

**A Retrospective Study to Examine the Efficacy
and Safety of Obinutuzumab + Chlorambucil
and Obinutuzumab Monotherapy in the Frontline
Treatment of CLL Patients-Outside Clinical Trials**

by

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A Retrospective Study to Examine the Efficacy and Safety of Obinutuzumab+Chlorambucil and Obinutuzumab Monotherapy in the Frontline Treatment of CLL Patients-Outside Clinical Trials

Primary objective:

1. PFS

Secondary objectives:

1. ORR and CRR (according to physician's assessment)
2. OS
3. Time To Next Treatment
4. PFS2
2. Relative Dose Intensity (RDI) and dose reductions
3. Safety in terms of Grade 3/4 adverse effects

ERIC in collaboration with the Israeli CLL Study Group

Total patients: 460
(Excluded: 28)

Medical centers: 51
represent 40 cities,
located in 13 different countries:

- Belgium (6 patients)
- Canada (3)
- Croatia (57)
- Czech Republic (36)
- Greece (9)
- Hungary (8)
- Israel (198)
- Italy (41)
- The Netherlands (1)
- Poland (30)
- Romania (35)
- Spain (30)
- Switzerland (3)



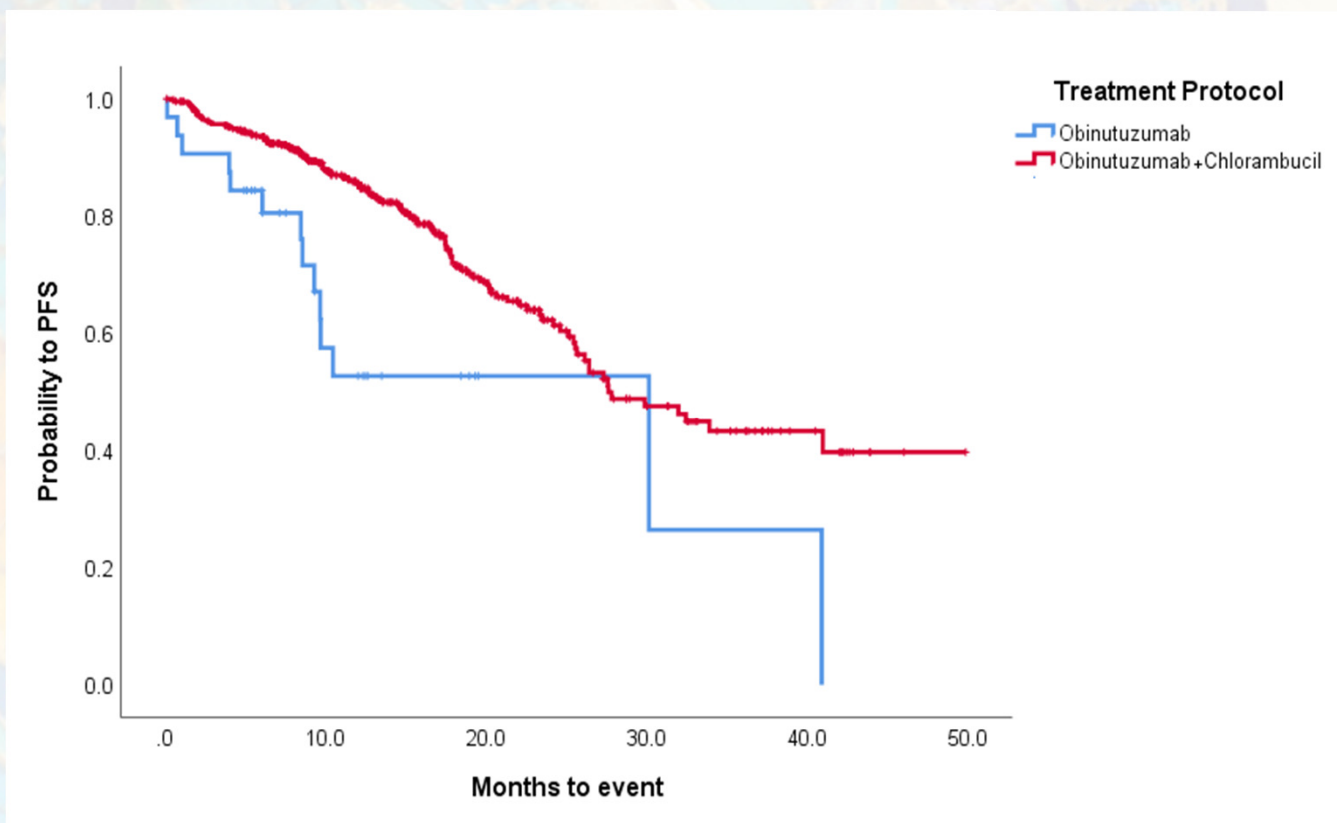
Patient characteristics



European research initiative on CLL

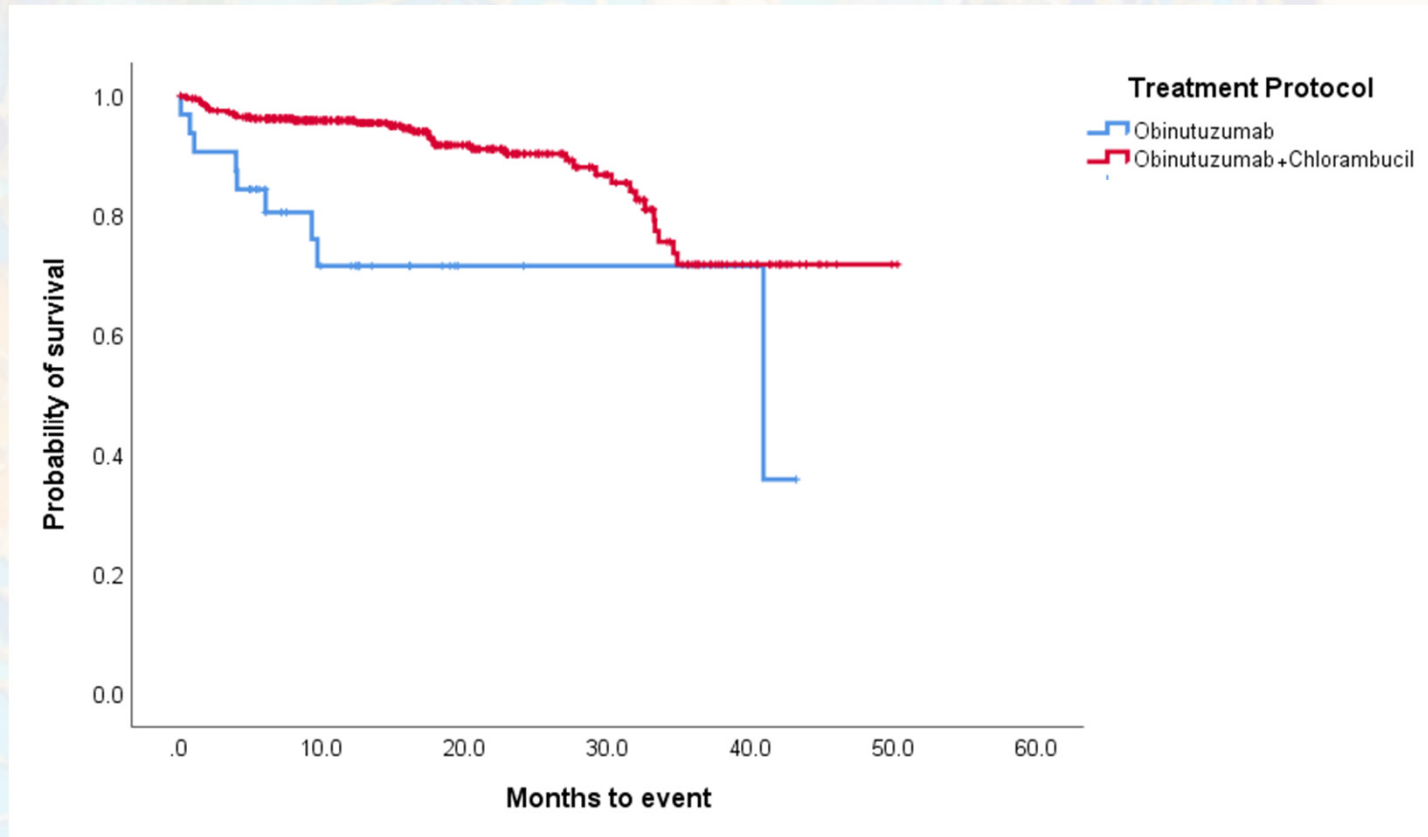
<i>Age at diagnosis</i>		
median [IQR]	72	[77.0 ,67.0]
mean (sd)	71.7	7.9
	<i>N</i>	<i>%</i>
<i>Male sex (N, %)</i>	271	58.9
<i>Binet (available = 454)</i>		
A	78	17.2
B	175	38.6
C	201	44.3
<i>Total CIRS Score >=6 (available = 282)</i>	284	62.6
<i>Calculated creatinine clearance (available = 384)</i>		
<70mL/min	139	36.2
<i>FISH Doher Hierarchical (available = 333)</i>		
Normal	114	34.2
del13q	92	27.6
Trisomy 12	46	13.8
del11q	62	18.6
del17p	19	5.7
<i>IGHV mutational status (available = 125)</i>		
Mutated	44	35.2
Unmutated	81	64.8
<i>TP53 mutational status (available = 186)</i>		
Mutated	9	4.8
Unmutated	177	95.2

Progression free survival



	Treatment protocol		Breslow's Test - overall comparison	
	Obinutuzumab	Obinutuzumab+Chlorambucil	c ² (df)	P
Median (months)	30.1 [5.2, 55.0]	27.6 [22.6, 32.6]	13.2 (1)	<0.001

Overall survival



	Treatment protocol		Log-Rank Test - overall comparison	
	Obinutuzumab	Obinutuzumab+Chlorambucil	c ² (df)	P
Median (months)	40.9 [0.0, 84.8]	NR	17.3 (1)	<0.001

**THANK YOU VERY MUCH
FOR YOUR ATTENTION**

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