

From: Rachna Khanna

Sent: Thursday, June 21, 2018 1:29 PM

To: Payal Kaul

Cc: Ramana Madhavi Sankara; V N S Rama Raju Mandapati; Vijay Kumar Sarakamu; Shukla Ishan Maheshbhai; Krishnakant Tulsiram Gandhi; P Uma Devi

Subject: Fw: Pomalidomide capsules-EM leverage

Attachments: Pomalidomide Data.xlsx

Dear Payal

Pl note change in pomalidomide interest [Redacted - Non-Responsive] global development

Hope ok, else pl let me know.

From: Anupama Rao Singh

Sent: Thursday, June 21, 2018 6:33:35 PM

To: Rachna Khanna

Cc: Raja MV SMA; Shyam Prasad Akku; Soumitra Dey

Subject: Pomalidomide capsules-EM leverage

Dear Rachna,

Based on revised discussion internally, we have looked at the data and the market trends and would like consider Poma as good to have

Pomalidomide is a thalidomide analogue indicated, in combination with [Redacted - Non-Responsive] for patients with multiple myeloma (MM) who have received at least two prior therapies including [Redacted - Non-Responsive] and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy. Among the IMiDs, pomalidomide seems to have a more potent anti-myeloma activity, and a similar safety profile compared with [Redacted - Non-Responsive]. Pomalidomide has the ability to induce remission in patients with heavily pre-treated MM. Also the toxicity profile is predictable and manageable.

Looking at the market data, we see a strong growth trajectory of Pomalidomide. At the global scale Pomalidomide grew by 40% becoming a ~ \$ 800 Mn brand. In the US, we see a sharp dip in usage of [Redacted - Non-Responsive] which clearly is being replaced by Pomalidomide in heavily pre-treated MM patients.

With [Redacted - Non-Responsive] already part of our portfolio, addition of Pomalidomide will strengthen our presence in Multiple Myeloma and also allow us to touch the lives of patients at every step of their journey.

Attached is the trend data.

From: Rachna Khanna

Sent: 12 June 2018 11:45

To: Anupama Rao Singh

Subject: Fw: Pomalidomide capsules-EM leverage

Hope no change in interest

From: P Uma Devi

Sent: Tuesday, June 12, 2018 11:42:15 AM

To: Ramana Madhavi Sankara; V N S Rama Raju Mandapati

Cc: Amar Agarwal; Rachna Khanna

Subject: RE: Pomalidomide capsules-EM leverage

Dear Madhavi/Raju,

As Pomalidomide capsules- [Redacted - Non-Responsive] we are not loading the samples for Zone 4 stability condition.

Pl confirm

Regards

Uma

From: Paritosh Nayak

Sent: 11 June 2018 5:12 PM

To: Amar Agarwal

Cc: P Uma Devi; Nitin Subhash Baheti; Pradip Kumar Ghosh

Subject: RE: Pomalidomide capsules-EM leverage

Dear Amar,

As discussed please find stability data of Pomalidomide for your reference.

As discussed please prepare the stability protocol for Zone-IV. If you need any help please let us know.

Thanks and regards,

Paritosh

From: Amar Agarwal

Sent: 06 June 2018 10:05

To: Paritosh Nayak

Cc: P Uma Devi; Nitin Subhash Baheti; Pradip Kumar Ghosh

Subject: RE: Pomalidomide capsules-EM leverage

Hi Paritosh

As per the last update, EB Timeline were under finalisation, request to update further on the same.

Additionally, request your support for some imp. Points with respect to EM leverage. Pls

- Pls support for blister pack stability data availability for any IPDO trial batches. [Redacted - Non-Responsive]

2. pls share details on EB batch size each strength and bifurcation w.r.t to packed samples (qty per strength each pack) as EB samples will be also required for EM Registration.

Amar Agarwal
Scientist-FR&D



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Good Health Can't Wait.

From: Paritosh Nayak
Sent: 09 February 2018 11:03
To: Amar Agarwal
Cc: P Uma Devi; Nitin Subhash Baheti; Pradip Kumar Ghosh
Subject: RE: Pomalidomide capsules-EM leverage

Dear Amar,
Please find all details in trailing mail as requested.

Thanks and regards,
Paritosh

From: Amar Agarwal
Sent: 09 February 2018 10:33
To: Paritosh Nayak
Cc: P Uma Devi; Nitin Subhash Baheti; Pradip Kumar Ghosh
Subject: Pomalidomide capsules-EM leverage

Hi,
As discussed, Understand that Pomalidomide capsules is under different phases of development.

Redacted - Non-Responsive

For preliminary product understanding and evaluation, following information would be helpful for leverage activity, request to please share :

Name of product	RLD name	Strengths under development at DRL	API source	FP mfg. site	FP EB timeline	API/FP specification availability	Packs proposed for US market	Availability of Blister pack stability	Are we planning 30/75 stability during EB	US Pivotal BE Study results timeline.
Pomalidomide capsules 1,2,3,4 mg	Pomalyst	1 mg, 2 mg, 3 mg & 4 mg	DRL	FTO-7	Yet to finalize	Available	21's bottle, 100's bottle	10's blister will be packed in EB	yes	Yet to finalize

Also please share the finalised test product composition for Pivotal BE study.

S. No.	Material Name	Pharm. Reference	mg/unit			
			1 mg	2 mg	3 mg	4 mg
1	Pomalidomide	IH	1.00	2.00	3.00	4.00
2	Anhydrous Lactose (Supertab 21 AN)	USNF	25.00	50.00	75.00	100.00
3	Pregelatinized starch (Starch 1500)	USNF	33.70	67.40	101.10	134.80
4	Sodium stearyl fumarate	USNF	0.30	0.60	0.90	1.20

Thanks for the support, Regards

Amar Agarwal
Scientist-FR&D



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