NEW THERAPEUTIC APPROACHES IN ADVANCED CTCL MANAGEMENT - IS IT REALISTIC?

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THE UK
PHOTOPHERESIS
SOCIETY

University Hospitals Birmingham
NHS
NHS Foundation Trust

Disclosures

- Consultancy Mallinckrodt, Innate Pharma, Takeda, Codiak Sciences, Recordati, Kyowa

University Hospitals Birmingham
NHS Foundation Trust

Prof Youn Kim
U Stanford

WHAT HAVE WE LEARNT ABOUT THE TREATMENT OF ADVANCED STAGE MYCOSIS FUNGOIDES AND SEZARY SYNDROME FROM THE PROCLIPI STUDY? HOW CAN WE APPLY THIS TO PATIENT MANAGEMENT TO IMPROVE OUTCOMES?

PROspective **C**utaneous **L**ymphoma **I**nternational **P**rognostic **I**ndex Study

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On Behalf of the EORTC Gp & Cutaneous Lymphoma International Consortium

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PROCLIPI: 471 advance stage patients (IIB-IVB) MF/SS from 52 sites, from 19 countries, 6 continents since 2015

Julia Scarisbrick
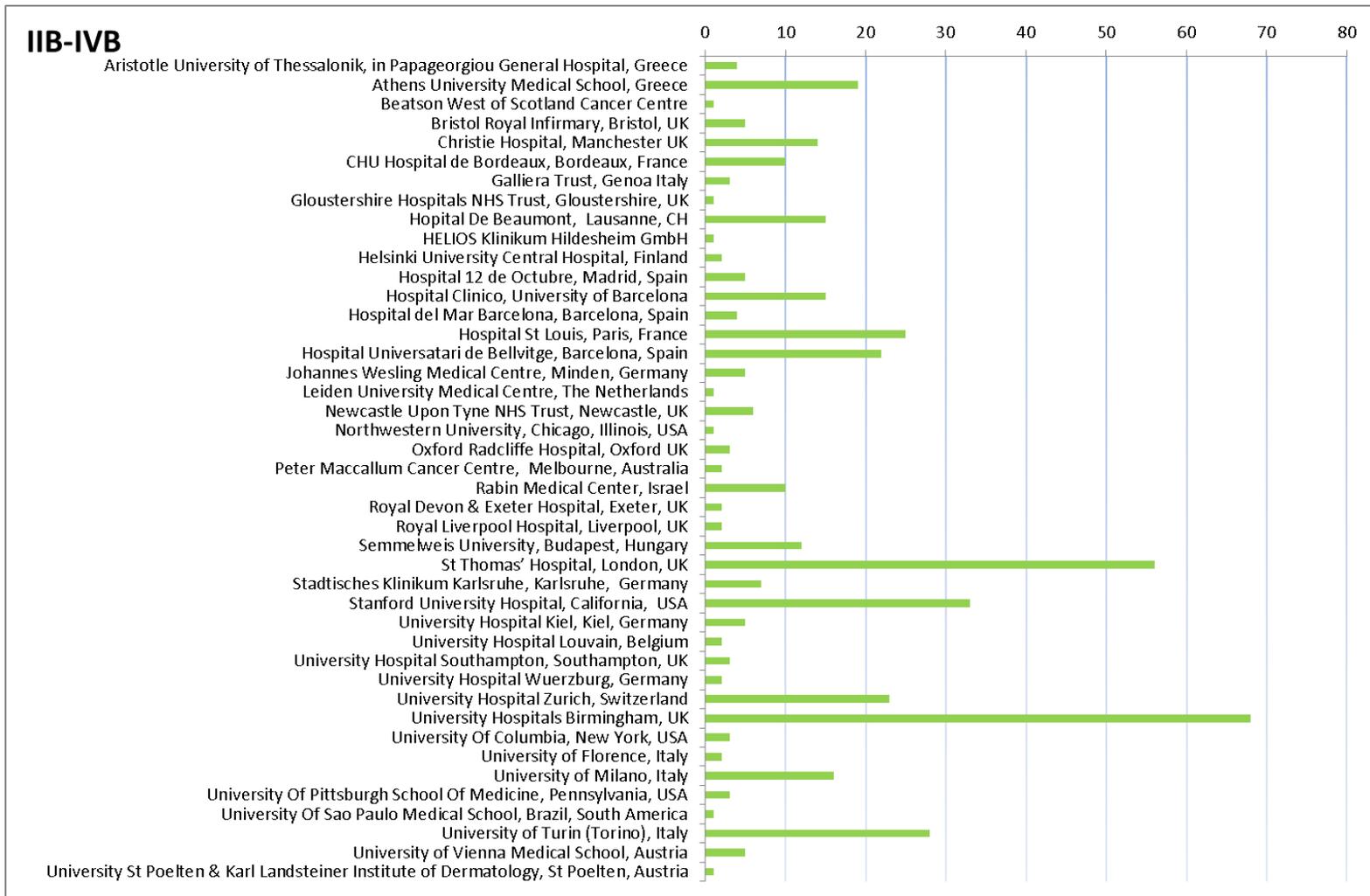
Overall Survival In Advanced MF/SS Cohort Diagnosed from 2015 onward , median follow up 38 months

- Median survival reached only in IVA(2)

- % Survival at each time point and 95% CI

Time (IQR)	IIB	IIIA	IIIB	IVA(1)	IVA(2)
1 year survival	83.1% (75.4-88.5)	95.7% (84.0-98.9)	88.0% (73.5-94.8)	88.4% (81.2-93.0)	79.5% (63.1-89.2)
2 year survival	72.0% (62.9-79.2)	76.6% (60.8-86.7)	71.5% (54.3-83.2)	81.1% (72.6-87.1)	56.7% (39.1-70.9)
3 year survival	61.6% (51.6-70.2)	69.0% (52.6-80.7)	65.7% (48.1-78.5)	72.3% (62.6-79.8)	50.5% (33.2-65.5)
4 year survival	57.2% (46.6-66.4)	66.1% (49.4-78.5)	55.8% (37.9-70.5)	66.8% (56.4-75.3)	45.9% (28.3-61.9)
5 year survival	46.1% (34.0-57.4)	59.0% (41.3-72.9)	44.8% (25.3-62.5)	50.0% (37.6-61.2)	35.7 (18.4-53.5)

- There is a significantly worse survival IVA2 than any other stages (p=0.026)

- No significant difference in survival stage IIB-IVA1

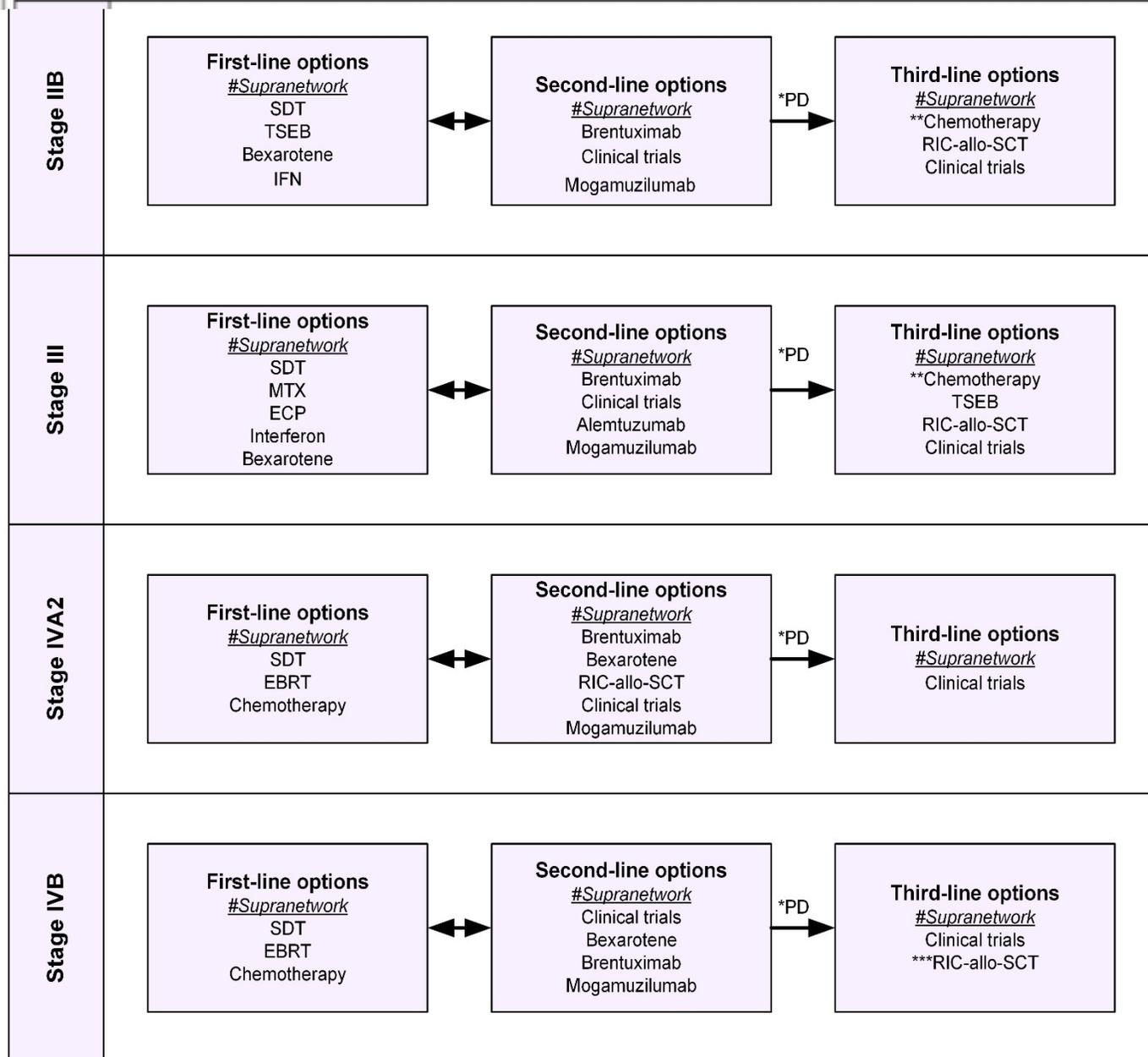- No improvement in survival since publication of the retrospective CLIC[1] from 2005-2015

[1] Scarisbrick J et al. Cutaneous Lymphoma International Consortium (CLIC) Study of Outcome in Advanced Stages of Mycosis Fungoides & Sézary Syndrome: Effect of specific prognostic markers on survival and development of a prognostic model. *J Clin Oncology*. 2015;33(32):3766-73

CURRENT GUIDELINES IN CTCL

British Association of Dermatologists and UK Cutaneous Lymphoma Group

Treatment options for mycosis fungoides

Stage	First-line options		Second-line options		Third-line options
Stage IIB	First-line options *#Supranetwork* SDT TSEB Bexarotene IFN	↔	Second-line options *#Supranetwork* Brentuximab Clinical trials Mogamuzilumab	*PD →	Third-line options *#Supranetwork* **Chemotherapy RIC-allo-SCT Clinical trials
Stage III	First-line options *#Supranetwork* SDT MTX ECP Interferon Bexarotene	↔	Second-line options *#Supranetwork* Brentuximab Clinical trials Alemtuzumab Mogamuzilumab	*PD →	Third-line options *#Supranetwork* **Chemotherapy TSEB RIC-allo-SCT Clinical trials
Stage IVA2	First-line options *#Supranetwork* SDT EBRT Chemotherapy	↔	Second-line options *#Supranetwork* Brentuximab Bexarotene RIC-allo-SCT Clinical trials Mogamuzilumab	*PD →	Third-line options *#Supranetwork* Clinical trials
Stage IVB	First-line options *#Supranetwork* SDT EBRT Chemotherapy	↔	Second-line options *#Supranetwork* Clinical trials Bexarotene Brentuximab Mogamuzilumab	*PD →	Third-line options *#Supranetwork* Clinical trials ***RIC-allo-SCT

EBRT: external beam radiotherapy with photons or electrons for lymph node, soft tissue or visceral lymphoma; **ECP:** extracorporeal photopheresis; **IFN:** interferon; **MTX:** methotrexate;

PD: progressive disease; **RIC-allo-SCT**, reduced intensity allogeneic stem cell transplantation;

*PD and exhausted first- and second-line options. **Chemotherapy only as recommended by the supranetwork MDT.

***Consider only if the patient has durable complete response.

↔ indicates that after treatment, patients may respond to treatments included in earlier 'line' options. Patients can move between first- and second-line options.

How can we improve our outcomes in advanced CTCL?

Can we gain additional information from real world treatment data ?

REAL WORLD TREATMENT DATA WITH IN CTCL

- Retro CLIC paper
- PROCLIPI data
- Time To Next Treatment data

* UVADEX (methoxsalen)/ECP is not indicated for mortality outcomes or as first-line treatment of skin manifestations of CTCL

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ORIGINAL ARTICLE

Global patterns of care in advanced stage mycosis fungoides/Sezary syndrome: a multicenter retrospective follow-up study from the Cutaneous Lymphoma International Consortium
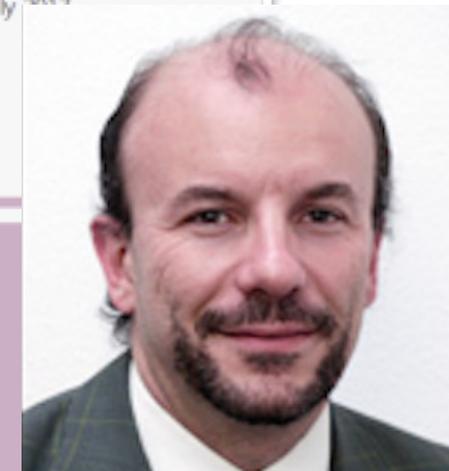
P. Quaglino[1*†], M. Maule[2†], H. M. Prince[3,4], P. Porcu[5], S. Horwitz[6], M. Duvic[7], R. Talpur[7], M. Vermeer[8], M. Bagot[9], J. Guitart[10], E. Papadavid[11], J. A. Sanches[12], E. Hodak[13,14], M. Sugaya[15], E. Berti[16], P. Ortiz-Romero[17], N. Pimpinelli[18], O. Servitje[19], A. Pileri[20], P. L. Zinzani[21], T. Estrach[22], R. Knobler[23], R. Stadler[24], M. T. Fierro[1], S. Alberti Violetti[16], I. Amitay-Laish[13,14], C. Antoniou[11], C. Astrua[1], S. Chaganti[25], F. Child[26], A. Combalia[22], S. Fabbro[5], P. Fava[1], V. Grandi[18], C. Jonak[23], E. Martinez-Escala[10], M. Kheterpal[6], E. J. Kim[27], C. McCormack[3,4], T. Miyagaki[15], D. Miyashiro[12], S. Morris[26], C. Muniesa[19], V. Nikolaou[11], G. Ognibene[28], F. Onida[16], S. Osella-Abate[1], S. Porkert[23], C. Postigo-Llorente[17], C. Ram-Wolff[9], S. Ribero[1], K. Rogers[28], M. Sanlorenzo[1], R. Stranzenbach[24], N. Spaccarelli[27], A. Stevens[25], D. Zugna[2], A. H. Rook[27], L. J. Geskin[28], R. Willemze[8], S. Whittaker[26], R. Hoppe[29], J. Scarisbrick[25‡] & Y. Kim[29‡]

Global patterns of care in advanced stage mycosis fungoides/Sezary syndrome: a multicenter retrospective follow–up study from the Cutaneous Lymphoma International Consortium

P. Quaglino, M. Maule, H. M. Prince, P. Porcu, S. Horwitz, M. Duvic, R. Talpur, M. Vermeer, M. Bagot, J. Guitart E. Papadavid, J. A. Sanches, E. Hodak, M. Sugaya, E. Berti, P. Ortiz-Romero, N. Pimpinelli, O. Servitje, A. Pileri, P. L. Zinzani, T. Estrach, R. Knobler, R. Stadler, M. T. Fierro, S. Alberti Violetti, I. Amitay-Laish, C. Antoniou, C. Astrua, S. Chaganti, F. Child, A. Combalia, S. Fabbro, P. Fava, V. Grandi, C. Jonak, E. Martinez-Escala, M. Kheterpal, E. J. Kim, C. McCormack, T. Miyagaki, D. Miyashiro, S. Morris, C. Muniesa, V. Nikolaou, G. Ognibene, F. Onida, S. Osella-Abate, S. Porkert, C. Postigo-Llorente, C. Ram-Wolff, S. Ribero, K. Rogers, M. Sanlorenzo, R. Stranzenbach, N. Spaccarelli, A. Stevens, D. Zugna, A. H. Rook, L. J. Geskin, R. Willemze, S. Whittaker, R. Hoppe, J. Scarisbrick, Y. Kim

This study included 853 patients from 21 specialist centres (14 European, 4 USA, 1 each Australian, Brazilian and Japanese).

'large treatment heterogeneity with up to 24 different drugs, modalities or combinations used as first-line treatment'

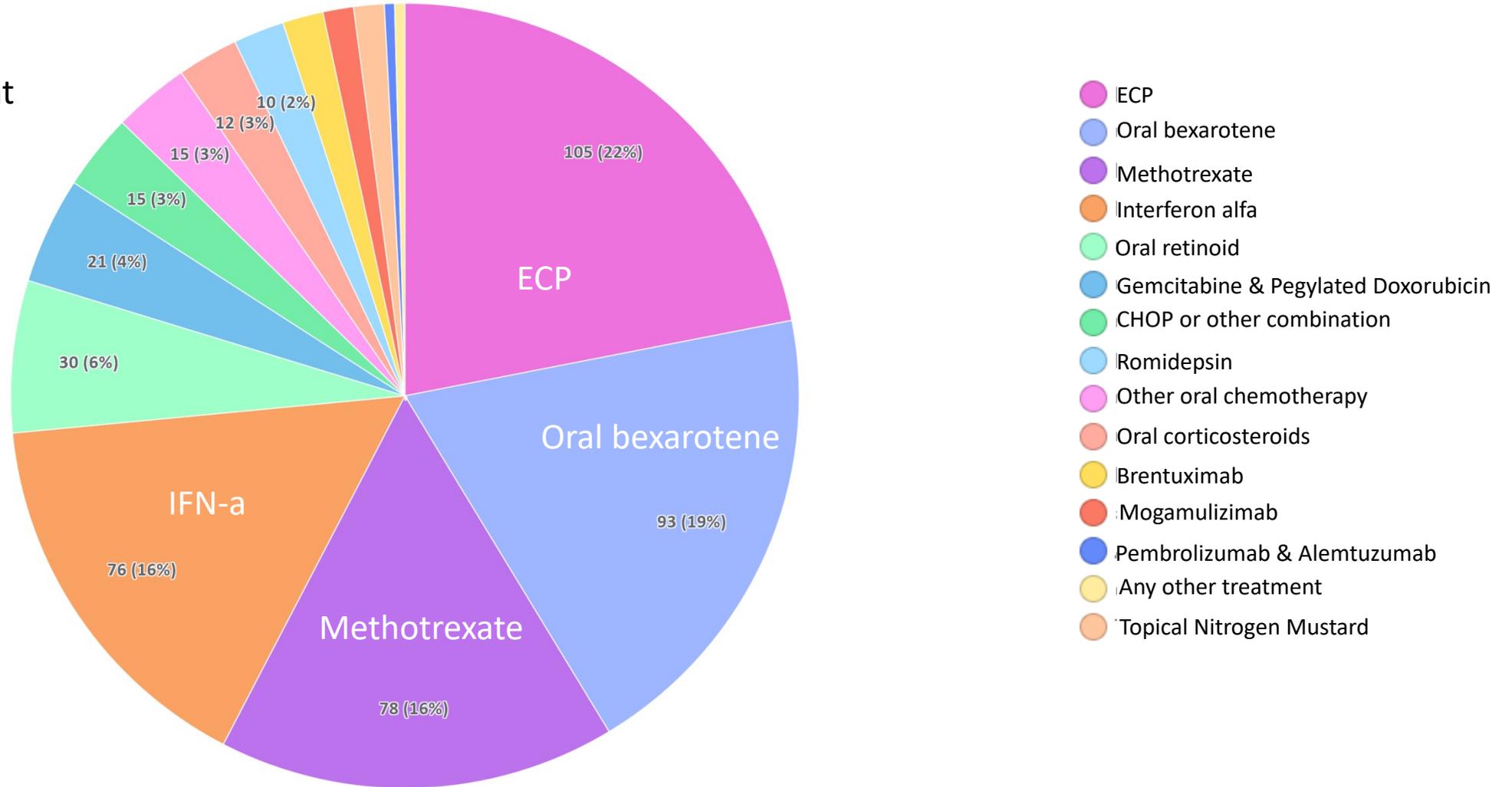'chemotherapy as first treatment is associated with a higher risk of death'

'The most commonly used first approach was ECP either alone (10%) or in combination (8.6%), followed by bexarotene and phototherapy. ECP was also the most commonly used second line therapy'

'significant differences were found between USA and non-USA centres, but these differences did not significantly impact on survival'

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PROCLIPI: First Line Treatments in Advanced Stage MF/SS IIB-IVB 471 patients

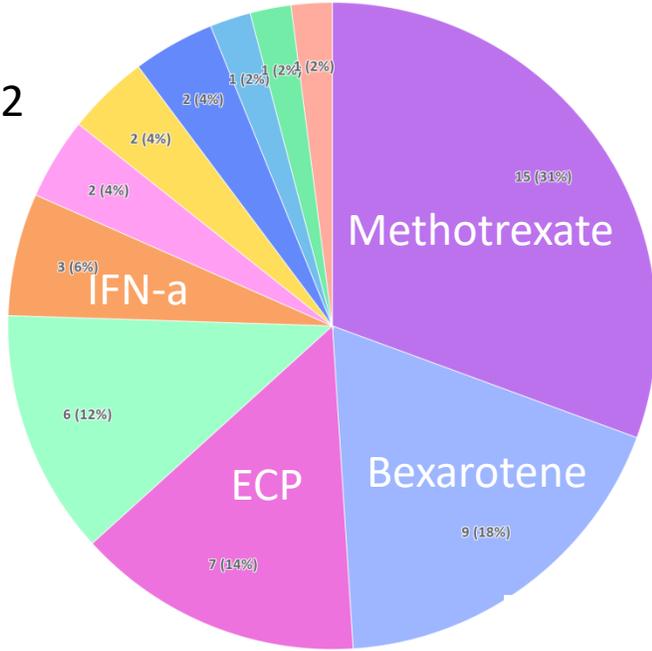More than 15 different treatment modalities for first line in advanced stage disease
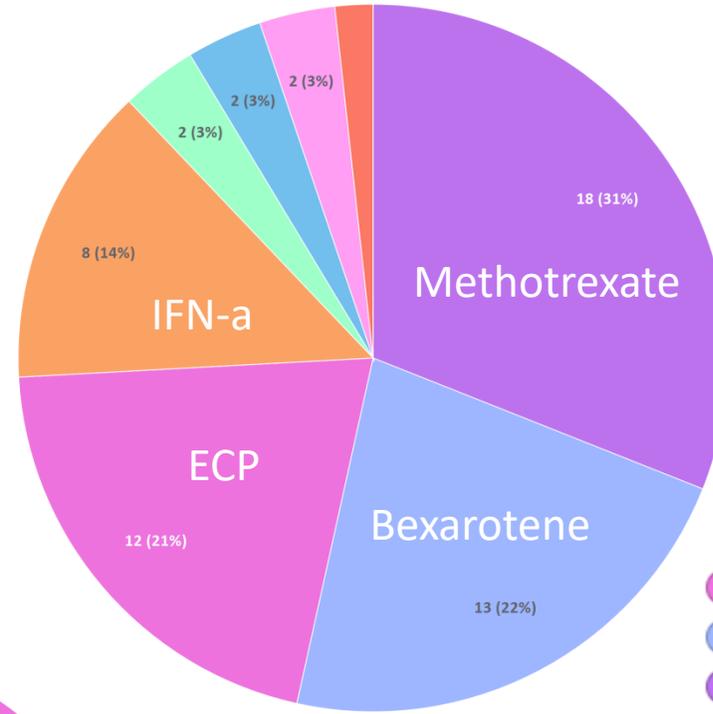

Legend:
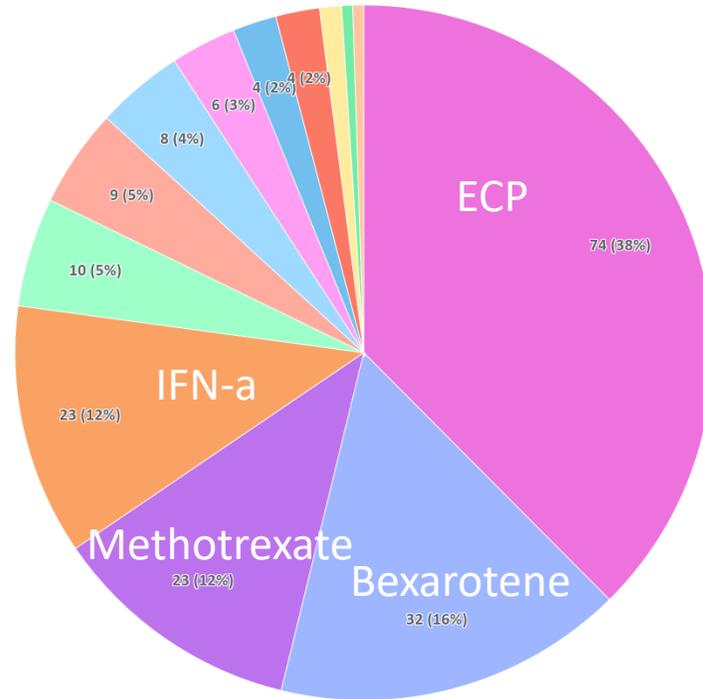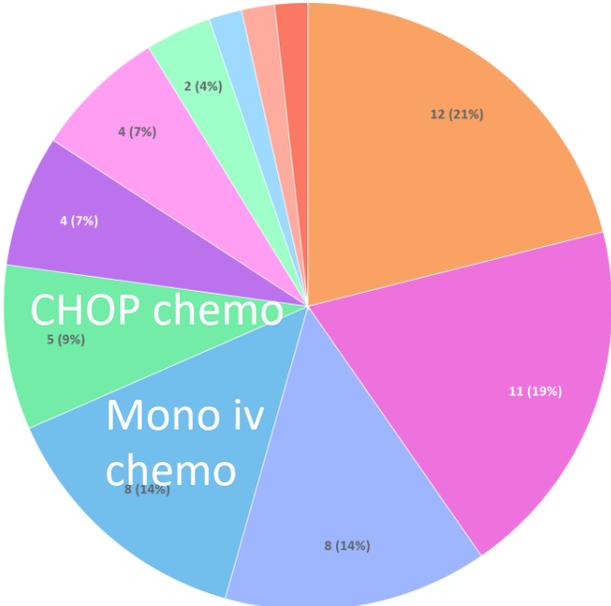- ECP
- Oral bexarotene
- Methotrexate
- Interferon alfa
- Oral retinoid
- Gemcitabine & Pegylated Doxorubicin
- CHOP or other combination
- Romidepsin
- Other oral chemotherapy
- Oral corticosteroids
- Brentuximab
- Mogamulizimab
- Pembrolizumab & Alemtuzumab
- Any other treatment
- Topical Nitrogen Mustard

Pie chart values:
- ECP: 105 (22%)
- Oral bexarotene: 93 (19%)
- Methotrexate: 78 (16%)
- IFN-a: 76 (16%)
- Oral retinoid: 30 (6%)
- 21 (4%)
- 15 (3%)
- 15 (3%)
- 12 (3%)
- 10 (2%)

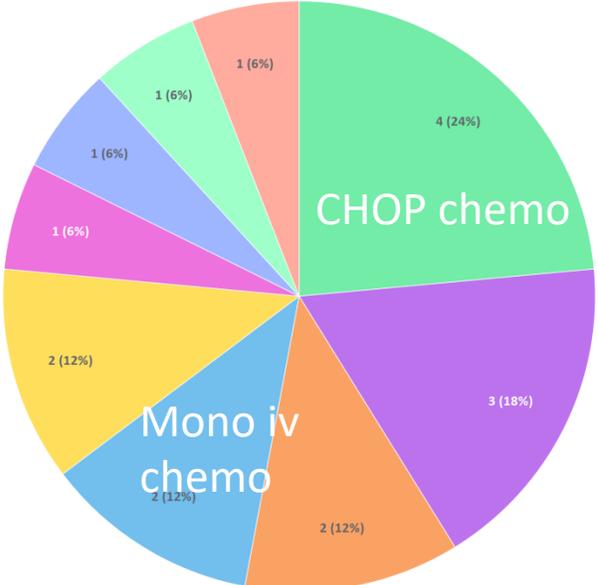# First Line Treatments Tumour Stage IIB

IIB
N=158
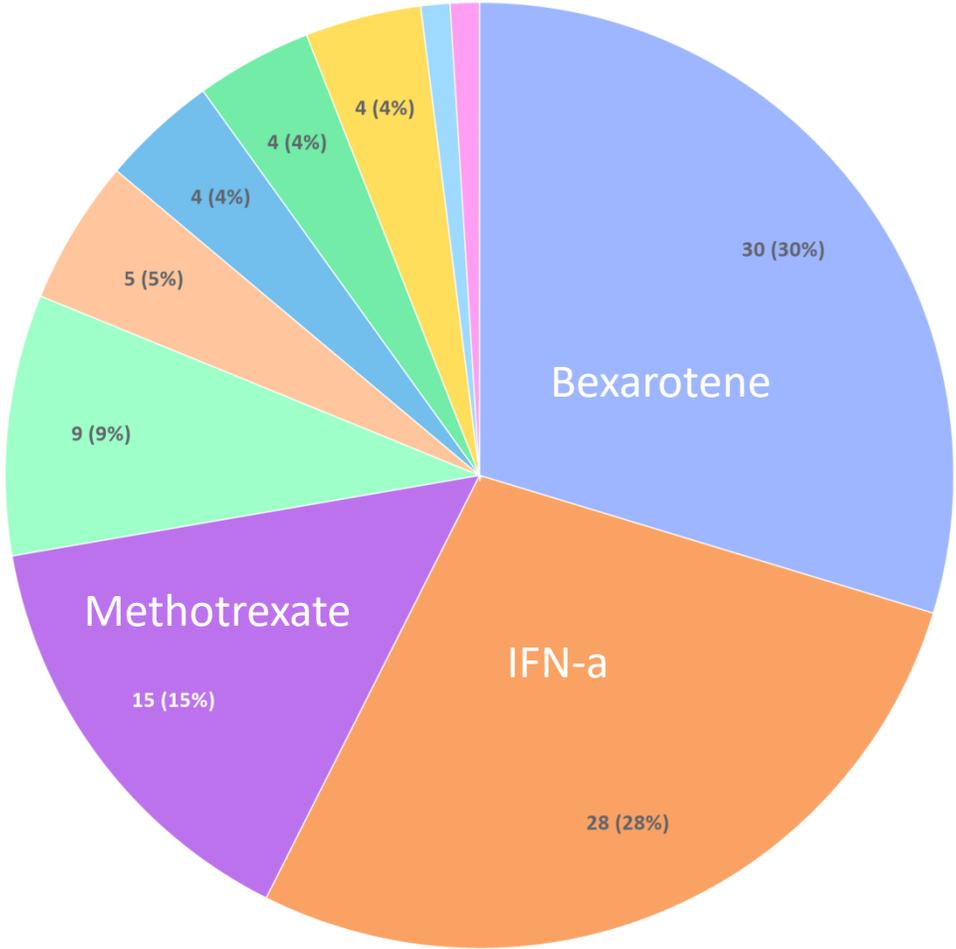
Legend:
- ECP
- Oral bexarotene
- Methotrexate
- Interferon alfa
- Oral retinoid
- Gemcitabine & Pegylated Doxorubicin
- CHOP or other combination
- Romidepsin
- Other oral chemotherapy
- Oral corticosteroids
- Brentuximab
- Mogamulizimab
- Pembrolizumab & Alemtuzumab
- Any other treatment
- Topical Nitrogen Mustard

Pie chart segments:
- Bexarotene: 30 (30%)
- IFN-a: 28 (28%)
- Methotrexate: 15 (15%)
- 9 (9%)
- 5 (5%)
- 4 (4%)
- 4 (4%)
- 4 (4%)

First Line Treatments Erythrodermic MF IIIA , IIIB & Sezary IVA1


IIIA
N=52

IIIB
N=50

IVA1
N=149

Legend:
- ECP
- Oral bexarotene
- Methotrexate
- Interferon alfa
- Oral retinoid
- Gemcitabine & Pegylated Doxorubicin
- CHOP or other combination
- Romidepsin
- Other oral chemotherapy
- Oral corticosteroids
- Brentuximab
- Mogamulizimab
- Pembrolizumab & Alemtuzumab
- Any other treatment
- Topical Nitrogen Mustard

First Line Treatments in Stage IV MF/SS

IVA2
N=47

IVB
N=1

Legend:
- ECP
- Oral bexarotene
- Methotrexate
- Interferon alfa
- Oral retinoid
- Gemcitabine & Pegylated Doxorubicin
- CHOP or other combination
- Romidepsin
- Other oral chemotherapy
- Oral corticosteroids
- Brentuximab
- Mogamulizimab
- Pembrolizumab & Alemtuzumab
- Any other treatment
- Topical Nitrogen Mustard
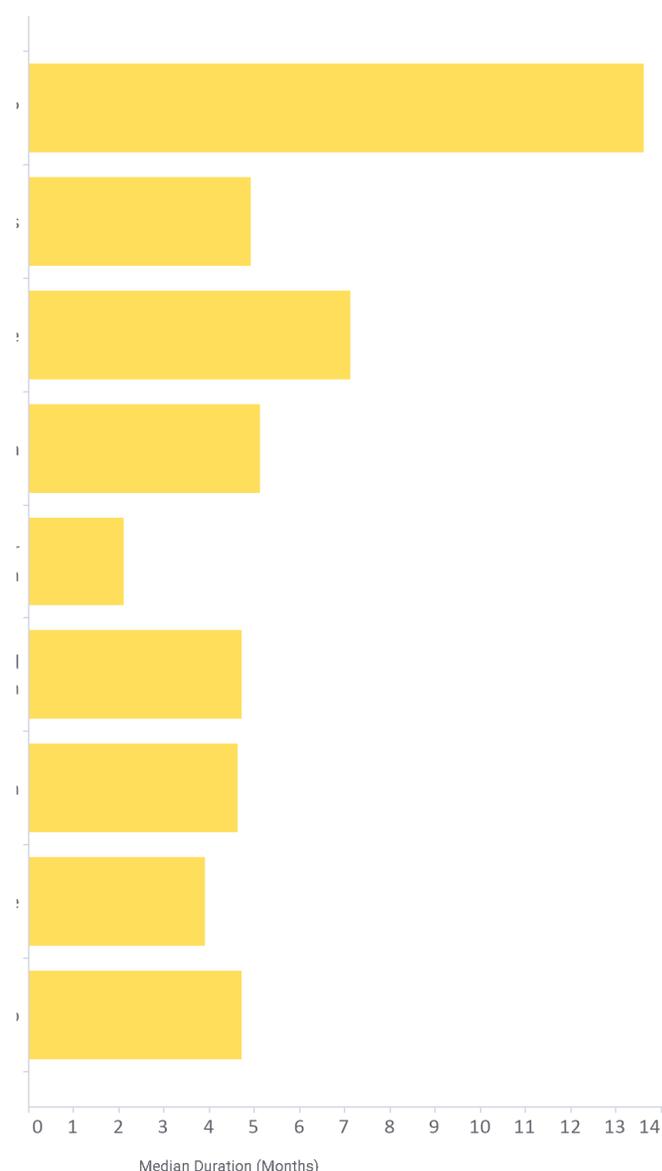
First line Treatments in Advanced Stage MF/SS IIB-IVB

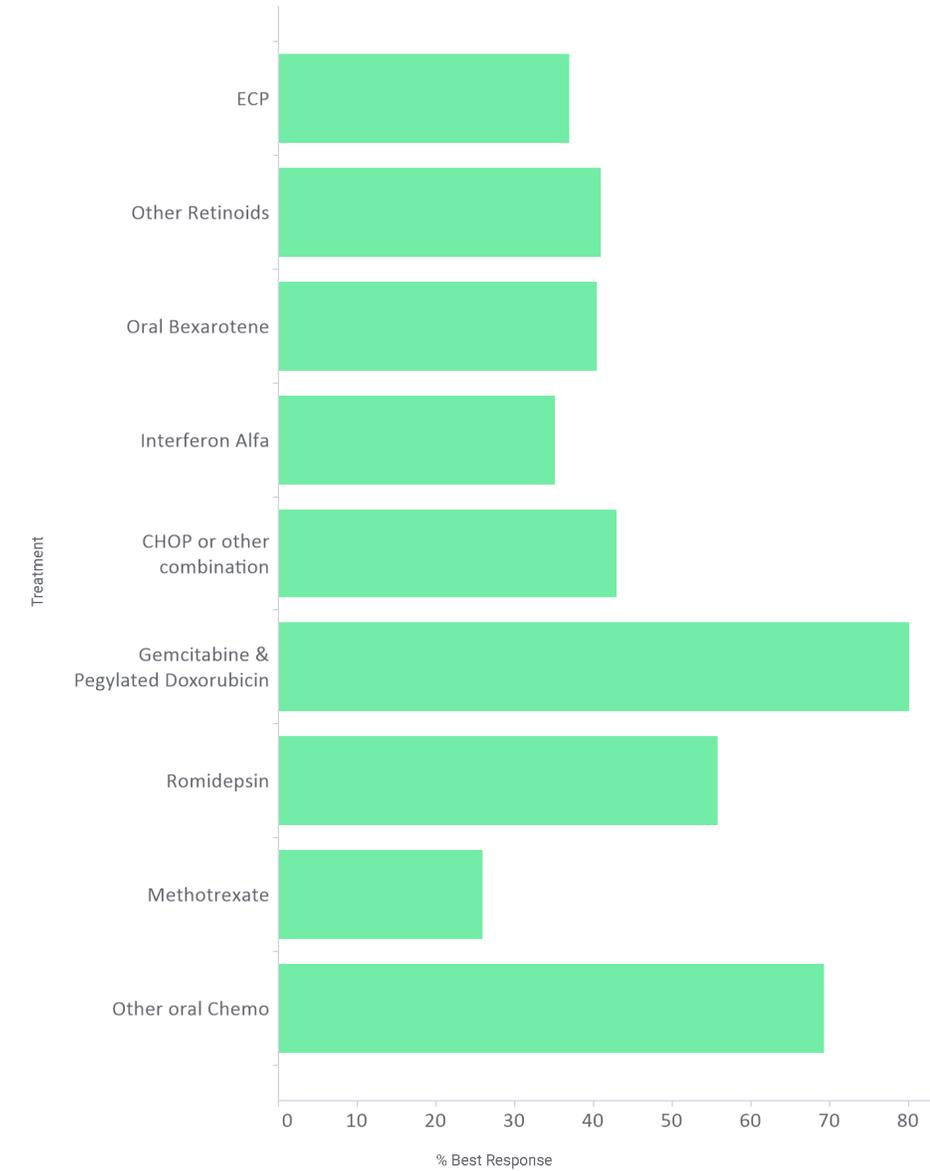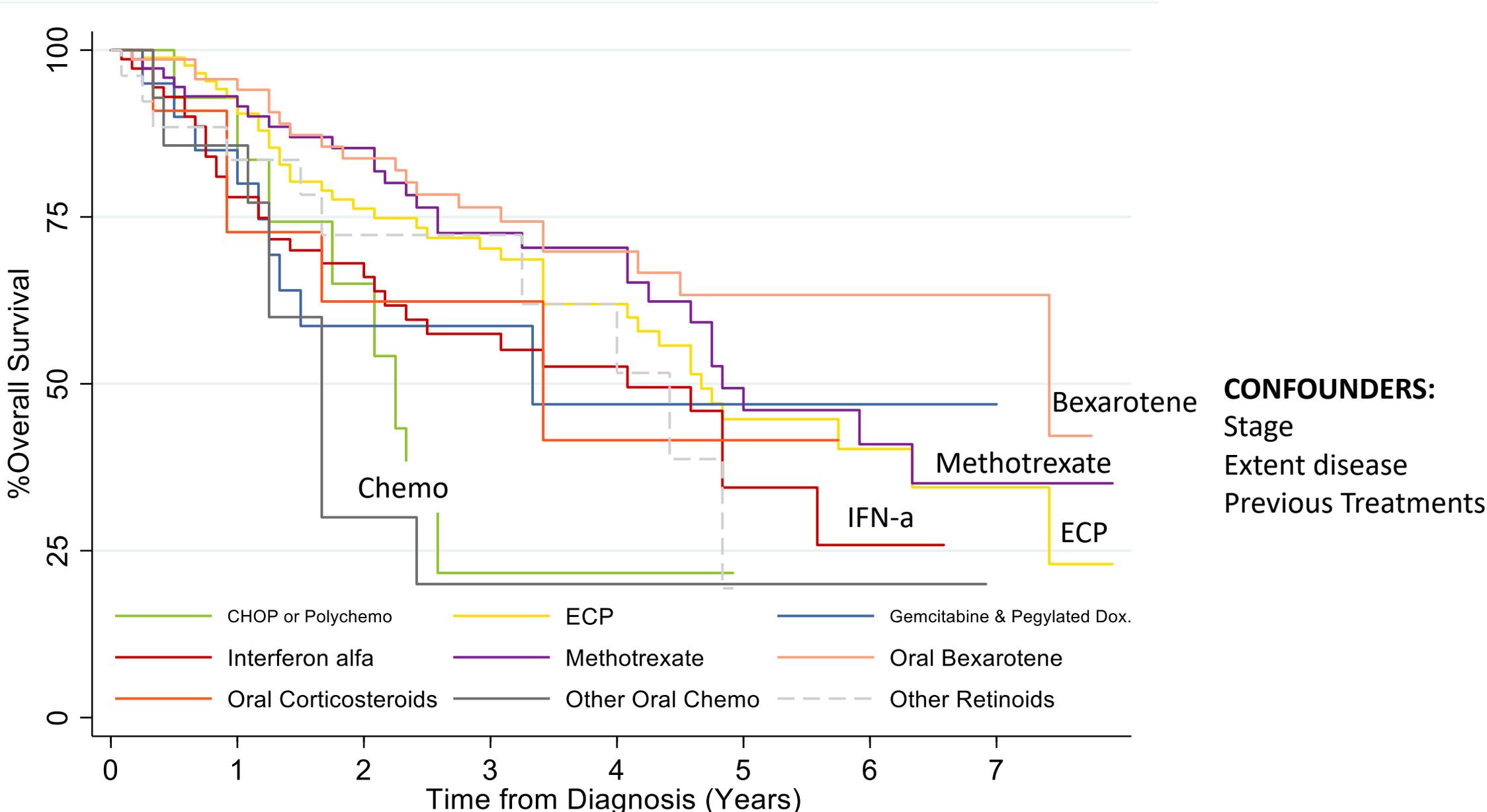|	N (%)	In Combination	Median Duration	TTNsT	Response Rate
ECP	105 (22.4%)	61 (58.1%)	13.6 (5.1-22.3)	28.7 (14.0-45.0)	25 (36.8%)
Oral Bexarotene	93 (19.8%)	57 (61.3%)	7.1 (3.8-13.5)	13.3 (6.3-45.2)	27 (40.3%)
Methotrexate	78 (16.6%)	31 (39.7%)	3.9 (2.5-8.7)	8.7 (4.0-40.1)	16 (25.8%)
Interferon Alfa	76(16.2%)	58 (76.3%)	5.1 (1.7-11.1)	12.1 (4.7-44.9)	21 (35.0%)
Other Retinoids	30 (6.4%)	17 (56.7%)	4.9 (2.6-12.5)	22.6 (5.7-NR)	9 (40.9%)
Gemcitabine & Pegylated Doxorubicin	21 (4.5%)	8 (38.0%)	4.7 (2.6-5.5)	7.3 (5.0-30.7)	16 (80.0%)
CHOP or other combination	15 (3.2%)	6 (40.0%)	2.1 (1.4-3.4)	7.5 (2.3-27.5)	6 (42.9%)
Romidepsin	10 (2.1%)	1 (10.0%)	4.6 (4.1-5.0)	6.0 (5.0-10)	5 (55.6%)
Other oral Chemo	14 (3.0%)	8 (57.1%)	4.7 (1.4-6.1)	6.6 (2.5-8.0)	9 (69.2%)
Oral Corticosteroids	12 (2.6%)	10 (83.3%)	3.0 (2.1-3.2)	NR	2 (33.3%)
Brentuximab	8 (1.7%)	3 (37.5%)	3.3 (2.1-12)	4.0 (3.5-38.0)	5 (62.5%)
Mogamulizumab	6 (1.3%)	0	4.0 (3.2-4.9)	7.4 (2.9-22.3)	4 (100%)
Pembrolizumab /or Alemtuzumab	2 (0.4%)	0	1.6	N/a	0
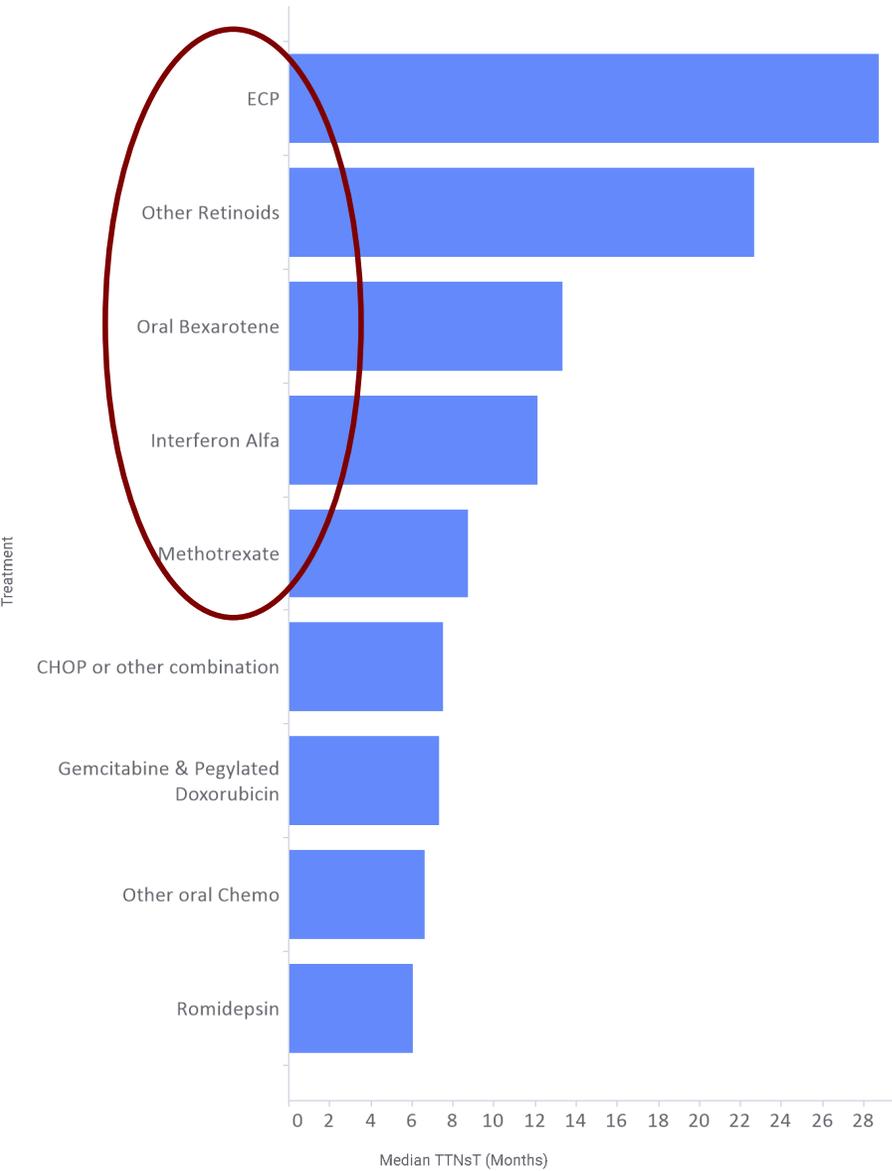
First line treatments TTNsT, median duration & % with response (PR or CR)

Overall survival – Advanced Stage MF/SS according to first line therapy

# PROCLIPI: Second line treatment options in advanced stages MF/SS

|	N (%)	In Combination	Median Duration	TTNsT	Response Rate
Oral Bexarotene	36 (12.8%)	16 (44.4%)	4 (2.0-11.3)	14.4 (4.3, NR)	6 (20.7%)
Gemcitabine or Pegylated Doxorubicin	32 (11.4%)	9 (28.3%)	2.8 (1.4-3.7)	7.0 (3.5-27.9)	8 (28.6%)
Brentuximab	24 (8.5%)	4 (16.7%)	4.3 (2.4-8.0)	55.5 (8.0, NR)	8 (36.4%)
Anti-CCR4 - Mogamulizumab	32 (11.4%)	3 (9.4%)	6.8 (2.5- 9.6)	NR	13 (76.5%)
ECP	21 (7.5%)	9 (42.9%)	7.7 (1.7-18.4)	36.6 (13.6, NR)	5 (33.3%)
Interferon Alpha	21 (7.5%)	11 (52.4%)	5.2 (1.9-13.8)	6.9 (4.3-60.6)	5 (27.8%)
Methotrexate	18 (6.4%)	6 (33.3%)	5.2 (2.3-18.7)	23.9 (11.2, NR)	5 (41.7%)
CHOP or other combination	12 (4.3%)	5 (41.7%)	3.1 (0.9- 6)	4.6 (3.2-8.3)	6 (54.6%)
Any other therapy	7 (2.4%)	2 (28.6%)	1.4 (0.8-6.2)	12.7 (1.8, NR)	4 (57.1%)
Other Retinoid	13 (4.6%)	1 (7.7%)	5.9 (2.5-9.3)	14.4 (5.2-16.8)	2 (22.2%)
Other oral chemotherapy	10 (3.6%)	5 (50.0%)	3.0(1.8-3.9)	4.2 (3.8, NR)	0.00%
Romidepsin	3 (1.1%)	0		2.7 (2.7, NR)	
Pembrolizumab &/or Alemtuzumab	5 (1.8%)	0	2.5 (2.5- 2.8)	7.7 (3.3, NR)	4 (80%)

Second line treatments TTNsT, median duration & % with response (PR or CR)
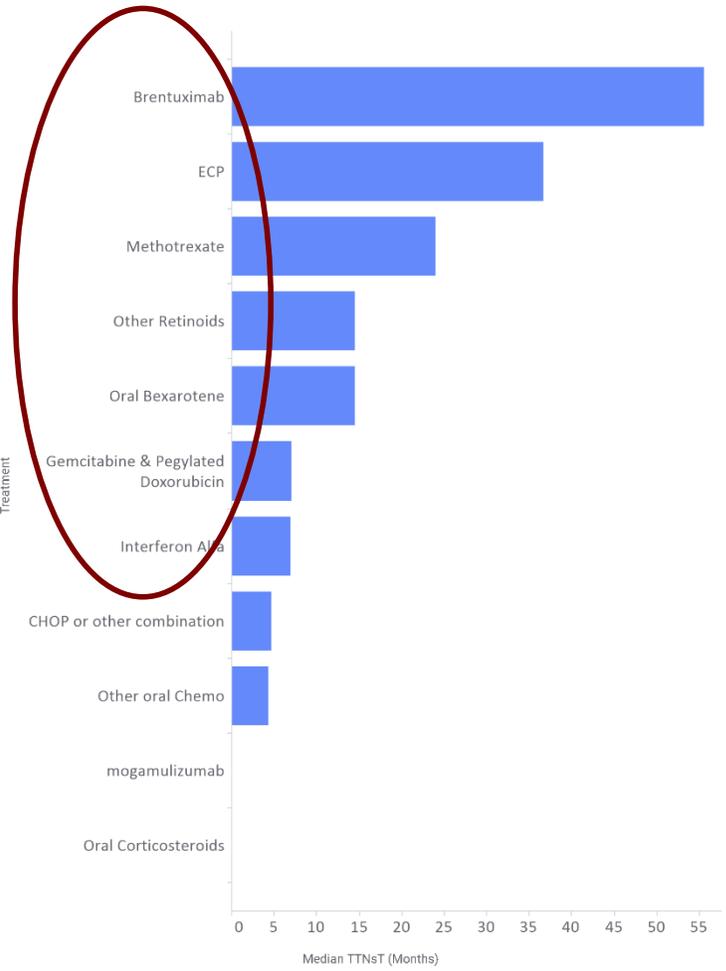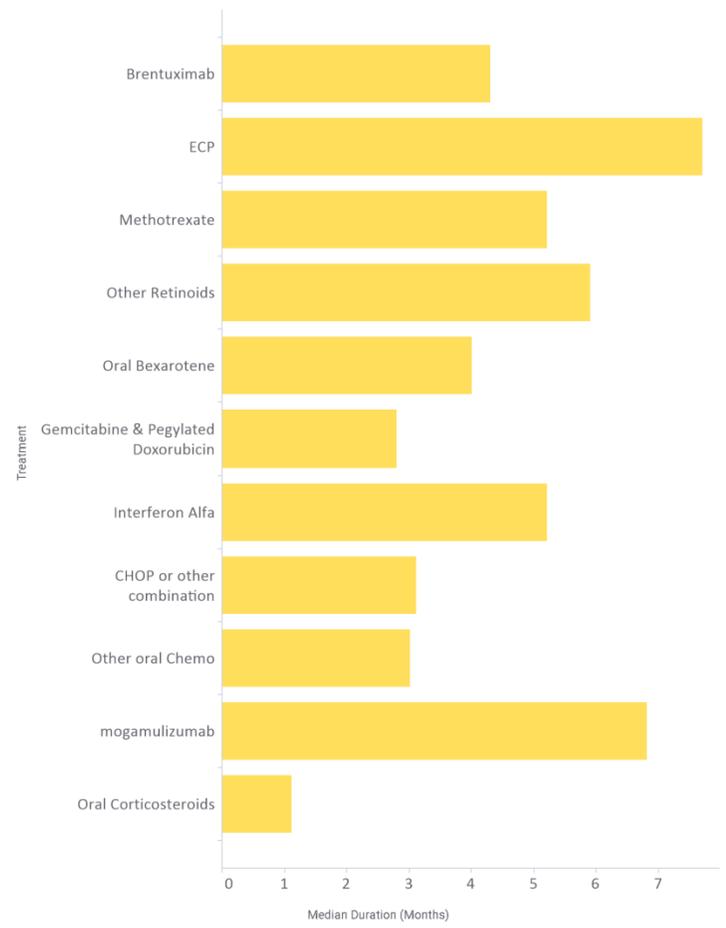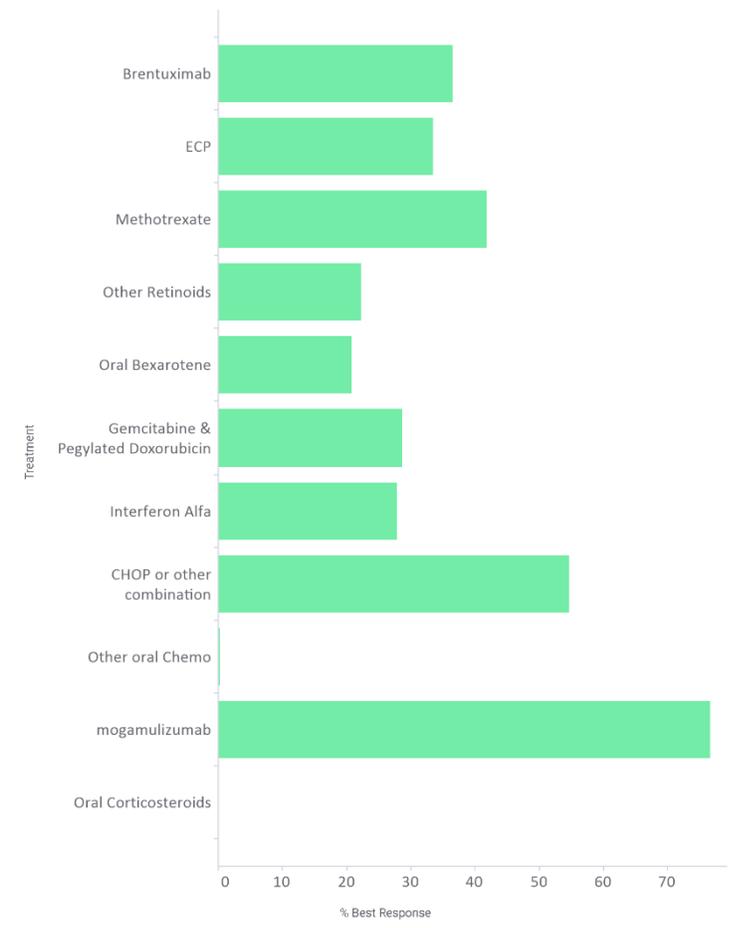
Treatment efficacy for Sézary syndrome: an international, multi-centre, comparative study of current systemic therapies using TTNT

Belinda A Campbell, Gabor Dobos, Zahra Haider, Martine Bagot, H. Miles Prince, Chris McCormack, Caroline Ram-Wolff, Maryam Miladi, Julia Scarisbrick

Acknowledgements

Results TTNT 178 Sezary patient

Median follow-up:

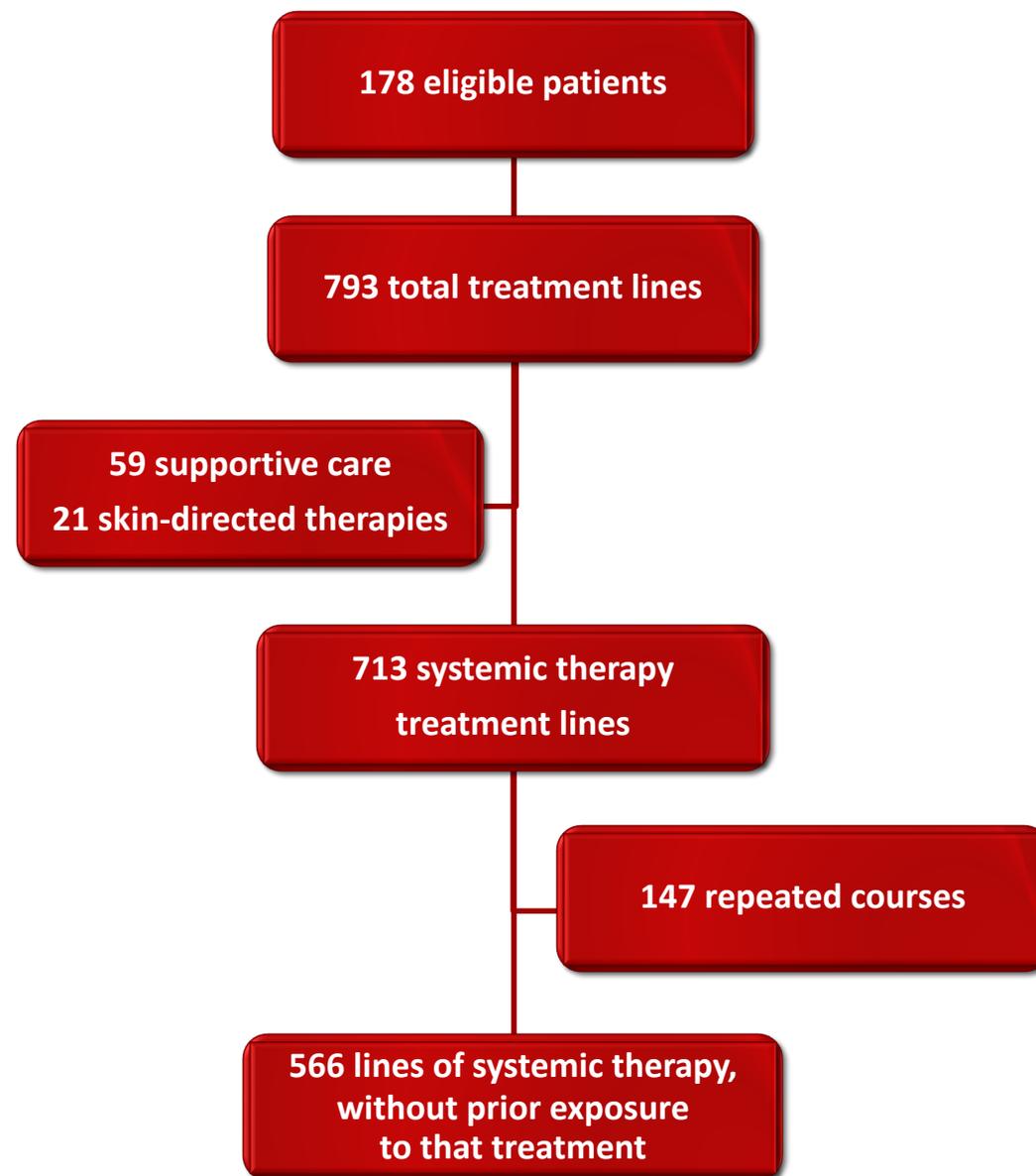36.4 (range, 0.9 – 106.6) months

57% male, median age diagnosis 66 years, 27% preceding MF

Median number treatment 4 (1-16)

Median survival 60 months

178 eligible patients

793 total treatment lines

59 supportive care
21 skin-directed therapies

713 systemic therapy treatment lines

147 repeated courses

566 lines of systemic therapy, without prior exposure to that treatment

Patterns of care: first line therapies

First line therapies	N = 178
interferon monotherapy	21 (11.8%)
methotrexate monotherapy	26 (14.6%)
monoclonal antibody monotherapy	4 (2.2%)
HDAC inhibitor monotherapy	4 (2.2%)
retinoid monotherapy	33 (18.5%)
ECP monotherapy	16 (9.0%)
single agent chemotherapy monotherapy	16 (9.0%)
multi-agent chemotherapy monotherapy	8 (4.5%)
ECP-based combination therapy	36 (20.2%)
interferon-based combination therapy	4 (2.2%)
other combination therapies	1 (0.6%)
skin directed monotherapy	4 (2.2%)
supportive care only	5 (2.8%)

Median TTNT of first line systemic therapies in Sezary syndrome: 5.7 months (95% CI: 4.7-6.6)

First line systemic therapies*	n	Median TTNT (months)	TTNT 95% CI	1 year free from next line of treatment
interferon monotherapy	21	4.8	4.1 -5.5	14.3%
methotrexate monotherapy	26	5.0	3.8 - 6.1	29.0%
monoclonal antibody monotherapy	4	2.0	1.1 - 2.9	0%
HDAC inhibitor monotherapy	4	3.6	0.0 - 8.3	25%
retinoid monotherapy	33	4.4	2.2 - 6.7	24.2%
ECP monotherapy	16	8.0	4.3 - 11.7	20.8%
single agent chemotherapy monotherapy	16	4.9	2.7 - 7.2	0%
multi-agent chemotherapy monotherapy	8	4.7	3.5 - 5.8	0%
ECP-based combination therapy	36	9.8	6.0 - 13.5	40.1%
interferon-based combination therapy	4	9.2	0.0 - 47.3	50.0%
other combination therapies	1	10.0	-	0%

*excluding skin-directed therapies, 4; supportive care only, 5

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Longer TTNT after first line combination therapies

Median TTNT: 10.0 vs 5.0 months, p=0.004

TTNT remained statistically significant after adjusting for stage

Combination systemic therapies

Systemic monotherapies

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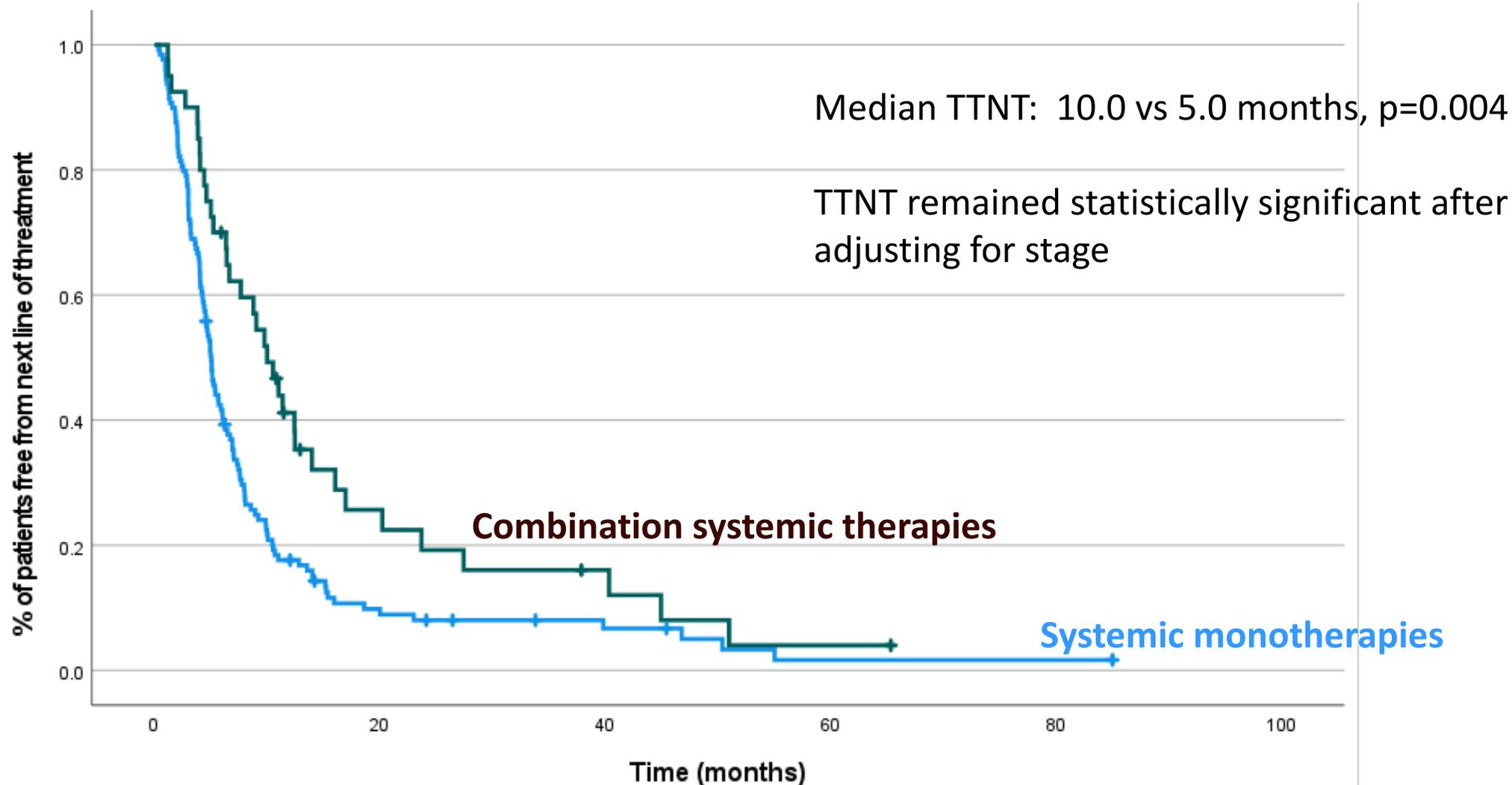
Novel Drugs in Clinical Trials for MF/SS

- Toll like receptor 7/8 agonist (resiquimod)
- Lenalidomide
- Pralatrexate (folate analog metabolic inhibitor)
- Everolimus
- Cobomarsen, dyregulates MicroRNA(MiR)-155
- Forodesine purine nucleoside phosphorylase inhibitor (PNP
- Resminostat – HDAC-I maintenance

- Zanolimumab (HuMax-CD4)
- Duvelisib (phoinositide 3-kinase-I)
- Enzastaurin (protein kinase C-I)
- Pembrolizumab, Nivolumab, Ipilimumab, lambrolizumab (PD-1 antagonist)
- PD-1L antagonist, ateloizumab

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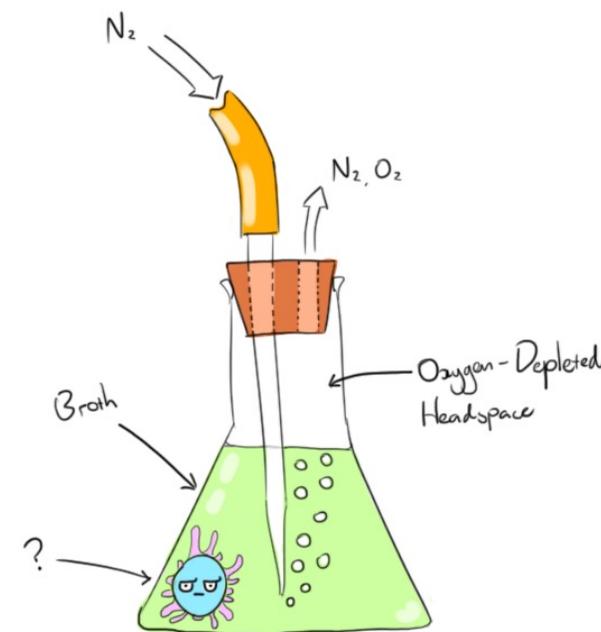
Screening Patients for Effective Clinical Trial Entry *'SPECTA'*
a collaborative platform knowledge development
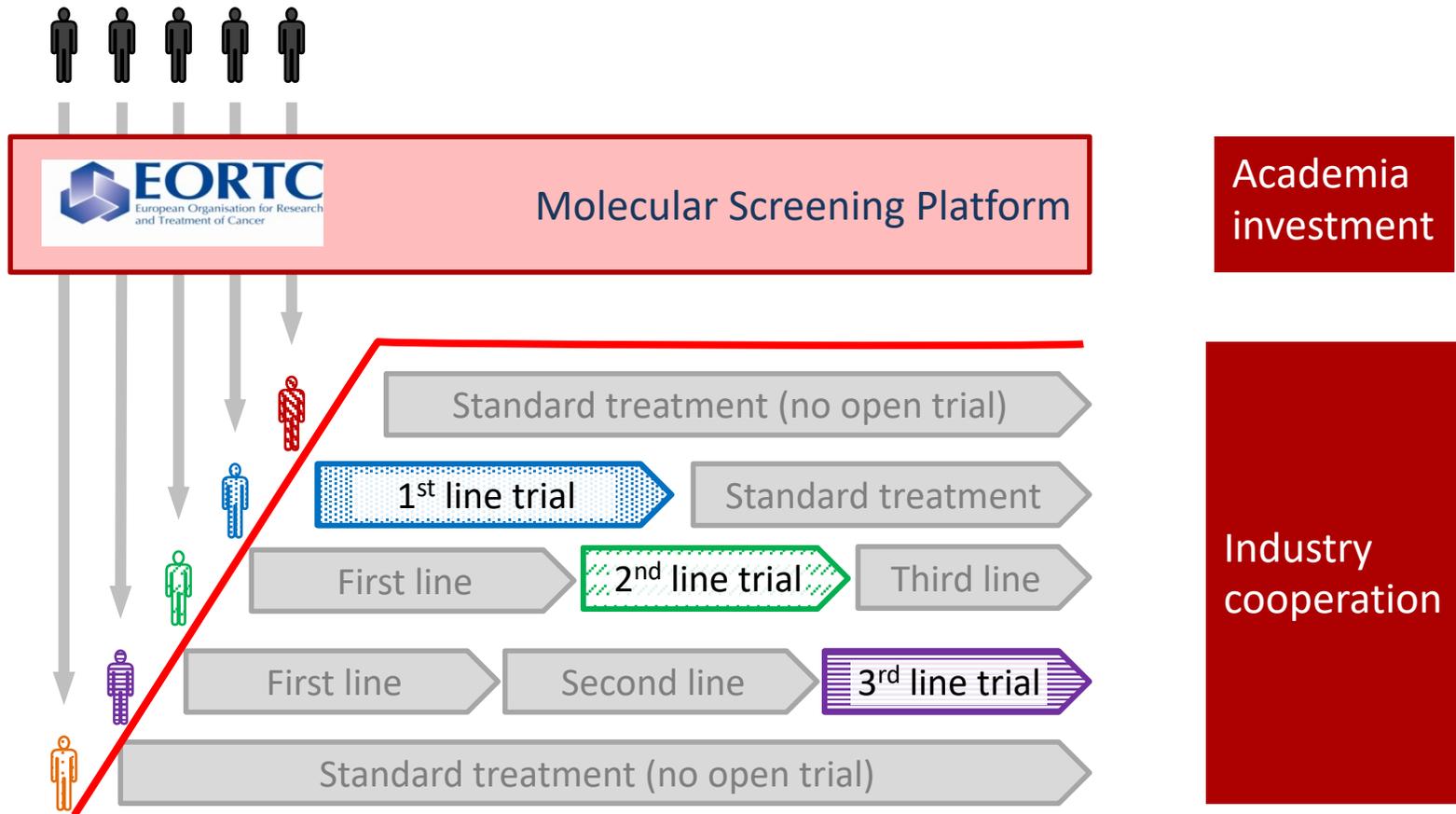
A prospective and longitudinal clinically annotated biobank
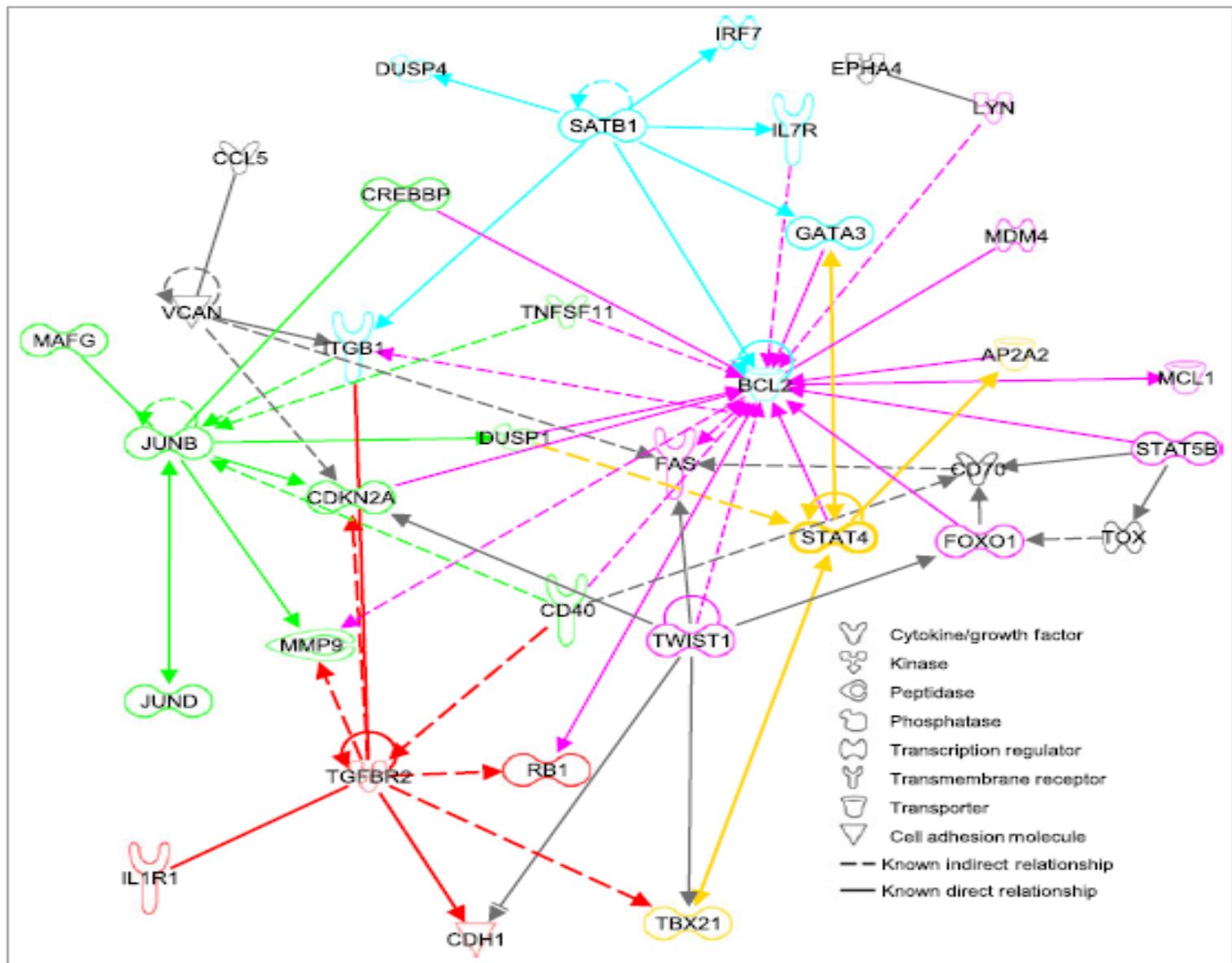
Fig 1. Known relationships between dysregulated genes. Ingenuity Pathway Analysis was conducted to determine the relationships between dysregulated genes in cutaneous T-cell lymphoma. Five genes, SATB1 (blue), BCl2 (magenta), JUNB (green), TGFBR2 (red) and STAT4 (yellow), and their connections are highlighted. Reprinted with permission of Ingenuity® Systems, www.ingenuity.com.

Dulmage & Geskin. Lessons learned from gene expression profiling of CTCL. Br J Derm. 2013;169:1188–97. Pittsburgh, US

Gene Content in the TruSight Tumor 170 Assay

SNVs and Indels (from DNA)

AKT1	BRIP1	CREBBP	FANCI	FGFR2	JAK3	MSH3	PALB2	RAD51B	TET2
AKT2	BTK	CSF1R	FANCL	FGFR3	KDR	MSH6	PAX3	RAD51C	TMPRSS2
AKT3	CARD11	CTNNB1	FBXW7	FGFR4	KIT	MTOR	PAX7	RAD51D	TP53
ALK	CCND1	DDR2	FGF1	FLT1	KMT2A (MLL)	MUTYH	PDGFRA	RAD54L	TSC1
APC	CCND2	DNMT3A	FGF2	FLT3	KRAS	MYC	PDGFRB	RB1	TSC2
AR	CCNE1	EGFR	FGF3	FOXL2	MAP2K1	MYCL1	PIK3CA	RET	VHL
ARID1A	CD79A	EP300	FGF4	GEN1	MAP2K2	MYCN	PIK3CB	RICTOR	XRCC2
ATM	CD79B	ERBB2	FGF5	GNA11	MCL1	MYD88	PIK3CD	ROS1	
ATR	CDH1	ERBB3	FGF6	GNAQ	MDM2	NBN	PIK3CG	RPS6KB1	
BAP1	CDK12	ERBB4	FGF7	GNAS	MDM4	NF1	PIK3R1	SLX4	
BARD1	CDK4	ERCC1	FGF8	HNF1A	MET	NOTCH1	PMS2	SMAD4	
BCL2	CDK6	ERCC2	FGF9	HRAS	MLH1	NOTCH2	PPP2R2A	SMARCB1	
BCL6	CDKN2A	ERG	FGF10	IDH1	MLLT3	NOTCH3	PTCH1	SMO	
BRAF	CEBPA	ESR1	FGF14	IDH2	MPL	NPM1	PTEN	SRC	
BRCA1	CHEK1	EZH2	FGF23	INPP4B	MRE11A	NRAS	PTPN11	STK11	
BRCA2	CHEK2	FAM175A	FGFR1	JAK2	MSH2	NRG1	RAD51	TERT	

Amplifications (from DNA)

AKT2	BRCA2	CHEK1	ERCC2	FGF5	FGF14	FGFR4	MDM4	NRG1	RAF1
ALK	CCND1	CHEK2	ESR1	FGF6	FGF19	JAK2	MET	PDGFRA	RET
AR	CCND3	EGFR	FGF1	FGF7	FGF23	KIT	MYC	PDGFRB	RICTOR
ATM	CCNE1	ERBB2	FGF2	FGF8	FGFR1	KRAS	MYCL1	PIK3CA	RPS6KB1
BRAF	CDK4	ERBB3	FGF3	FGF9	FGFR2	LAMP1	MYCN	PIK3CB	TFRC
BRCA1	CDK6	ERCC1	FGF4	FGF10	FGFR3	MDM2	NRAS	PTEN	

Fusions and Splice Variants (from RNA)

ABL1	BRAF	EML4	ETV4	FGFR4	KIF5B	MYC	NTRK2	PIK3CA	TMPRSS2
AKT3	BRCA1	ERBB2	ETV5	FLI1	KIT	NOTCH1	NTRK3	PPARG	
ALK	BRCA2	ERG	EWSR1	FLT1	KMT2A (MLL)	NOTCH2	PAX3	RAF1	
AR	CDK4	ESR1	FGFR1	FLT3	MET	NOTCH3	PAX7	RET	
AXL	CSF1R	ETS1	FGFR2	JAK2	MLLT3	NRG1	PDGFRA	ROS1	
BCL2	EGFR	ETV1	FGFR3	KDR	MSH2	NTRK1	PDGFRB	RPS6KB1	

Assumption : Therapies targeting individual tumour biology improve outcomes

Conclusions – Real world treatment data

- In Real world data ECP is the most commonly used first line treatment, followed by bexarotene, IFN-a and methotrexate

- Wide range of treatment selections for advanced patients with >15 different 1st line Tx options and no clear pathway

- First line combination therapies may result in longer TTNT

- Second line therapies frequently include one of the newer drugs available (mogamulizumab & brentuximab)

- TTNT provides a measure of duration of clinical therapeutic efficacy

- Overall, median TTNT of first line systemic treatments is short, measuring < 6 months.

- There remains a high need for exploration of newer treatments & therapeutic drug combinations, plus investigation into the optimal treatment sequencing for advanced MF/SS

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Principles of Management of Advanced Stage MF/SS

1. Improve symptoms and QoL

2. Delay progression

3. Aim for allo HSCT in first remission of suitable patients

Longer survival in IIB-IIIB disease allows treatments to be less aggressive

Survival in patients with IVA2 disease is short & if eligible allo HSCT should not be delayed

Consider immunotherapies before chemotherapy