Median prior lines of therapy	6	5	10	7	7	6
Overall response rate (partial response or better), % (95% CI)	12.5% (0.3–52.7)	60.0% (42.1–76.1)	0	38.5% (13.9–68.4)	31% (20.8–42.6)†	34% (23.9–46.0)†
Median duration of response, months (95% CI)	Not assessed in Part 1	14.3 months (10.6–not reached)	Not assessed in Part 1	6.7 months (5.3–not reached)	Not reached (Not reached–not reached)	Not reached (4.9–not reached)

DREAMM, DRiving Excellence in Approaches to Multiple Myeloma; CI, confidence interval. *IQR (inter quartile range) rather than range is shown for DREAMM-2. † 97.5% CI given for ORR in DREAMM-2, as per study protocol.

1. Trudel S et al. *Lancet Oncol* 2018;19:1641; 2. Trudel S et al. *Blood Cancer J* 2019;9:37. 3. Lonial S et al. *Lancet Oncology*, 2019, epub ahead of print.

Dose selection based on benefit / risk

Single-agent belantamab mafodotin based on DREAMM-2 data



DREAMM-2 was not designed to compare belantamab mafodotin doses or address non-inferiority; comparisons were made for exploratory purposes

Efficacy (intention-to-treat population)	belantamab mafodotin 2.5 mg/kg (N=97)	belantamab mafodotin 3.4 mg/kg (N=99)
Overall response rate (partial response or better), n (%), (97.5% CI)*	30 (31) (20.8–42.6)	34 (34) (23.9–46.0)
Median duration of response, months (95% CI)	NR (NR-NR)†	NR (4.9-NR)†
Median progression-free survival, months (95% CI)	2.9 (2.1–3.7)†	4.9 (2.3–6.2)†
Safety (safety population)	belantamab mafodotin 2.5 mg/kg (N=95)	belantamab mafodotin 3.4 mg/kg (N=99)
Adverse events		
• Keratopathy‡ (Grade 1-2)	41 (43)	53 (54)
• Keratopathy‡ (Grade 3-4)	26 (27)	21 (21)
• Thrombocytopenia¶ (Grade 3-4)	19 (20)	33 (33)
• Neutropenia** (Grade 3-4)	9 (9)	15 (15)
Adverse events leading to dose delays	51 (54)	61 (62)
Adverse events leading to dose reductions	28 (29)	41 (41)
Serious adverse events	38 (40)	47 (47)
• Fatal serious adverse events	3 (3)	7 (7)

2.5mg/kg dose selected based on:

- similar anti-myeloma activity
- favourable safety profile

 favourable benefit / risk

*As assessed using 2016 IMWG criteria (Kumar S et al. *Lancet Oncol* 2016; 17: e328); †NR = not reached for responders in either cohort and median duration of follow-up was 6.3 and 6.9 months, respectively; ‡Keratopathy (corneal epithelial changes as observed by ophthalmic examination); ¶Thrombocytopenia includes preferred terms thrombocytopenia, decreased platelet count, and cerebral hemorrhage; **Neutropenia includes preferred terms neutropenia, febrile neutropenia and neutrophil count decreased. CI, confidence interval. 3. Lonial S et al. *Lancet Oncology*, 2019, epub ahead of print.

Belantamab mafodotin demonstrated differentiated response in highly refractory patients



Increasingly refractory patient populations (indirect comparison)

Regimen	Agent	Pomalyst (pomalidomide) capsules +Dex	Kyprolis (carfilzomib) +Dex	DARZALEX (daratumumab)	Post-daratumumab approval	XPOVIO (selinexor) 200 mg tablet +Dex	belantamab mafodotin 2.5 mg/kg Q3W
	mLoT	5 (N=455)	5 (N=266)	5 (N=106)		8 (N=83, anti-CD38 failures)	7 (N=97, anti-CD38 failures)
Efficacy	ORR	31%	24%	29%	25.3%	31%	
	mDoR	7.0 mos	7.8 mos	7.4 mos	3.8 mos	Not reached	
Adverse events		Neutropenia 48% G3/4	Thrombocytopenia 29% G3/4	Lymphopenia 40% G3/4, Neutropenia 20% G3/4	Thrombocytopenia 61% G3/4, Fatigue 22% G3/4, Anemia 40% G3/4; Neutropenia 21% G3/4	Keratopathy 27% G3, Thrombocytopenia 20% G3/4, Neutropenia 9% G3/4	

AE, adverse event; BCMA, B-cell maturation antigen; dara, daratumumab; Dex, dexamethasone; G, grade; mDoR, median duration of response; MLoT, median lines of prior therapy; ORR, overall response rate; Q3W, every 3 weeks; RRMM, relapsed or refractory multiple myeloma.

1. San Miguel et al. *Lancet* 2013;14:1055–1066; 2. Siegel et al. *Blood* 2012;120:2817–2825; 3. Lonial et al. *Lancet* 2016;387:1551–1560; 4. Xpovio US PI, 2019. 5. Lonial et al. *Lancet Oncology* 2019, epub ahead of print. Cross trial analysis should be read with caution as these are not head to head comparisons.

Four upcoming pivotal study starts across 3L, 2L and 1L multiple myeloma (MM)



Development strategy for use in:

4L/3L
monotherapy and combinations

				Study start	Est launch
DREAMM-1	pilot	relapsed/ refractory patients	Belantamab mafodotin monotherapy, single arm, n=73	2014	---
DREAMM-2	pivotal	daratumumab failures	Belantamab mafodotin monotherapy, single arm, n=223	Jun 2018	2020
DREAMM-3	pivotal	failed lenalidomide and proteasome inhibitor	Belantamab mafodotin monotherapy vs. PomDex, n=320	2H19	2022
DREAMM-4	pilot	relapsed/ refractory patients	Belantamab mafodotin + PD1 combination, single arm, n=40	Mar 2019	---
DREAMM-5	platform	relapsed/ refractory patients	Belantamab mafodotin + novel combinations, n=514	Oct 2019	---

36k
patients*

2L
combination with SOC

DREAMM-6	pilot	failed 1 prior therapy	Belantamab mafodotin+LenDex OR +BorDex, open label, n= 99	Oct 2018	---
209418	ISS	relapsed/ refractory patients	Belantamab mafodotin+PomDex, n= 78	Jan 2019	---
DREAMM-7	pivotal	failed 1 prior therapy	Belantamab mafodotin+BorDex vs. Dara+BorDex, n= 478	1H20	2023
DREAMM-8	pivotal	failed 1 prior therapy	'916+PomDex vs. PomBorDex, n= 450	1H20	2024

50k
patients*

1L
combination with novel
and SOC agents

DREAMM-9	pivotal	transplant ineligible	Belantamab mafodotin+BorLenDex vs. BorLenDex; n=798	2H19	TBC
DREAMM-10	pivotal	transplant ineligible	Belantamab mafodotin+novel agent vs SOC, n=TBC	2021	TBC

80k
patients*

Unique features of different BCMA targeting modalities



	ADC/ immuno-conjugate	CAR-T	Bispecific
Most advanced development stage	Registrational	Phase 3	Phase 1
Commercial scalability	+++	+	++
Dosing/administration	30 minutes, Q3W ¹	One off administration Hospitalisation Lymphodepletion ²⁻⁴	~1-2 hours, QW-Q2W More data needed ^{5,6}
Accessibility	++	+	++
Combinability	+++	More data needed	More data needed
Efficacy:			
Response rate	31% ¹	52.6% – 100%	43.3% – 57%
Duration of response	Not reached	10.6 – 27.0 months ²⁻⁴	9 months - not reached ⁵⁻⁷
Safety	Corneal events ¹ (MMAF based)	Cytokine release syndrome Neurotoxicity ²⁻⁴	Cytokine release syndrome Neurotoxicity ⁵⁻⁷

In development for multiple myeloma. ADC, antibody drug conjugate; CAR, chimeric antigen receptor. 1. Lonial et al. Lancet Oncology 2019 epub ahead of print 2. Raje et al. NEJM 2019 3. BMS Press Release Dec 5, 2019 4. Madduri D et al. ASH 2019 Abstr 577 5. Costa et al. ASH 2019 6. Coper et al. ASH 2019 7. Topp M et al. ASCO/EHA 2019
Accessibility = patient population eligible to receive, cost, facilities needed to administer and treatment associated AEs

Belantamab mafodotin: critical features



- First BCMA-targeted agent in multiple myeloma
- DREAMM-2 demonstrated deep and durable responses in a heavily pre-treated patient population including those who were refractory to an anti-CD38 antibody
- Treatment-related corneal events were manageable with use of artificial tear drops along with recommended dose modifications
- Easy administration (30 minute infusion every 3 weeks)
- Scalable manufacturing
- Potential for synergistic combinations in earlier lines (SoC and novel/novel)

Monotherapy BLA filed in December 2019 for RRMM



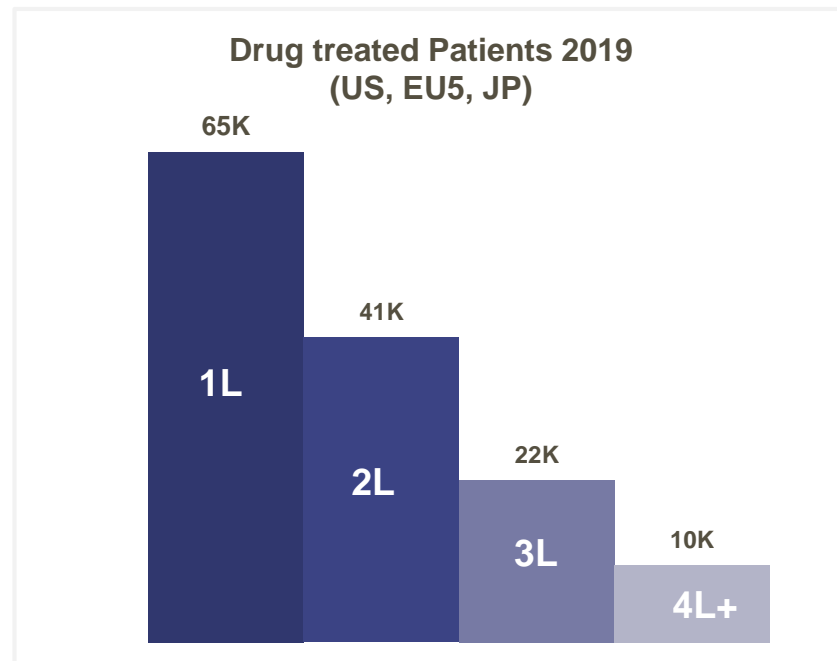
Commercial ambitions in multiple myeloma

Luke Miels, President Global Pharmaceuticals

Multiple myeloma (MM) is the 2nd most common haematological malignancy with high unmet need, despite new treatments



- High incidence rates: **>160K** cases / year globally
- High relapse rates: **40%** of patients progress to 3L+
- Low survival: **~52%** five-year survival
- **Severe clinical co-morbidities:** bone lesions, spinal cord compression, hyper viscosity symptoms, recurrent infections, hypercalcemia, acute renal failure



Kantar Health, Patient Metrics, MM, Drug therapy (accessed on 4 Feb'19)

Growing market with opportunity for more durable, innovative agents

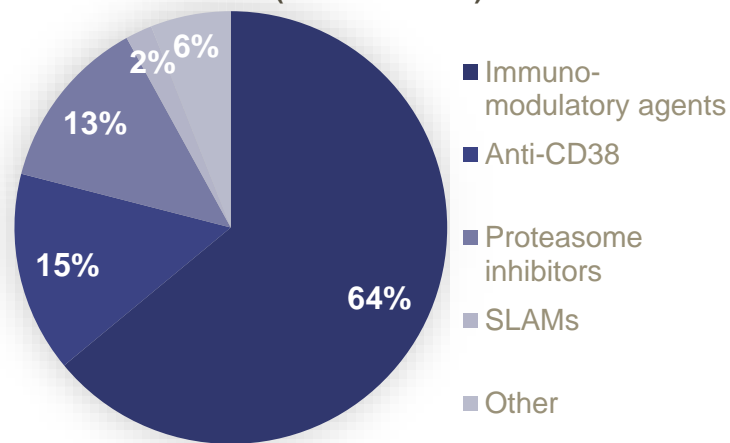


Market value ~\$19bn in 2019, estimated to grow ~7% CAGR reaching ~\$24bn by 2023

Key drivers of growth:

- Aging population – increasing incidence
- Longer duration of therapy, multiple lines
- Innovation and combinations

MM global drug market share (2019 estimated)



Darzalex (daratumumab, anti-CD38 mAb) among a emerging class showing synergy with existing standards of care and delivering improved efficacy

Building our oncology commercial capability



Improved engagement with HCPs

Updated HCP engagement policies to improve how we help prescribers understand new data and clinical experience with our innovative products

Attracting and retaining the best sales force talent

Competitive sales force incentives for Specialty area in place to recruit, motivate and retain sales teams with the right levels of expertise and experience

Seamless execution across functions and in markets

Aligned efforts to ensure launch readiness for exciting oncology launches and drive value for patients and shareholders

3 potential oncology launches in 2020

Zejula (PARP inhibitor) 1L ovarian cancer maintenance therapy (PRIMA) presented at ESMO 2019

- Significantly improved PFS in the overall population
- Filing planned by end 2019

Belantamab mafodotin (BCMA immunoconjugate 4L multiple myeloma (DREAMM-2) published in *The Lancet Oncology*

- Study met primary objective and demonstrated clinically meaningful ORR
- Filed December 2019

Dostarlimab (PD-1) in recurrent endometrial cancer (GARNET) with interim data presented at SGO 2019

- Filing planned by end 2019

Q&A



Hal joined GSK as Chief Scientific Officer and President, R&D on 1 January 2018. He is a member of the Board and the Corporate Executive Team.

His previous role was President, R&D at Calico (California Life Company). Prior to this, Hal was Executive Vice President, Head of Global Product Development, and Chief Medical Officer of Roche, responsible for all the products in the combined portfolio of Roche and Genentech. At Genentech, he was Senior Vice President of Development and Chief Medical Officer.

Hal was a Non-Executive Director and Chair of the Science & Technology Committee at Juno Therapeutics, Inc until March 2018, when it was acquired by Celgene Corporation.

Hal is Associate Adjunct Professor, Epidemiology & Biostatistics, University of California, San Francisco. He is also a Non-Executive Board Director of GRAIL, Inc, an early cancer detection healthcare company and a member of the Advisory Board of Verily Life Sciences LLC, a subsidiary of Alphabet Inc.

Hal holds a Bachelor of Science degree in Physics from Washington University in St. Louis and a medical degree from Yale University. He completed his training in Cardiology and Internal Medicine at the University of California, San Francisco.

He has been issued several patents for his work in thrombosis and angiogenesis and has published more than 90 papers in peer-reviewed scientific journals.

Dr Peter Voorhees



Dr. Peter Voorhees trained as a Hematology-Oncology Fellow at the University of North Carolina from 2001 – 2004 where he first developed an interest in multiple myeloma. He subsequently joined the faculty at UNC and became the head of their Multiple Myeloma Program in 2007.

In the Fall of 2016, he elected to join the growing multiple myeloma effort at the Levine Cancer Institute (LCI). His research focuses on the clinical development of novel therapeutic strategies for the treatment of multiple myeloma at all phases of the disease from smoldering multiple myeloma to relapsed and refractory disease. Education about best evidence-based practices for the treatment of multiple myeloma is a key component of his work, from health care professional in training to Hematology-Oncology providers to patients and their loved ones.

He is a member of the American Society of Hematology, the American Society of Clinical Oncology, the International Multiple Myeloma Working Group, the International Myeloma Society and Multiple Myeloma Committee for the Alliance Cooperative Group.

At LCI, he functions as the Director of Clinical Operations and Outreach for the Division of Hematologic Oncology and Blood Disorders. He has presented and published extensively in the area of multiple myeloma.



Axel is SVP, R&D Governance Chair, and Therapeutic Area (TA) Head for Oncology at GSK, responsible for discovery and development in Oncology. As R&D governance chair he oversees technical and funding review committees. Axel also serves as Chairman of the Board of Trustees of the Sabin Vaccine Institute, a Global Health organization, Director on the Board of Imugene, a biotech company, Co-Director of the Cancer Immunotherapy Consortium and Scientific Advisory Board Member of the Cancer Research Institute. Through his leadership a paradigm for the development of cancer immunotherapies has been defined, which helped launch the field of Immuno-Oncology (Nat. Rev. Drug Discovery 2016, 15(4):, 235-47).

Previously, Axel was the Global Medical Lead in Immunology/Oncology at BMS where he developed Yervoy (Ipilimumab), the first life-extending therapy and the first checkpoint inhibitor drug in Immuno-Oncology. The discovery of ipilimumab's scientific mechanism was honored with the Nobel prize for Physiology or Medicine to Dr. James Allison in 2018. Before BMS, Dr. Hoos was Senior Director of Clinical Development at Agenus Bio (previously Antigenics), a biotech company.

Dr. Hoos holds an MD from Ruprecht-Karls-University and a PhD in molecular oncology from the German Cancer Research Center (DKFZ) both in Heidelberg, Germany. He trained in surgery at the Technical University in Munich and further in surgery, molecular pathology and tumor immunology at Memorial Sloan-Kettering Cancer Center in New York City. He is an alumnus of the Program for Leadership Development at Harvard Business School.



Luke joined GSK as President, Global Pharmaceuticals in September 2017. He is a member of the Corporate Executive Team.

At GSK, he is responsible for commercialising a portfolio of medicines and vaccines with annual sales of more than £20 billion and operations in over 100 markets. His previous role was Executive Vice President of AstraZeneca's European business and, prior to that, Executive Vice President of Global Product and Portfolio Strategy, Global Medical Affairs and Corporate Affairs.

Luke joined AstraZeneca from Roche, where he was Regional Vice President Asia Pacific for the Pharmaceuticals Division. Before then, he held roles of increasing seniority at Sanofi-Aventis in Asia and the US. He also co-led the US integration of Sanofi and Aventis. Prior to that, he held general management roles in Thailand and New Zealand, following his entry into the industry in Australia.

He holds a Bachelor of Science degree in Biology from Flinders University in Adelaide and an MBA from the Macquarie University, Sydney.

Christine Roth



Christine re-joined GSK as SVP, Global Oncology Therapy Area Head in December 2017, reporting to Luke Miels. As the global commercial lead for oncology, Christine is a member of the Pharmaceutical Leadership Team, Forecast Review Committee, Research Investment Board, Development Review Board, and Global Pharmaceutical Leadership Team.

After beginning her career as a scientist, Christine joined BMS and progressed through commercial leadership roles in multiple therapeutic and functional areas. Together with Axel Hoos, she was a pioneer in Immuno-Oncology, serving as the commercial lead for the first approved I-O therapy, Yervoy (ipilimumab) and working on BMS's String of Pearls strategy which led to the acquisition of Medarex and the first PD-1, Opdivo.

Christine was delighted to return to GSK and partner again with Axel and the GSK Oncology team to build a new and improved, world-class oncology organization.



Ira re-joined GSK as VP, Medicines Development Leader – belantamab mafodotin, Global Oncology Therapy Area Head in January 2018. As the Medicine Development Leader, Ira has the ‘Single Point of Accountability’ for belantamab mafodotin and she leads a cross-discipline Medicine Development Team and collaborates with Oncology Commercial to develop belantamab mafodotin strategy in indications that meets the needs of patients, physicians and payers.

After beginning her career as Medical Director in India, Ira moved to GSK, USA in 2007 initially working in the early phase organization and subsequently joining Oncology in 2008. Here, she provided strategic and clinical leadership for the Global Clinical Development Plan across all oncology indications for Arzerra (ofatumumab) and the BET inhibitor. In 2016, Ira transitioned to Celgene Corporation, where she was responsible for the clinical development strategy for Isocitrate dehydrogenase (IDH) inhibitors that led to the successful NDA submission and approval of IDHIFA in patients with relapsed or refractory acute myeloid leukemia (AML) with an IDH2 mutation.

Ira is a physician from India who earned her doctorate (MBBS) at Maharashtra University of Health Sciences and went on to complete degrees in Business Management (DBM) and Pharmacology (MD).