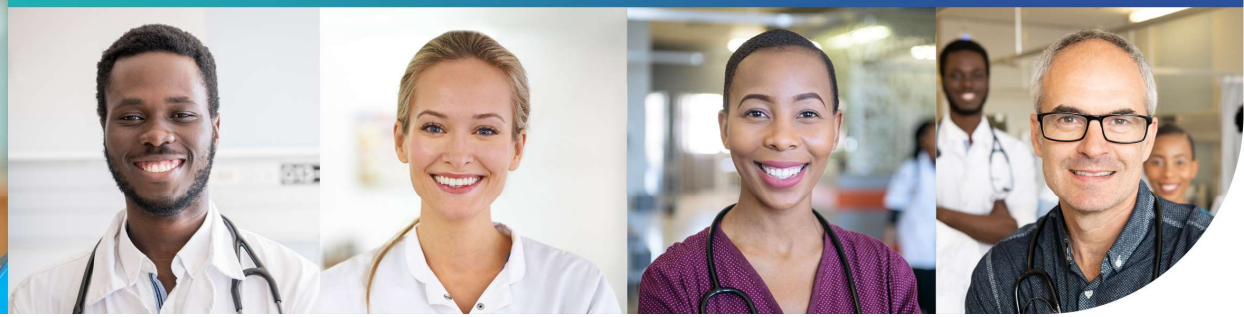
MS Nurse Professional

A pan European MS nurse community and e-learning curriculum



MS Nurse PRO

A European community for MS professionals

Annual MS Nursing Community Gathering

29 April 2022

Housekeeping

- This is a networking opportunity, please have your **camera on**
- Please **mute** yourself when not speaking
- Please **unmute** yourself when speaking
- If you would like to make a comment, please send your question in the '**Questions**' tab
- When speaking, please keep typing or other background noise to a minimum
- Should you need assistance: please message 'Simina | MS Nurse PRO' via the chat or email community.msnursepro@emsp.org

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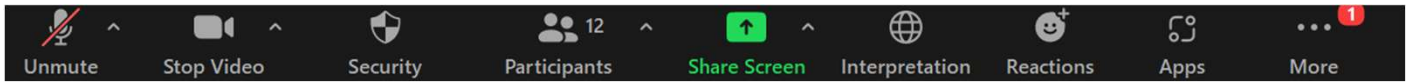
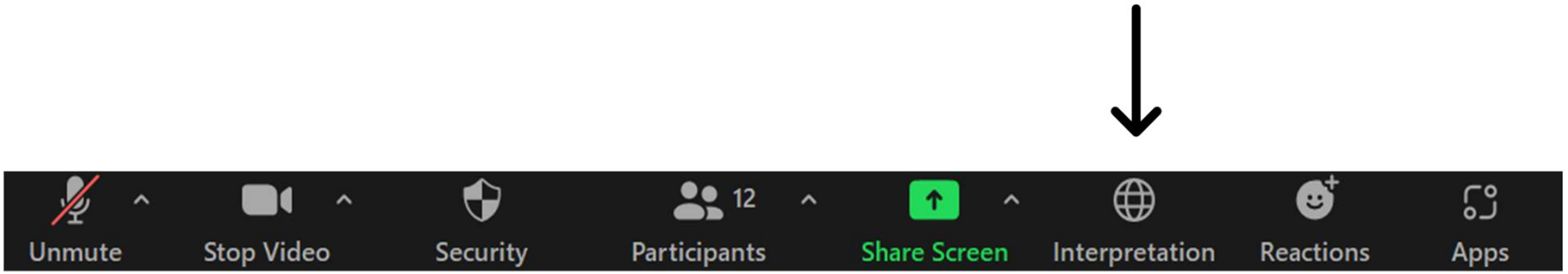
A European community for MS professionals



Interpretation



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A European community for MS professionals

Dominika Czarnota

MS Nurse PRO
Chair Steering Committee

MS Nurse Professional

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Join for free today via www.msnursepro.org

Six accredited e-learning courses

- Understanding MS
- Diagnosis & Assessment
- Treatment
- Clinical Presentation
- Care & Support
- Rehabilitation

One active community

- Complete your profile, track your own learning and contributions and show your expertise to colleagues
- Find colleagues near you
- Engage in topical discussions related to MS patient care
- Submit questions in your own mother tongue to other experts

+ 7000 users, 12 languages

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A European community for MS professionals

Certificate of accreditation from

International Council of Nurses

emsp EUROPEAN MULTIPLE SCLEROSIS PLATFORM

RIMS

IOMSN www.iomsn.org

Piet Eelen

MS Nurse PRO
Chair Syllabus Committee

National MS center Melsbroek

Disease Modyfing Therapies for MS in 2022

Piet Eelen – April 2022

Content

- What and Why a DMT
- Overview of 25 years of DMT's
- What do I have to know about the most recent DMT's?
  - When starting, during therapy, managing side effects, vaccination advice, switching
  - Siponimod, Ozanimod, Plegridy IM, Posenimod, Ofatumumab & Tysabri SC

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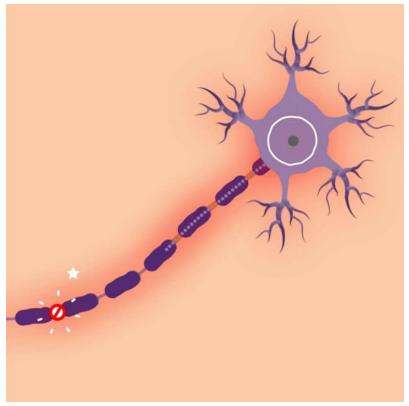
What is a DMT?



- DMT's modulates / suppress, via different mechanism of actions,

  the auto-immune process in MS

  - ➢ Understanding the immuno-pathological process
- Try to decrease the disease activity, in frequency and/or in severity of the relapses, and progression
  - ➢ Being able to translate evidences from research / studies
- Challenging unpredictability of individual respons and the occurence of side effects
- Looking for the best DMT to stabilise the disease activity
- A relaps: an increase of existing symptoms and/or an appearance of new complaints that last for at least 24 hours and at least one month sepparated from earlier relaps
  - ➢ Listen to the PlwMS and support patient shared decisions

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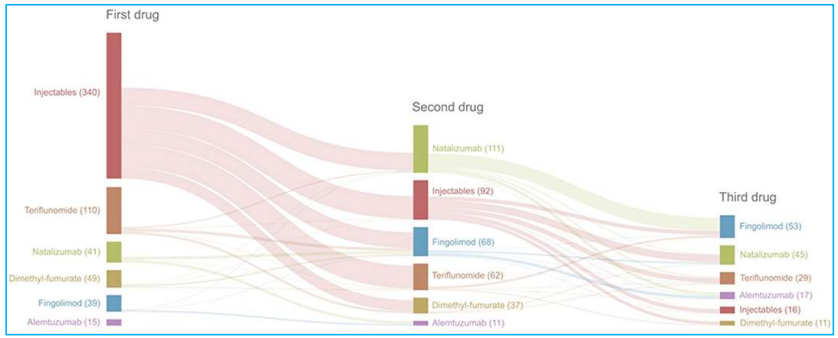
What is a DMT?



- DMT for RMS and for PMS
- Critical assesment of possible strategies is needed before starting or switching a DMT, especially in benign MS
- Early intervention with a DMT could prevent permanent damage to the myeline of the CNS
- Only limited treatments are approved to use during pregnancy or to be used in the period before becoming pregnant women or for during breastfeeding
- A treatment is in fact for undetermined time, unless side effects are unbearable, disease activity in insufficient under control or more appropriate treatments becomes available
- DMT's are no curative treatment. They can reduce the frequency or severity of the relapses and they can reduce the cumulative damage overtime

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Why treating MS with a DMT?

- RCT: DMT's have / can have an influence on:
  - **Inflammation** in the CNS (T1 & T2 leasions)
  - DMT's reduce the annual relaps rate
  - Impact the severity of the disease activity
  - Can have an impact on symptoms (cognition, fatigue, walking, …)
  - Impact on **progression**
- **Inflamation** predominantly during the beginning of MS
- Which can lead from the start to irreparable dammage of the CNS
- Long term effects of early treatment
- **Progression** leads to longitudinale changes of the immuno-pathological proces which will lead to decrease of the efficacy of the auto-repare mechanismes

Rational for early treatment interventions in Multiple Sclerose

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Why is treating MS more then a DMT?

- Limited eveidence of long term effects of early treatment
- Treating MS is more then starting a DMT
- Increasing evidence of the impact of life style and life style interventions
  - Aiming a complete physical, mental and social health and well being
  - Respect and optimise physical and mental reserves
- Relaps treatment
- Symptomatic treatment

Rational for comprehensive approach of Multiple Sclerosis

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From Patient shared decision to Personalized Medicine

- Technological innovations: developping high resolution DNA-microarrays (chips for gen & DNA research) and 2nd generation sequences will lead to huge increase of genomic profiling research

- New bio markers: important progress in magnetic imaging, body fluids (neurofilaments and acid proteins) and neuro-physiology will give opportunities to orient treatment decisions and monitoring

- New tools in information technology: improving MS-care by applying advanced and powerfull analysis of big-databases and of the health platforms which could lead to improved care models

AIM: Improving care for people with MS by generating data to:
- Support decision taking
- Predict therapeuti effects
- Predict the progression of the desease or treatment reaction

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MS Barometer 2018: Availability of 12 DMT's

- Access to DMT's has improved significantly since the previous MS Barometer survey in 2015
- However, gaps in access to a variety of DMT's persist:
  - Eight countries require some out-of-pocket payments for DMT's
  - Most countries did not have full availability of the latest therapy approved by the EMA
- 43% of people with MS in Europe were not receiving DMT treatment.
- Barriers to use of DMT's noted by the respondents include:
  - Unacceptably high co-payments
  - Reluctance on the part of hospitals to approve changes to more expensive therapies
  - A shortage of neurologists to prescribe and oversee treatments
  - Geographical challenges in accessing treatment

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Targets and Mechanisms of Action

Affecting functioning:
Influencing the function of the lymfocytes

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Targets and Mechanisms of Action

Dimethyl fumaraat
Glatiramere Acetate
Interferons

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Influencing the function of the lymfocytes

Migration inhibition:
Blocking migration of the lymfocytes from lymph nodes to the periphery and through the BBB

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Targets and Mechanisms of Action

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Glatiramere Acetate
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Affecting functioning:
Influencing the function of the lymfocytes

Fingolimod
Natalizumab

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Cladribine
Ocrelizumab

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Inhibition of production and proliferation of the lymfocytes in the bone marrow, lymph nodes and blood

Teriflunomide
Cladribine

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Therapeutic Decision Making 2022: Relapsing MS

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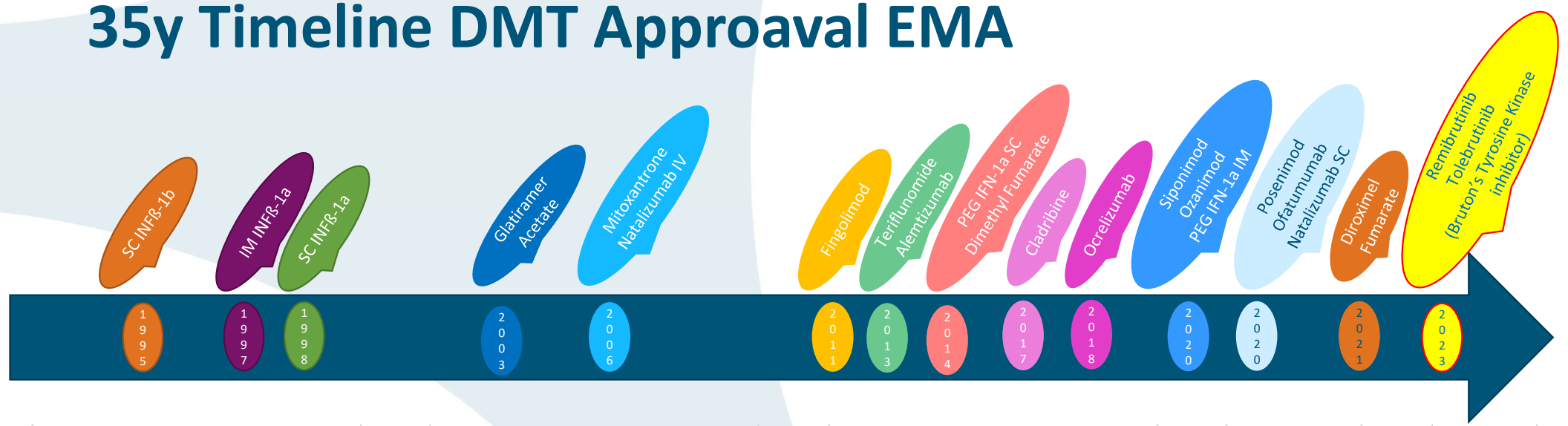
35y Timeline DMT Approaval EMA



1990 - 1999	2000 - 2009	2010 - 2019	2020 - 2022	2023 - ..
3	3	7	7	2+

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2 Names for 1 DMT / use (approximatelly)

Generice name	Brand name	
Interferon ß-1b SC	Betaferon	1,4%
Interferon ß-1a IM	Avonex	6,8%
Interferon ß-1a SC	Rebif	3,9%
Glatirameer Acetaat	Copaxone	8,0%
Mitoxantrone	Novantrone	0%
Natalizumab IV	**Tysabri IV**	**5,0%**
Fingolimod	Gilenya	9,5%
Teriflunomide	**Aubagio**	**13%**
Alemtizumab	Lemtrada	4,2%
PEG Interferon ß-1a SC	Plegridy SC	3,2%

Generice name	Brand name	
Dimethyl Fumarate	**Tecfidera**	**18%**
Cladribine	**Mavenclad**	**10%**
Ocrelizumab	**Ocrevus**	**10%**
Siponimod	Mayzent	1,0%
Ozanimod	Zeposia	0,8%
PEG Interferon ß-1a IM	Plegridy IM	0,8%
Posenimod	Ponvory	0,4%
Ofatumumab	Kesimpta	1,0%
Natalizumab SC	**Tysabri SC**	**5,5%**
Diroximel Fumarate	Vumerity	0%

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Most recent DMT's

Generice name	Brand name
Interferon ß-1b SC	Betaferon
Interferon ß-1a IM	Avonex
Interferon ß-1a SC	Rebif
Glatirameer Acetaat	Copaxone
Mitoxantrone	Novantrone
Natalizumab IV	Tysabri IV
Fingolimod	Gilenya
Teriflunomide	Aubagio
Alemtizumab	Lemtrada
PEG Interferon ß-1a SC	Plegridy SC

Generice name	Brand name
Dimethyl Fumarate	Tecfidera
Cladribine	Mavenclad
Ocrelizumab	Ocrevus
Siponimod	**Mayzent**
Ozanimod	**Zeposia**
PEG Interferon ß-1a IM	**Plegridy IM**
Posenimod	**Ponvory**
Ofatumumab	**Kesimpta**
Natalizumab SC	**Tysabri SC**
Diroximel Fumarate	Vumerity

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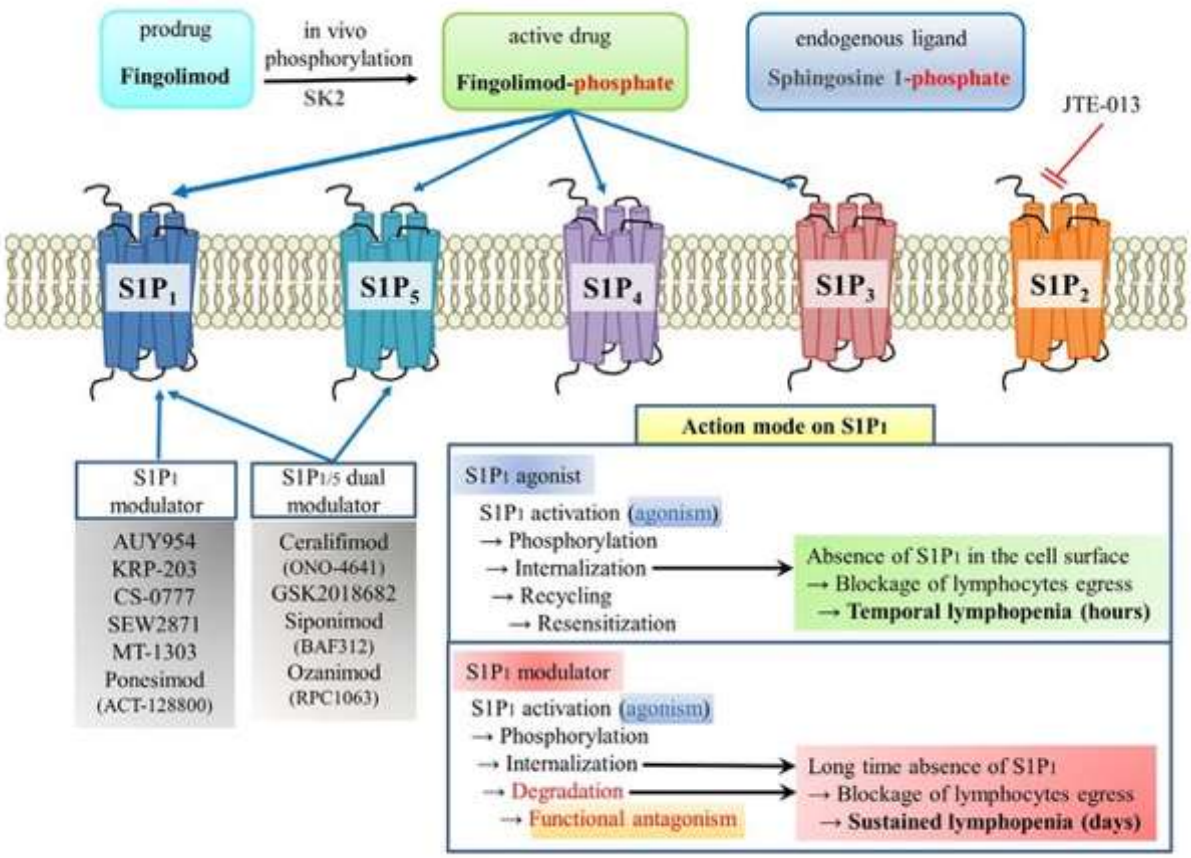
Siponimod (Mayzent®)



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Mayzent®	Siponimod	Novartis
Product characteristic	Classification	Immuno-modulator Sfingosine-1-phosphate receptor modulator (S1P) S1P1 en S1P5 selective agonist (NOT on S1P3 in hart muscle) **SPMS with disease activity after a start with relapses** EDSS ≤ 6,5 2nd line 2nd
	Galenic form	Gastric fluid resistant capsule Available in open pharmacy ⇒ Startkit: box of 12 co of 0,25mg ⇒ 2mg: box of 28co ⇒ 1mg => box of 120co of 0,25mg 
	Administration	Oral Titration start Dose of 2 mg or 1 mg Can be taken with food and / or drinks / best on fixed moment
	Storage	Room themperature 8-25°C

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Mayzent®	Siponimod	Novartis
Start	Laboratory	CBC with Lymfocytes subpopulation Liver- and kidneyf° / VZV Additional: HBV / HBC / IGRA / JCV **CYP2C9 genotyping for metabolisation of molecule** (85% - 14,5% - 0,5%) ⇒ Specific lab
	Exams	Exclude acute infections / Check parameters If neccesary brain MRI ECG Eventually cardio advice (bradycardie, AV block, …) Dermatological evaluation (by neurologist is OK) Ophtalmological evaluation in case of diabetes mellitus, uveitis or retina problems in history
	Pregnancy	Test before start AC during Tx STOP before conception (min 10 days) Restart after pregnancy NOT during breast feeding

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Mayzent®	Siponimod	Novartis
Start	Vaccination	Before start: mandatory VZV if IgG are negative Non-living: OK / Living: 4 weeks prior or 4 weeks after Tx COVID : probably reduced immuunrespons to the vaccin
	SuPportMS platform	Electronic platform to Support PlwMS and neurologist ⇒ Information and IC for the PlwMS to participate in progran ⇒ IC of PlwMS for genotyping => Blood sample for genotyping at home
	Start	Wait for result genotyping Dose: 2mg or 1mg If cardio risk: 6u monitoring If not: start can be doen at home Neurologist: reimbursement certificate
	Inform	Supply oral and written information Available in hospital or open pharmacy Titration scheme Follow-up blood samples Protection for UV-A and UV-B AC ! If visual problems occur: report!! Ask for it!!

Titratie schema 2 mg:

Dag 1 : 1 x 0.25 mg
Dag 2 : 1 x 0.25 mg
Dag 3 : 2 x 0.25 mg
Dag 4 : 3 x 0.25 mg
Dag 5 : 5 x 0.25 mg

Dag 6 : 1 x 2 mg

Titratie schema 1 mg:

Dag 1 : 1 x 0.25 mg
Dag 2 : 1 x 0.25 mg
Dag 3 : 2 x 0.25 mg
Dag 4 : 3 x 0.25 mg
Dag 5 : 5 x 0.25 mg

Dag 6 : 4 x 0.25 mg

Mayzent®	Siponimod	Novartis
Monitoring Tx	Laboratory	First year: after month 1, 3, 6, 9, 12: CBC and liverf° After first year: every 3 to 6 months: CBC and liverf°
	Exams	Ophtalmology: after 3 to 4 months Dermatology: after 6 to 12 months MRI if neccesary New monitoring when dose missed or after interruption: ⇒ During first 6 days: re-start titration with new titration kit ⇒ After day 6: - If just 1 day: take tablet day after, no double dose !! - 4 days or more: re-start titration
	Tx SE	Few to no complaints Possible symptoms: Headache / Hypertensia / Nausea / Diarrhea Possible risks: liverf° problems / Herpes zoster infection / Lymfopenia / Macula oedema / AV-block / heart rithme problems / Perifere oedeema
	Switching	Check repopulatie lymfocyten before the start

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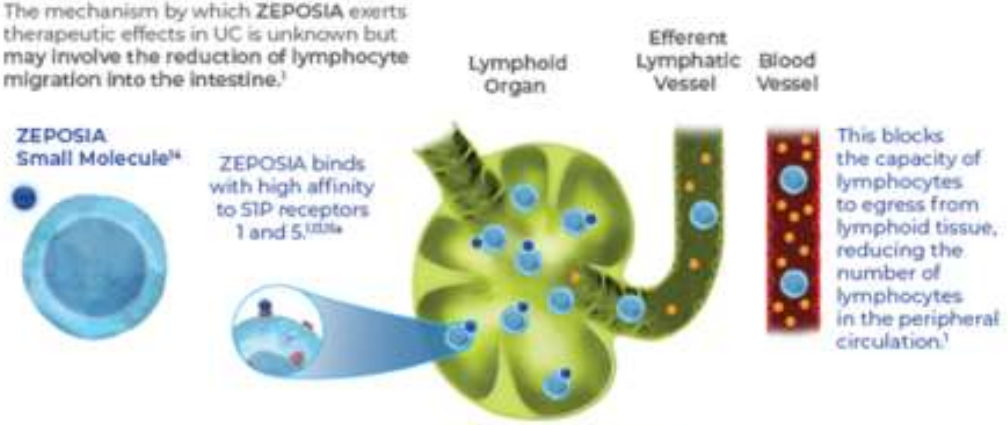
Ozanimod (Zeposia)

The mechanism by which **ZEPOSIA** exerts therapeutic effects in UC is unknown but **may involve the reduction of lymphocyte migration into the intestine.**[1]



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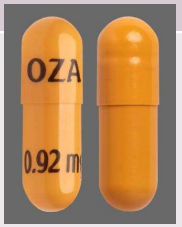
Zeposia® po	Ozanimod	BMS
Product	Classificatie	Immuno-modulator Sfingosine-1-phosphate receptor modulator (S1P) S1P1 en S1P5 selective agonist (NOT on S1P3 in hart muscle) EDSS ≤ 6,5 1st line
	Galenic form	Hard capsule of 0,92mg Available in open pharmay Startkit: 7 capsules (4 of 0,23mg + 3 of 0,46mg) Treatment box: 28 capsules of 0,92mg
	Administration	Oral To start with titration Dose: 0,92 mg Can be taken with drinks and / or food / best on fixed moment
	Storage	Under 25°C



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Zeposia® po	Ozanimod	BMS
Start	Laboratory	CBC / liverf° / VZV ⇒ Optionnal: HBV / HBC / IGRA / JCV
	Exams	Eliminate acute infections / Check parameters If neccesary brain MRI ECG In case of cardiac history: cardiological evaluation If history of diabetes mellitus, uveïtis or retina problems: advice oftalmology
	Pregnancy	Test before start AC during Tx and at least 3 months after stop Tx STOP in case of conception during Tx NOT during breast feeding
	Vaccination	Before start: mandatory VZV if IgG are negative / at least 1 month before start / also if no data of vaccination! Living: at least 1 month before start, not during Tx en NOT to 3 months after stop Non-Living & COVID : no guidelines yet

Zeposia® po	Ozanimod	BMS
Start	Start scheme	Day 1 to day 4: 1 x 0,23mg Day 5 to day 7: 1 x 0,46mg From day 8: 1 x 0,92mg /dag
		If a dose is skipped: start same titration scheme as on the initial start of Tx if interruption of: ⇒ 1 day or more in the first 2 weeks of the Tx ⇒ > 7 consecutive days between day 15 and day 28 ⇒ > 14 consecutive days after day 28 of Tx

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Zeposia® po	Ozanimod	BMS
	Exams	Parameters If neccesary brain MRI In case of visual problems or oftalmological problems in history: ⇒ Oftalmo FU after 3 to 4 months
	Tx SE	Infections Headache Bradycardia Breathing problems Macula oedeem
	Switching	Check repopulatie lymfocyten Be aware of the longer half-life of the molecule of several months!! Evaluate disease activity but additional immuno modulating affect of Zeposia must be taken into account before starting another DMT

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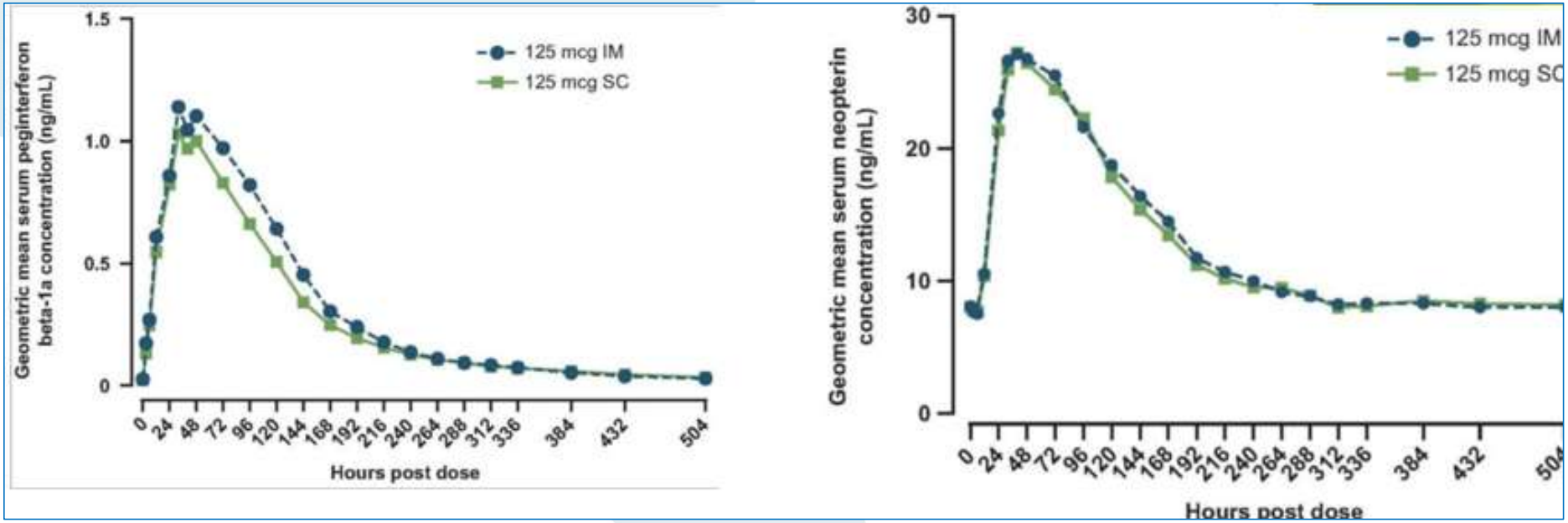
Plegridy IM



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TEAE, *n* (%)	Peginterferon beta-1a 125 mcg IM (*n* = 132)	Peginterferon beta-1a 125 mcg SC (*n* = 134)
Any TEAE	81 (61.4)	89 (66.4)
ISR TEAEs [a]	19 (14.4)	43 (32.1)
TEAEs occurring in >2% of participants by MedDRA preferred term		
Headache	46 (34.8)	52 (38.8)
Chills	46 (34.8)	36 (26.9)
Pain	29 (22.0)	19 (14.2)
Injection site pain	15 (11.4)	19 (14.2)
Pyrexia	13 (9.8)	11 (8.2)
Dizziness	8 (6.1)	3 (2.2)
Feeling hot	8 (6.1)	7 (5.2)
Nausea	8 (6.1)	7 (5.2)
Decreased appetite	6 (4.5)	4 (3.0)
Pain in extremity	6 (4.5)	1 (0.7)
Myalgia	4 (3.0)	5 (3.7)
Somnolence	4 (3.0)	1 (0.7)
Arthralgia	3 (2.3)	5 (3.7)
Back pain	3 (2.3)	11 (8.2)
Injection site erythema	3 (2.3)	34 (25.4)
Influenza-like illness	3 (2.3)	3 (2.2)
Vomiting	3 (2.3)	2 (1.5)
Eye irritation	2 (1.5)	3 (2.2)
Nasal congestion	2 (1.5)	3 (2.2)
Injection site induration	1 (0.8)	4 (3.0)
Injection site pruritus	1 (0.8)	11 (8.2)
Injection site warmth	0	5 (3.7)
Fatigue	0	4 (3.0)

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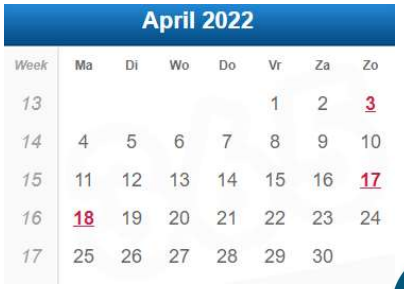
Plegridy® IM	PEG Interferon ß-1a	Biogen
Product	Classification	Immuno Modulator Pegylated interferon (cfr IM versie)
	Galenic form	Prefilled syringe
	Administration	125µg – 1x/ 14 days – titration at the start (63µg -> 94µg -> 125µg) – **with clips!!** **Not for autoinjection**
	Storage	2-8°C (until 30 days at room T°, but outside the influence of light
Start	Labo	CBC + liver- and kidneyf°
	Exams	Check infection and parameters / MRI if necc
	Pregnancy	Test before start / AC during Tx / STOP at conception and during pregnancy / Re-rstart after pregnancy / Breast feeding is possible
	Vaccination	Living: not recommended / Not-living: possible / COVID: probably nl immuunrespons
Monitoring Tx	Laboratory	CBC + liver- and kidneyf°
	Exams	MRI if neccesary
1st	Tx SE	SE cfr SC version (mostly after 24 tot 48 hours), but less ISR FLS / depression / liverproblems / TMA
	Switching	No guidelines -> check re-population of lymfocytes

Ponvory® po	Posenimod	Janssen
Product	Classificatie	Immuno modulator Sfingosine-1-fosfaat receptor modulator **S1P1 selectief!!!** 
	Galenische vorm	Comprimé
	Toediening	20mg/dag met opstartschema van 2 wkn van 2mg tot 20mg
	Bewaring	15-25°C
Start	Labo	CBC / leverf° / VZV
	Onderzoek	Check infecties en parameters / ECG / igv cardiale VG: zn cardio advies / igv VG diabetes mellitus, uveïtis of retinale aandoeningen: advies oftalmo / epilepsie in VG
	Zwangerschap	Test voor start / regelmatige monitoring / AC tijdens Tx / STOP min 1 week voor conceptie / Mag NIET tijdens de borstvoeding
	Vaccinatie	Voor start: VZV zo gn AS min 1 mdn voor start Tx / Levend: 4 wkn voor start, niet tijdens Tx niet tot 4 wkn na stop Tx / Niet-levend: kan tijdens Tx / COVID : onvoldoende data
Behandeling	Labo	CBC / leverf°
	Onderzoek	zn MRI / oftalmo na 3 mdn / dermato na 1 jr / nieuwe monitoring bij onderbreking
??	Tx NE	Infecties / hoofdpijn / bradycardie / ademhalingsproblemen / macula oedeem
	Switching	Check repopulatie / Ponvory is na 7 dgn uit het lichaam verdwenen

Kesimpta® SC	Ofatumumab	Novartis
Product	Classification	Immuno suppressivum Monoclonal anti-CD-20 antibody (epitoop on B-cells) ⇒ **B-cell therapie** RMS Ofatumumab is a fully (100%) humanised monoclonaal antibody *(via DNA technology)* EDSS ≤ 6,5 2nd line
	Galenic form	Prefilled syringe Auto-injections SC With the Sensoready® Pen1 “Click-and-go” Available in open pharmacy
	Administration	20mg Ofatumumab in 0,4ml Start via titration: day 1, 7, 14 and 28, then 1 time every month
	Storage	2-8°C (tolerance to 25°) Can be kept 7 days outside of fridge and then even 7 days more in fridge !!

2de

Kesimpta® SC	Ofatumumab	Novartis
Start	Laboratory	CBC / CRP / HBV ⇒ Optionnal: liver- and kidneyf° / HBC / IGRA / JCV
	Exams	Exclude acute infections / Check parameters MRI
	Pregnancy	Test before start AC during Tx STOP min **6 months** before conception Re-start after pregnancy Can during breast feeding from day 3 after giving birth
	Vaccination	Living: 4 wks before start, not during Tx Non-living: best 2 wks before start, during TX possibly less immuun espons COVID: still in study, probably less immuun respons to the vaccin



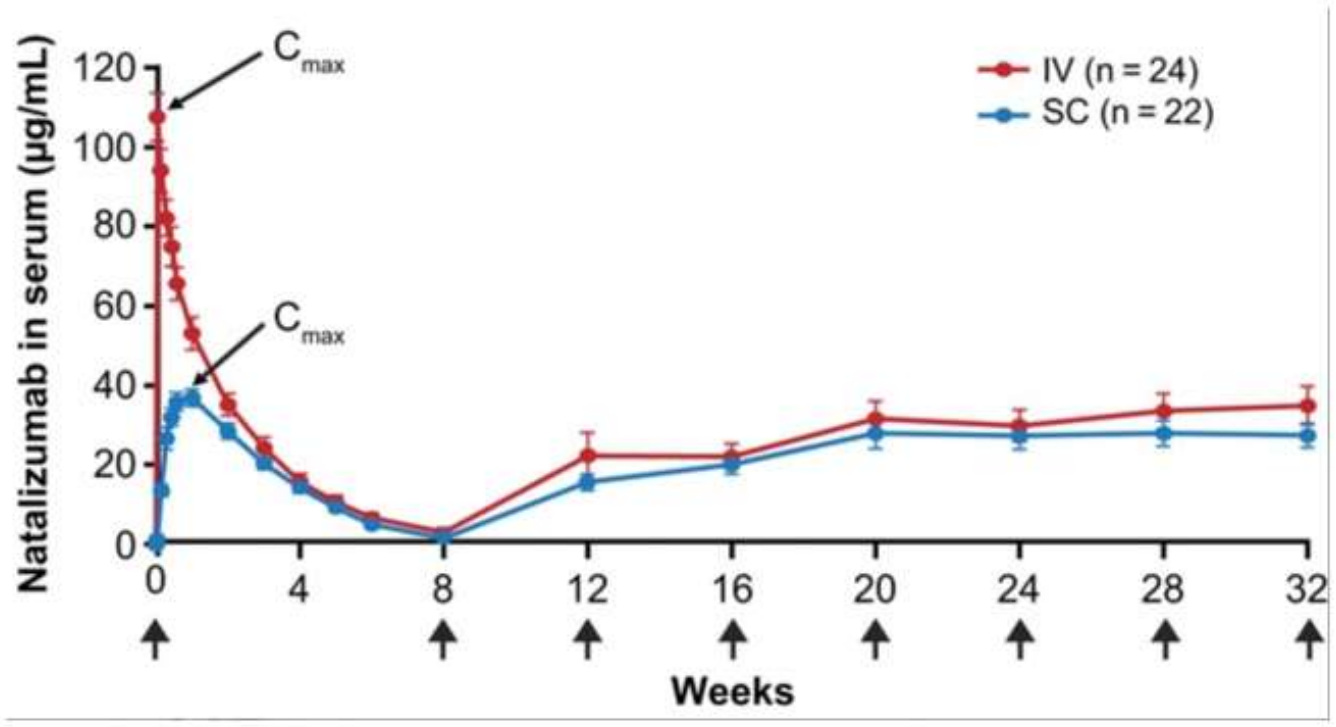
1ste dosis: 1 april (start)
2de dosis: 8 april (week 1)
3de dosis: 15 april (week 2)
4de dosis: 29 april (week 4)
5de en volgende dosis: 29ste van de maand

National MS center Melsbroek

Kesimpta® SC	Ofatumumab	Novartis
Monitoring during Tx	Laboratory	No indication to do regularly controles due to ‘safe’ profile of side effects ⇒ Hospital / neurologist dependent
	Exams	No indication to do regularly controles due to ‘safe’ side effects profile ⇒ Hospital / neurologist dependent Cave: PML bij anti-CD20 behandelingen (not in Kesimpta studies)
	Tx SE	Injection related reactions – espescially first 24 hours after injection and also after first injection Possible: ⇒ Redness, swelling, itching, pain ⇒ Headache, fever, fatigue, muscle pain, chills ⇒ Infections: upper airways, throat, bladder
	Switching	Re-population lymfocyten + specific guidelines per DMT !!!

National MS center Melsbroek

Natalizumab



National MS center Melsbroek

Tysabri® SC	Natalizumab	Biogen
Product	Classification	Immuno Modulator
	Galenic form	Pre-filled pen
	Administration	2 x 150mg every 4 weeks / every month
	Storage	2-8°C / max 24 hours at room T°
Start	Laboratory	CBC with Lymfocytes subpopulation / liver and kidneyf° / HSV / JCV
	Exams	Check infections / Parameters / MRI eventually before start
	Pregnancy	Test before start / AC during Tx / stop preferably during pregnancy / re-start after pregnancy / not during breast feeding
	Vaccination	Living: no data – no evidence / Not-living: no problem, probably some reduced and slower immuunrespons / COVID: probably nl immuunrespons
Monitoring Tx	Laboratory	Half yearly: CBC + liver- en kidneyf° + TSH + JCV
	Exams	MRI: JCVneg: 1x/Y – JCVpos: 1x in Y 1 / Every 6m in Y 2 / Every 4m from Y 3
2de	Tx SE	Anafylactic shock / Infections and parasitic diseases / ISR / Anemia / Trombocytopenie / ITP / PML
	Switching	Check repopulatie lymfocyten and CBC


That's all Folks!

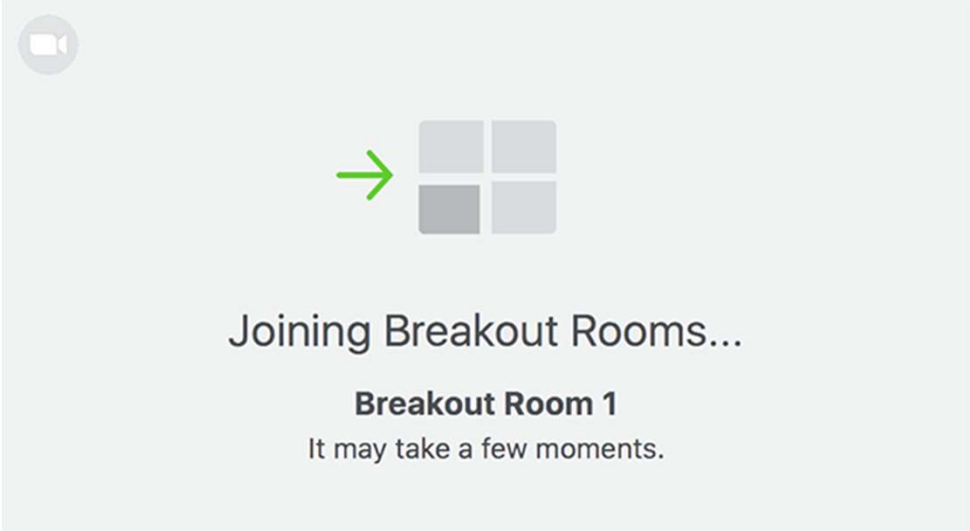
Stefaan De Corte

MS Nurse PRO
Project Coordinator

Interactive Session: National overview

- 5 break-out rooms depending on the language you speak/listen to
  - English,
  - Dutch(Flemish),
  - German,
  - Romanian
  - Spanish

  - If in the wrong room, message ’Simina | MS Nurse PRO’



MS Nurse PRO
A European community for MS professionals

Interactive Session: National overview

1. What do you see as the **biggest challenge in MS Care** today?

2. How do you experience **digitalization and the use of digital tools** in your day-to-day work? Is it an added value?

3. Where do you find **useful information** (additional information) on your nursing practice?

MS Nurse PRO
A European community for MS professionals

Interactive Session: National overview

1. Wat ziet u als de grootste uitdaging in de MS-zorg van vandaag?

2. Hoe ervaart u de digitalisering en het gebruik van digitale hulpmiddelen in uw dagelijkse werk? Is het een toegevoegde waarde?

3. Waar vindt u nuttige informatie (extra informatie) over uw verpleegkundige praktijk?

MS Nurse PRO
A European community for MS professionals

Interactive Session: National overview

1. Was sehen Sie als die größte Herausforderung in der MS-Pflege heute?

2. Wie erleben Sie die Digitalisierung und den Einsatz digitaler Tools in Ihrer täglichen Arbeit? Stellt sie einen Mehrwert dar?

3. Wo finden Sie nützliche Informationen (zusätzliche Informationen) für Ihre Pflegepraxis?

MS Nurse PRO
A European community for MS professionals

Interactive Session: National overview

1. Ce vedeți ca fiind cea mai mare provocare în MS Care astăzi?

2. Cum resimțiți digitalizarea și utilizarea instrumentelor digitale în activitatea dumneavoastră de zi cu zi? Este o valoare adăugată?

3. Unde găsiți informații utile (informații suplimentare) cu privire la practica dumneavoastră de asistență medicală?

MS Nurse PRO
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Interactive Session: National overview

1. ¿Cuál considera que es el mayor reto actual en el ámbito de la atención sanitaria de la EM?

2. ¿Cómo vive la digitalización y el uso de herramientas digitales en su trabajo diario? ¿Es un valor añadido?

3. ¿Dónde encuentra información útil (información adicional) sobre su práctica enfermera?

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Interactive Session: Exchange of best practice

MS Nurse PRO
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Dominika Czarnota

MS Nurse PRO
Chair Steering Committee

Closing remarks

+600
new members yearly from all regions of the world

+300
completers of the Foundation Programme annually

MS Nurse PRO
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