

NACASY Newsletter n° 22

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

June 2020

Sponsor

KYOWA KIRIN International plc

Co-ordinating Investigators

Dr Andrew Davies

Dr Jan Tack

Principal Objective

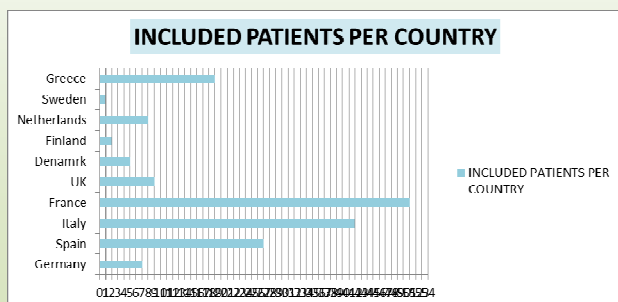
The objective of this study is to assess the **safety and efficacy of Naloxegol** in a real world setting in cancer patients.

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**



We would appreciate your collaboration **updating the eCRD information for all included patients during following days.**

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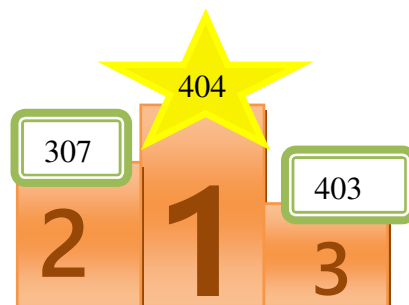
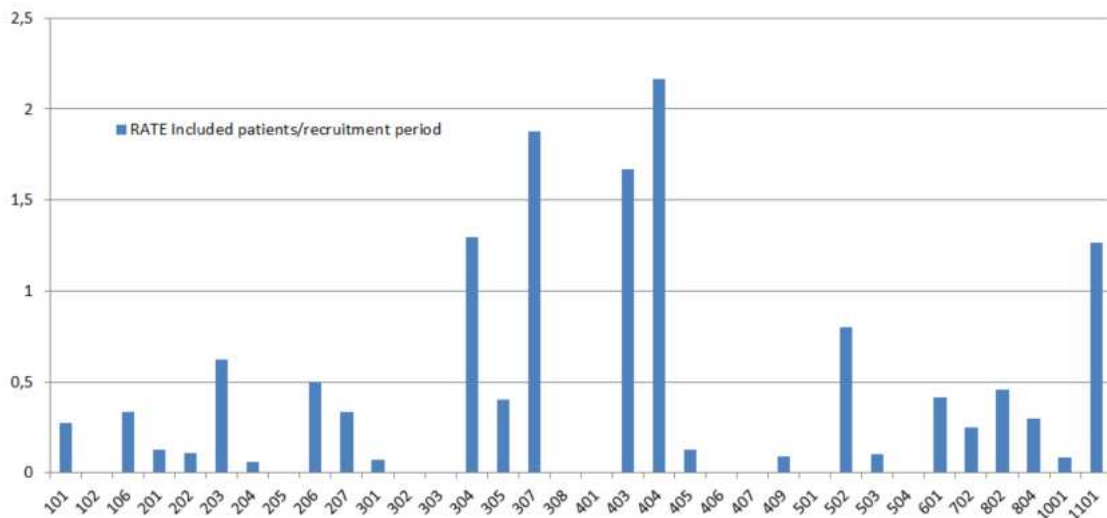
Recruitment per Country

	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	Ago-19	Sep-19	Oct-19	Nov-19	Dic-19	Jan-20	Feb-20	Mar-20	Abr-20	May-20	Jun-20	
Germany Actual Cumulative	-	-	-	-	-	-	-	-	1	2	2	2	2	5	5	7	7	7	7	7	7	7	7	7	7
Spain Actual Cumulative	0	0	1	2	4	8	9	14	17	22	24	24	24	24	26	29	29	27	27	27	27	27	27	27	27
Italy Actual Cumulative	0	2	2	2	6	8	11	12	12	18	20	22	22	23	25	24	26	30	42	38	38	38	38	38	38
France Actual Cumulative	-	-	-	-	-	-	3	7	11	17	25	31	33	36	37	43	41	44	51	53	53	53	53	53	53
UK Actual Cumulative	-	-	-	-	-	-	-	-	2	2	2	3	3	3	6	7	7	7	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
Finland Actual Cumulative	-	-	-	-	-	-	-	-	-	0	0	1	2	2	2	2	2	2	2	2	2	2	2	2	2
Netherlands Actual Cumulative	-	-	-	-	-	-	-	-	-	2	3	5	7	8	8	9	9	8	8	8	8	8	9	9	9
Sweden Actual Cumulative	-	-	-	-	-	-	-	-	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Greece Actual Cumulative	-	-	-	3	13	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19
Target Cumulative	1	37	72	106	142	176	212	247	279	315	315	315	315	315	315	315	315	315	315	315	315	315	315	315	315
Total Actual Cumulative	0	2	3	7	23	35	42	52	81	86	100	111	117	126	134	146	146	150	171	169	169	170	170	170	170



RECRUITMENT RATE PER SITE

RATE Included patients/recruitment period



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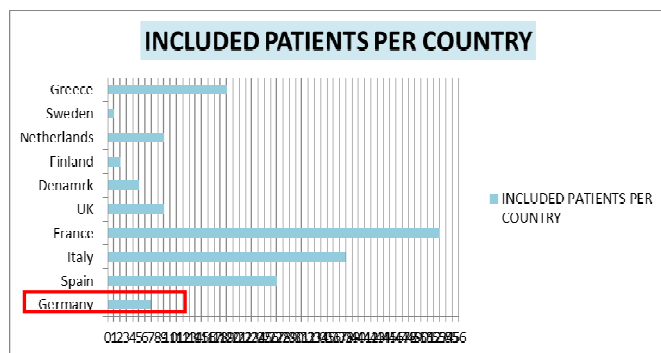
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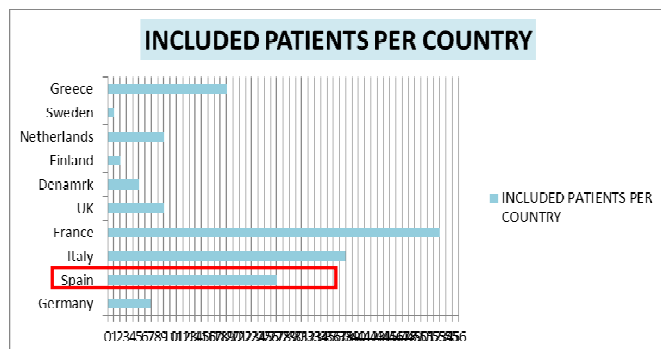
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RECRUITMENT PER SITE AND COUNTRY

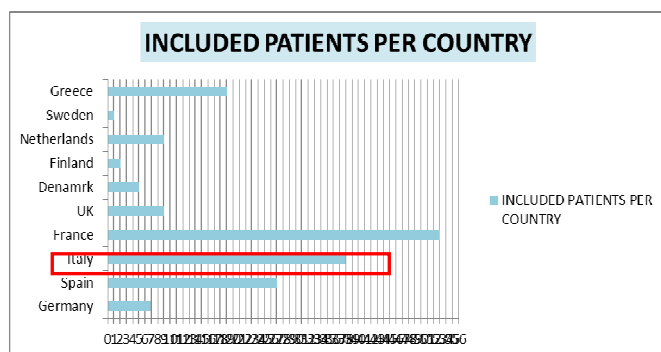
GERMANY		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
101	18/02/2019	3
102	21/01/2019	0
106	22/01/2019	4



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

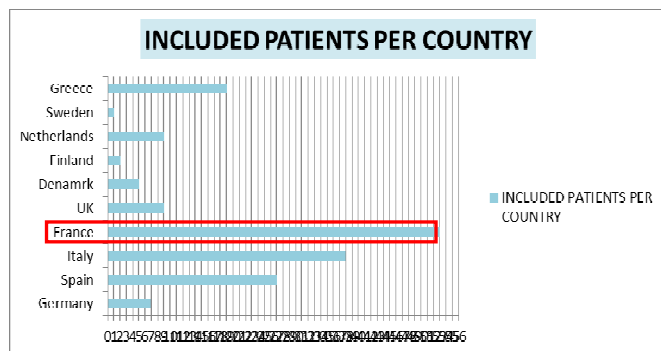


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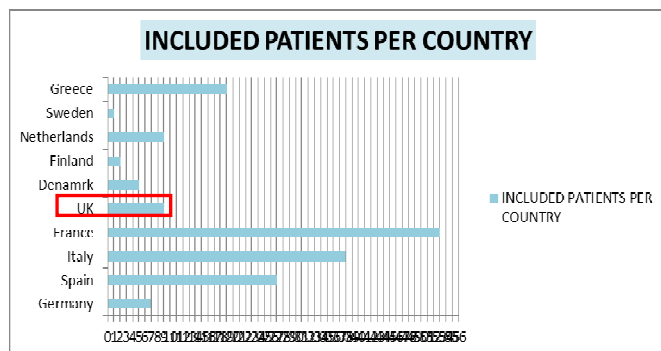
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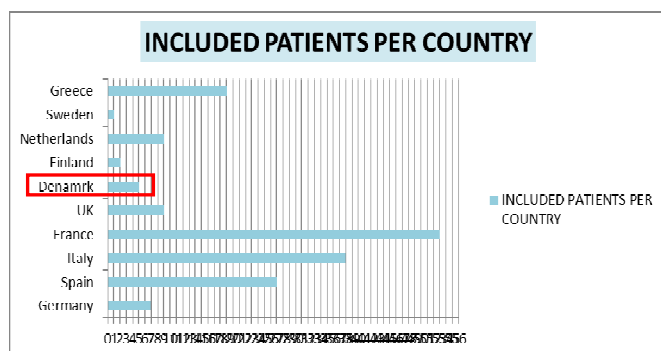
FRANCE		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
401	02/10/2019	2
403	10/01/2019	20
404	14/01/2019	26
405	29/05/2019	1
406	06/02/2019	0
407	09/10/2019	3
409	05/02/2019	1



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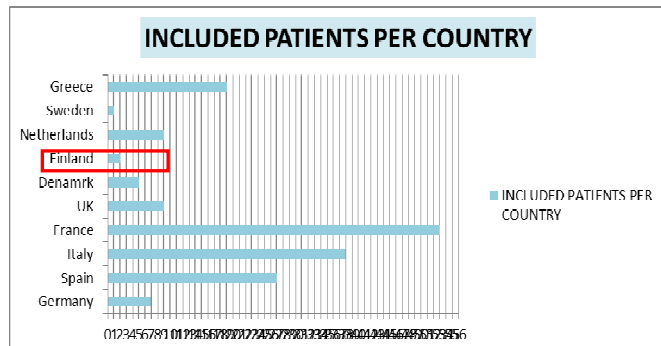
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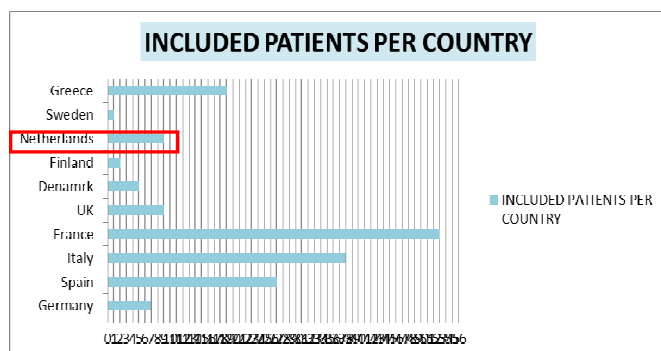
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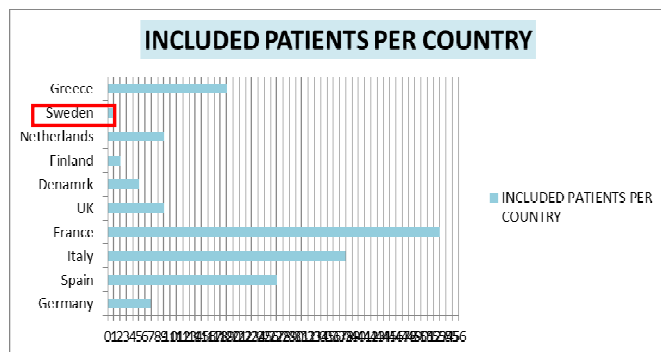
FINLAND		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
702	14/05/2019	2



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

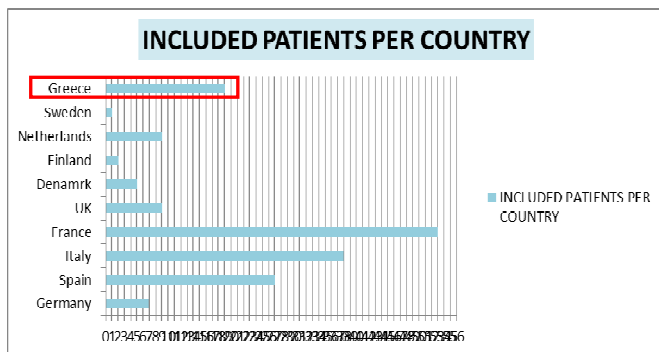


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GREECE		
SITE	SITE INITIATION VISIT	NUMBER OF PATIENT
1101	09/10/2018	19



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