

NACASY Newsletter nº 26

“Open label, multinational, multicentre, prospective, real world observational study of Naloxegol for patients with cancer pain diagnosed with Opioid Induced Constipation (OIC)”

October 2020

Sponsor

KYOWA KIRIN International plc

Co-ordinating Investigators

Dr Andrew Davies

Dr Jan Tack

Principal Objective

The objective of this study is to assess the **safety and efficacy of Naloxegol** in a real world setting in cancer patients.

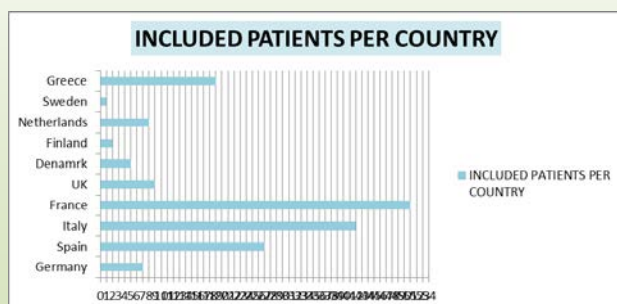
In order to meet the objective, we need to **emphasize the importance** of :

- Including patients who complete the 4 weeks treatment.
- Including patients who be able to complete the Patient's diary and required scales.
- Use Naloxegol according to SmPC, attending to its contraindications.

□



- Recruitment objective: 315 patients
- Number of patients: 170 patients
- Screening Failure: 13 patients
- End of recruitment: **January 31st**



Closure visits were requested and they will take place considering the sites availability.

Please, indicate dates as soon as possible to plan the visits.

Database will be closed on October 31st.

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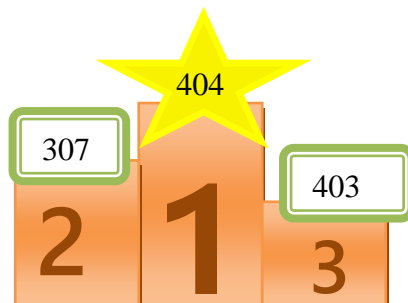
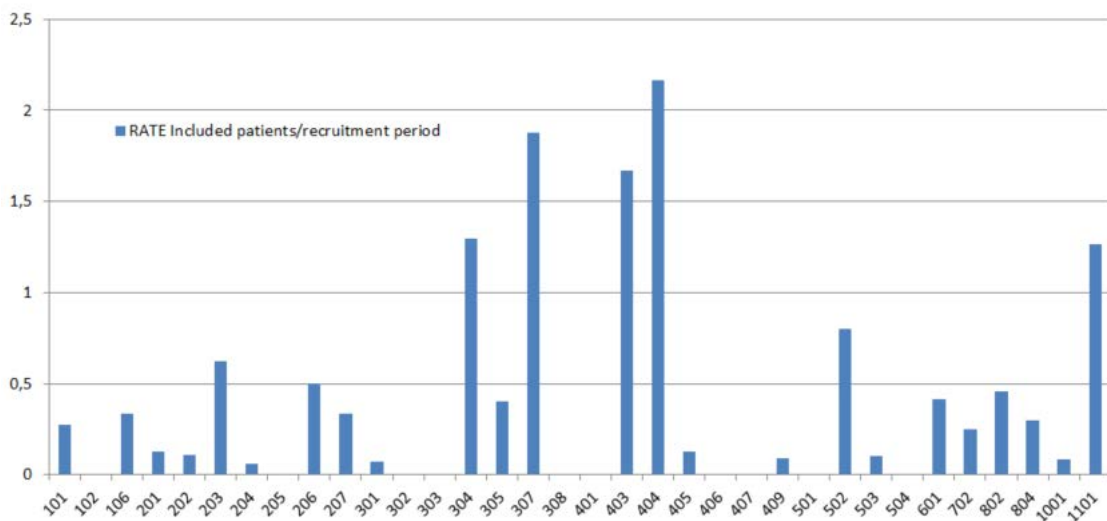
Recruitment per Country

	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dic-19	Jan-20	Feb-20	Mar-20	Abr-20	May-20	Jun-20	Jul-20	
Germany Actual Cumulative	0	0	1	2	4	8	9	14	17	22	24	24	24	26	28	29	29	27	27	27	27	27	27	27	27	27
Spain Actual Cumulative	0	2	2	2	5	8	11	12	12	18	20	22	23	24	25	24	26	24	24	42	38	38	38	38	38	38
Italy Actual Cumulative	-	-	-	-	-	-	3	7	11	17	25	31	33	36	37	43	41	44	51	53	53	53	53	53	53	53
UK Actual Cumulative	-	-	-	-	-	-	-	-	2	2	2	2	3	3	6	7	7	7	9	9	9	9	9	9	9	9
Denmark Actual Cumulative	-	-	-	-	-	-	-	-	1	3	4	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Finland Actual Cumulative	-	-	-	-	-	-	-	-	-	0	0	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Netherlands Actual Cumulative	-	-	-	-	-	-	-	-	-	2	3	5	7	8	8	8	9	9	9	9	9	9	9	9	9	9
Sweden Actual Cumulative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Greece Actual Cumulative	1	37	72	108	142	176	212	249	286	316	346	376	406	436	466	496	526	556	586	616	646	676	706	736	766	796
Target Cumulative	-	-	-	3	13	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19
Total Actual Cumulative	0	2	3	7	23	35	42	52	81	86	100	111	117	126	134	146	146	146	150	171	183	183	170	170	170	170



RECRUITMENT RATE PER SITE

RATE Included patients/recruitment period



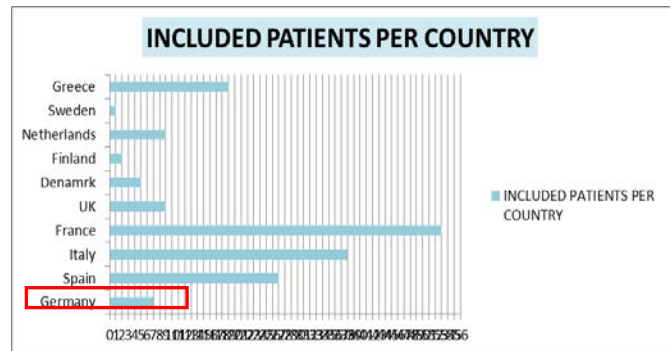
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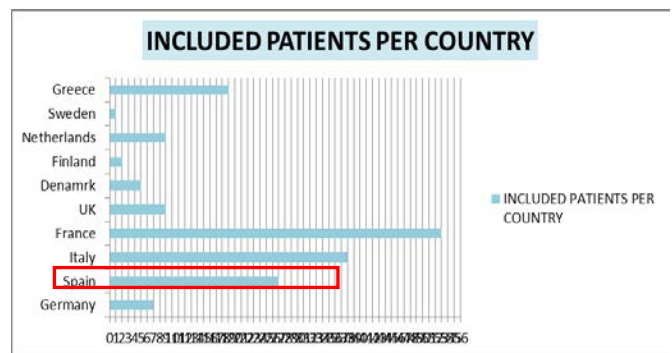
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RECRUITMENT PER SITE AND COUNTRY

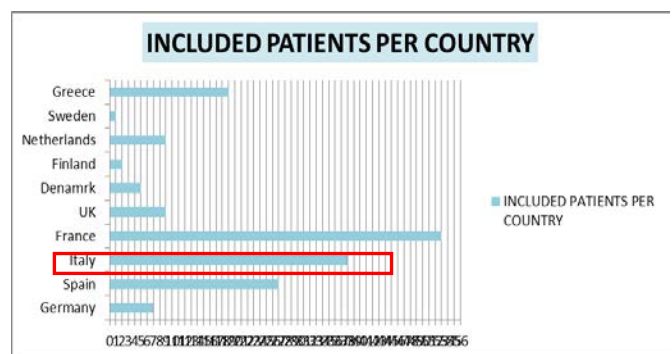
GERMANY		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
101	18/02/2019	3
102	21/01/2019	0
106	22/01/2019	4



SPAIN		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
201	06/09/2018	2
202	18/07/2018	2
203	12/09/2018	10
204	23/08/2018	1
205	19/07/2018	0
206	29/11/2018	7
207	04/10/2018	5



ITALY		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
301	20/11/2019	1
302	26/02/2019	0
303	07/02/2019	0
304	09/08/2018	22
305	06/03/2019	4
307	13/05/2019	11
308	29/08/2019	0

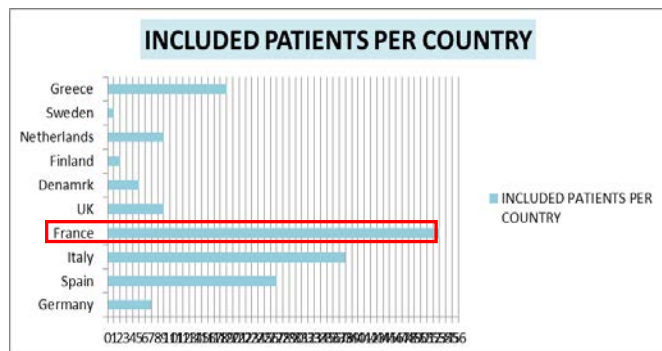


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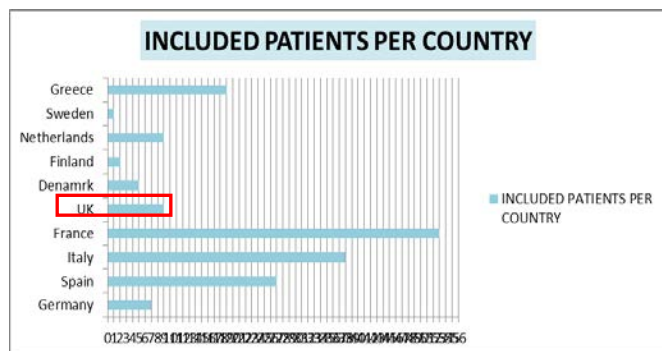
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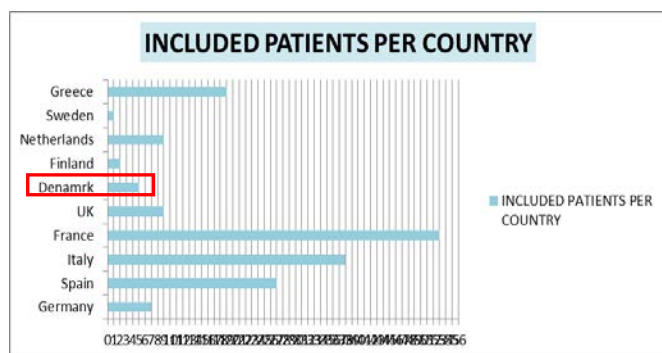
FRANCE		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
401	02/10/2019	2
403	10/01/2019	20
404	14/01/2019	26
405	29/05/2019	1
406	06/02/2019	0
407	09/10/2019	3
409	05/02/2019	1



UK		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
501	07/05/2019	0
502	28/03/2019	8
503	26/03/2019	1
504	18/03/2019	0



DENMARK		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
601	23/01/2019	5

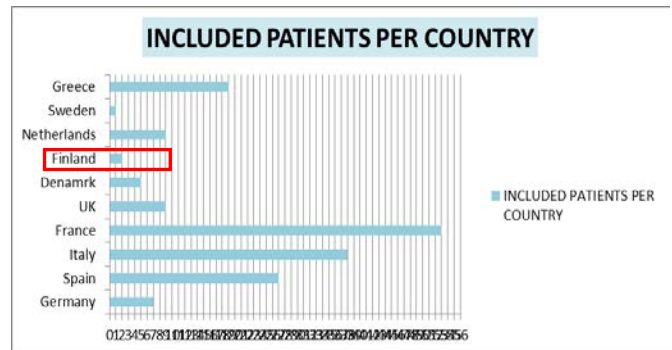


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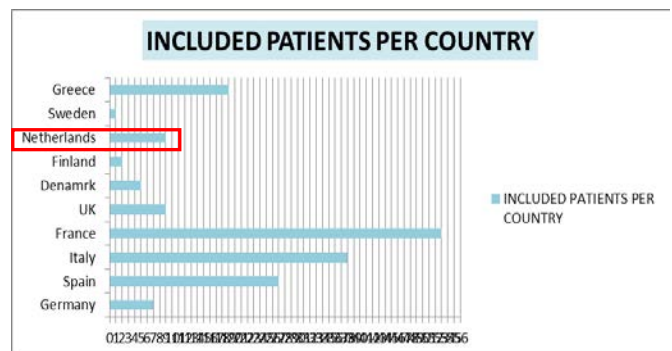
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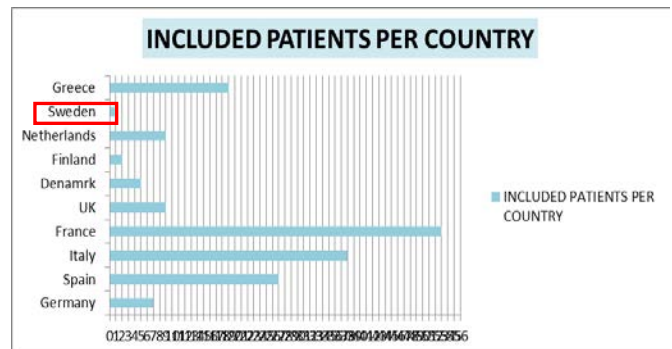
FINLAND		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
702	14/05/2019	2



NETHERLANDS		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
802	25/02/2019	5
804	07/03/2019	4



SWEDEN		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
1001	15/01/2019	1

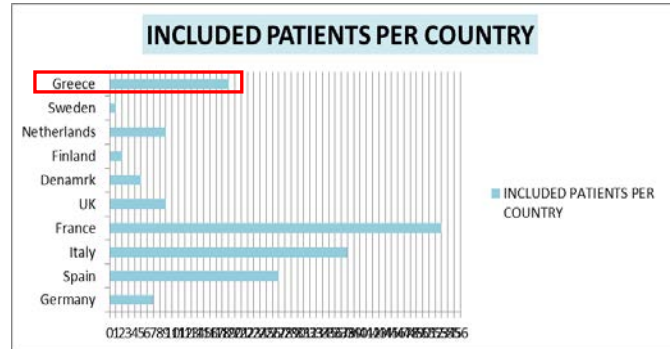


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GREECE		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
1101	09/10/2018	19



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August 2019

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