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Brand	KELUMPA	Creative	Ri/Danielle
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Version	Date	Comment	Copywriter
1	September 3, 2023	Initial copy development	RX
2	November 24, 2023	Internal feedback	RX
3	December 14, 2023	Internal feedback	RX

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[PAGE 1 – FRONT COVER]

[Headline]
Look to KELUMPA®. Find Convenience[1].

[Subhead]
The first and only self-injectable CD20-depleting Mab for RRMS.

[Indication]
KELUMPA® (jofalisumab injection) is indicated for: the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical and imaging features. (PM 4A)

[Abbreviations]
CD20, B cell cluster of differentiation 20; Mab, monoclonal antibody; RRMS, relapsing remitting multiple sclerosis.

[Logos]
KELUMPA® (jofalisumab injection)

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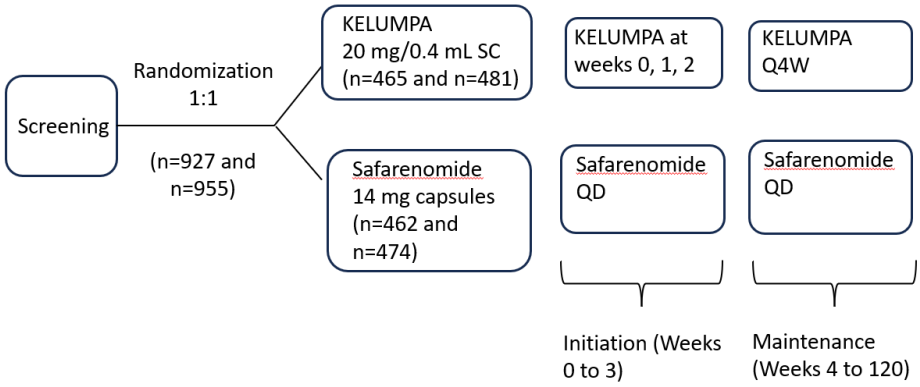
[PAGE 2]

[Eyebrow/Tab]
Study Design

[Headline]
ASCLOPSE I and ASCLOPSE II Idential Trials

[Subhead]
KELUMPA was studied in two Phase 3, double-blind, double-dummy, active-comparator (safarenomide) controlled trials for up to 30 months in patients with RMS[1*] (PM 17B)

[Visual - FPO] (PM 17B, 18C, 19D)



[Copy for visual]
Screening
Randomization 1:1
(n=927 and n=955)
KELUMPA 20 mg/0.4 mL SC (n=465 and n=481)

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KELUMPA at weeks 0, 1, 2
KELUMPA Q4W
Safarenomide 14 mg capsules (n=462 and n=474)
Safarenomide QD
Safarenomide QD

[Copy]
Inclusion criteria: Selected patients had active RMS, a disability status at screening with an EDSS score from 0 to 5.5, and were aged 18 to 55 years. They also had experienced at least one documented relapse during the previous year, or two relapses during the previous two years, or a positive Gd- enhancing MRI scan during the previous year. (PM 17Ba) The trial included both newly diagnosed patients and patients switching from their previous treatment due to lack of efficacy, safety or tolerability considerations. (PM 19Bb)
Primary efficacy endpoint: ARR based on EDSS (PM 19E) (PM 20F)
Key secondary endpoints: Time to disability progression on EDSS (confirmed at 3 months and 6 months)† (PM 19E)

[Copy]
The treatment duration for individual patients depended on when the end of study criteria were met (up to120 weeks). (PM 19D)

[Abbreviations]
RMS, relapsing forms of MS; SC, subcutaneous; QD, everyday; ARR, annualized relapse rate; EDSS, Expanded Disability Status Scale; Gd, gadolinium; MRI, magnetic resonance imagin.
[Footnotes]
*Double-dummy design: patients also received matching placebo corresponding to the other treatment arm to ensure blinding. Patients with active disease enrolled included both newly diagnosed patients and patients switching from their current treatment due to lack of efficacy, safety or tolerability considerations.
†Defined as an increase in EDSS of ≥1.5, ≥1, or ≥0.5 in patients with a baseline EDSS of 0, 1 to 5, or ≥5.5.

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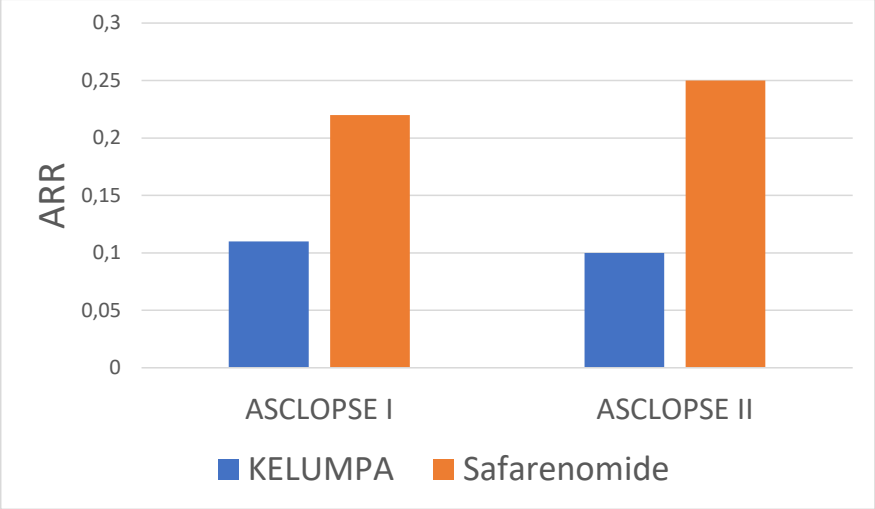
[PAGE 3 - Efficacy]

[Eyebrow/Tab]
Efficacy Data

[Headline]
KELUMPA significantly reduced ARR vs. safarenomide in both trials[1] (PM 20F, PM 21G)

[Graph title]
Significant ARR reduction

[Visual - FPO]



[Copy for graph]
[y-axis label] ARR
[y-axis range] 0 0.05 0.1 0.15 0.2 0.25
[x-axis labels] Trials

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[x-axis data labels] ASCLEPIO I ASCLEPIO II
[Labels] KELUMPA Safarenomide

[Callout]
KELUMPA achieved greater than 50% ARR reduction compared to safarenomide in both trials (**ARR reduction: 50.5%**, p<0.001 **and 58.5%**, p<0.001) (PM 20F, PM 21G)

[Abbreviations]
ARR, annualized rate of confirmed relapses.

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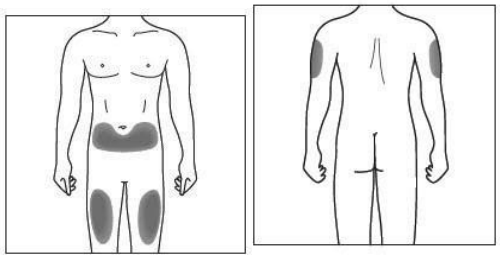
[PAGE 4 – Dosing/MOA]

[Headline]
Your patients or their caregivers may inject KELUMPA after training in SC injection technique[1]* (PM 34O)

Commented [RX1]: On PM Page 6, under 4.4 Administration, it says "Comprehensive instructions for the administration of KESIMPTA are provided in the Patient Medication Information." Therefore this part of information in the Patient Medication Information was used.

[Copy]
The dosage of KELUMPA:
Dose initiation period: 20 mg at weeks 0, 1 and 2
Dose maintenance period: 20 mg monthly starting at week 4 (PM 5N)

[Visual - FPO] (PM 34O)



[Copy near visual] (PM 34O)

- Patients can inject KELUMPA by themselves into areas including front thigh and lower stomach area except areas surrounding the belly button (5 cm distance)
- Healthcare professionals or caregivers can inject KELUMPA into patients' upper outer arms
- Choose a different site each time to inject KELUMPA.
- **Avoid** areas where the skin is tender, bruised, red, scaly, or hard, as well as areas with scars or stretch marks

[Copy near visual]
Adapted from product monograph

[Callout]
KELUMPA is available as a prefilled syringe or prefilled pen for individual use* (PM 7P)

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[Subhead] [ART NOTE: Ensure this section is visually distinct from the section above]
KELUMPA is an anti-CD20 B cell depleting Mab (PM 14Q)

[Copy]
KELUMPA: (PM 14R)

- Is a human monoclonal antibody that binds to human CD20 on B cells and T cells
- Depletes B cells and T cells expressing CD20at low or high concentrations

B cells that enter MS patients' brains play a major role in MS pathogenesis. Depleting B-cells reduces the production of pro-inflammatory cytokines, release of auto-reactive antibodies and activation of pathogenic T cells. (PM 14Q)

[Abbreviations]
SC, subcutaneous; CD20, B cell cluster of differentiate 20; Mab, monoclonal antibody; MS, multiple sclerosis.

[Footnotes]
*Provide proper training to patients and/or caregivers on the preparation and injection of KELUMPA before use. (PM 27S)

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[PAGE 5 – Safety]

[Eyebrow/Tab]
Safety Profile

[Headline]
KELUMPA demonstrated a generally well-tolerated safety profile[1] (PM 10H)

[Body copy]
KELUMPA demonstrated a similar safety profile as safarenomide (AEs: 83.6% vs. 84.2% and AEs leading to drug discontinuation: 5.7% vs. 5.2%). (PM 10H)

[Table title]
AEs with KELUMPA with incidence ≥1% and more common than safarenomide in RMS patients (ASCLOPSE I and II) (PM 11I)

[Table] (PM 11I)

Adverse drug reactions	KELUMPA 20 mg (n=946)	Safarenomide 14 mg (n=936)
Gastrointestinal disorders		
Constipation	2.5%	1.5%
General disorders and administration site conditions		
Injection site reaction (local)	10.9%	5.6%*
Pyrexia	3.9%	2.8%
Influenza-like illness	2.2%	1.1%
Infections and infestations		
Nasopharyngitis	18.0%	16.7%

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Urinary tract infection	10.3%	8.3%
Injury, poisoning and procedural complications		
Injection related reaction (systemic)†	20.6%	15.3%
Investigations		
Blood immunoglobulin M decreased	5.9%	2.2%
Immunoglobulins decreased	1.6%	0.2%
Musculoskeletal and connective tissue disorders		
Back pain	7.6%	6.2%
Muscular weakness	2.4%	1.4%
Psychiatric disorders		
Anxiety	4.5%	3.5%

[Copy]
The most common cause of discontinuation with KELUMPA was low Ig M (3.3%), defined as IgM at 10% below the lower limit of normal. (PM 10K)

[Abbreviations]
AE, adverse event; RMS, relapsing forms of MS; IgM, immunoglobulin M.

[Footnotes]
*Safarenomide group received matching placebo injections
† The most common AEs: occurring in >10% of patients

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[PAGE 6 – PSP]

[Headline]
KELUMPA ALONGSIDE Patient Support Program offers programs and resources for your patients[1]

[Icon/Copy]

<Insert icon>

Personalized support

- Dedicated coordinator providing personalized treatment experience

<Insert icon>

Affordable treatment

- Special access to public and private reimbursement

<Insert icon>

Customized patient portal

- Access resources and tools through the customized patient portal

[Callout]
Enroll your patients today
Visit KELUMPA.com

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[PAGE 7 – Balance]

Indications and clinical use:

KELUMPA® (jofalisumab injection) is indicated for:
the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical and imaging features. (PM 4A)
Pediatrics (<18 years of age): The safety and efficacy of KELUMPA in pediatric MS patients below the age of (<18 years of age) have not been studied. KELUMPA is not authorized for pediatric use. (PM 4T)
Geriatrics: KELUMPA was not studied in patients ≥55. (PM 4U)

Contraindications:

KELUMPA is contraindicated in patients:

- Who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container
- With active HBV infection
- With severe, active infections
- Who have or have had confirmed progressive multifocal leukoencephalopathy (PML)
- Who are in a severely immunocompromised state
- With known active malignancies

(PM 4V)

Other relevant warnings and precautions:

- Injection-related reactions (PM 7Wa)
- Possible Increased Risk of Immunosuppressant Effects with other Immunosuppressants (PM 7Wb)
- Vaccinations (PM 7Wc)
- Progressive Multifocal Leukoencephalopathy (PM 8Wd)
- Hepatitis B Virus Reactivation (PM 9We)

For more information:

Please consult the product monograph at https://health-products.canada.ca/dpd-bdpp/search for important information relating to adverse reactions, drug interactions, and dosing information,

which have not been discussed in this piece. The product monograph is also available by calling us at 1-800-XXX-XXXX.

[PAGE 8 – BACK COVER]

[Headline]
KELUMPA: The self-injectable anti-CD20 treatment that brings you and your RRMS patients convenience.[1]

[Icon/Copy]

<Icon>	<Icon>	<Icon>
Significant ARR Reduction	Self-injectable Anti-CD20 Drug	Well-tolerated Safety Profile
KELUMPA reduced >50% relapses vs. safarenomide in two identical phase 3 trials[2]	KELUMPA provides convenience for your RRMS patients	KELUMPA demonstrated similar AE rates as safarenomide

[Callout]
In the ASCLEPIO I and II trials, KELUMPA demonstrated ARR reductions of 50.5%, p<0.001 and 58.5%, p<0.001 vs. safarenomide (RR: 0.34, p=0.002)

[CTA]
Consider KELUMPA for your MS patients

[References]
[1]Product Monograph of KELUMPA

[Abbreviations]
ARR, annualized rate of confirmed relapses; RR, risk reduction.

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[Code]
XXXXXXE

[Logos]
<KELUMPA>
<Novartis>
<PAAB>

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