

A Multicenter, Staged-Design, Open-Label, Pilot Study to Assess the Activity and Safety of Extracorporeal Photopheresis (ECP) in Patients With Relapsed or Refractory Peripheral T-cell Lymphoma (PTCL) With a Circulating Clone

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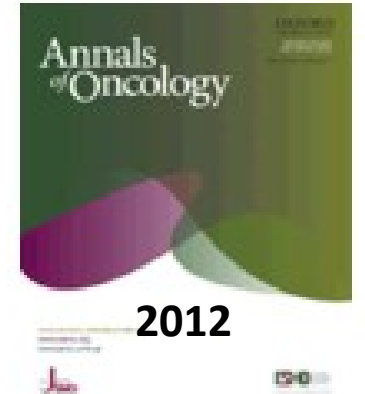
Cytapheresis advisor

CONGRÈS SOCIÉTÉ FRANÇAISE D'HÉMAPHÉRÈSE

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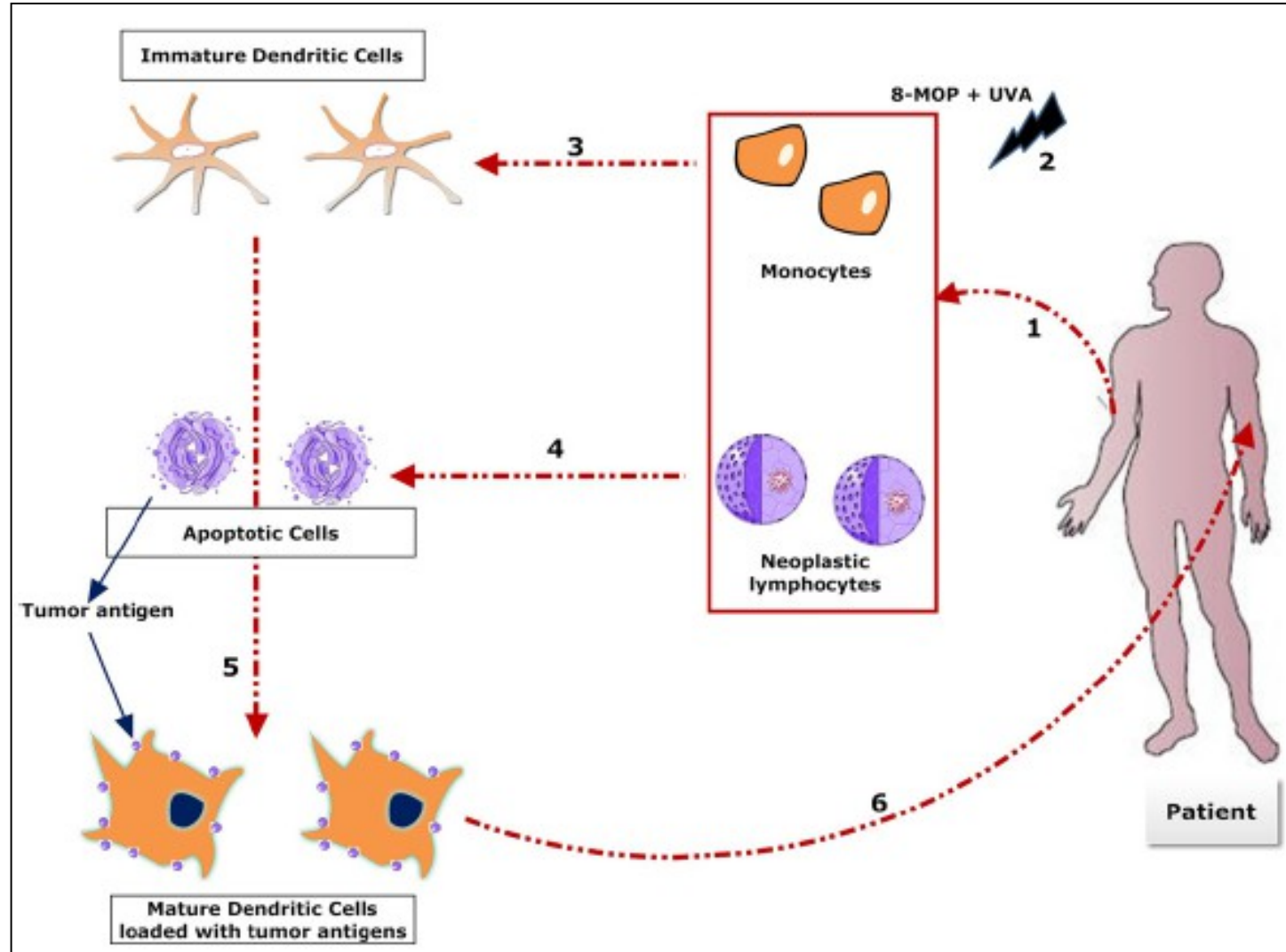
PROOF OF CONCEPT



Extracorporeal photopheresis as a curative treatment strategy in non epidermotropic T-cell lymphoma and large granular lymphocyte leukemia

F. Garban¹, S. Carras¹, P. Drillat², M. C. Jacob^{3,4}, B. Fabre⁵, M. Callanan^{4,6}, S. Courby¹, C. Makowski², J. Y. Cahn^{1,7} & R. Gressin^{1,4*}

SUSPECTED MECHANISMS OF ACTION

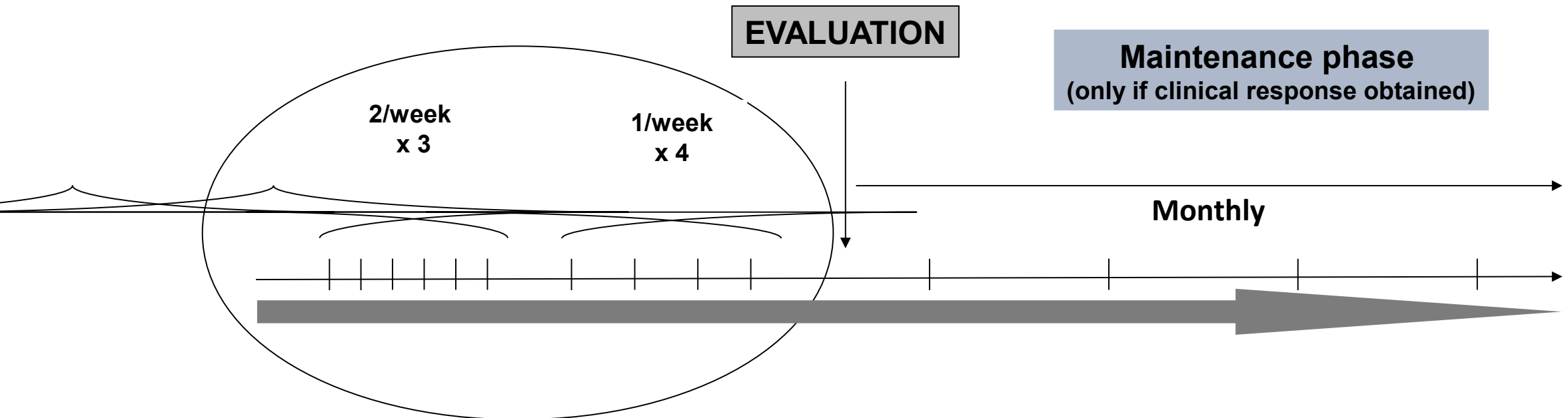


PUBLISHED SCHEDULE

Between 1997 and 2005:

12 relapsing or refractory patients with circulating clone have been treated
ECP :

- Vilbert Lourmat scheme (Spectra® cell separator (Cobe, USA))
- 8 MOP
- UVA Irradiation : 2J/cm²
- Product reinfusion < 3 hours



POPULATION / RESULTS

Characteristics at ECP D1				Previous treatment lines			ECP treatment			
UPN	Age	WHO	Organ	N	Delay	Type	N Courses	Response	Treatment Duration	
NHL	1	41	AITL	LN BM	2	1	Chemo	2	Prog	0,5
	2	42	AITL	LN BM skin	1	1	Chemo	6	NR	1
	3	53	PTCLnos	LN Ton	1	1	Chemo	31	PR (19 m)	21
	4	39	PTCLnos	LN BM Spl liv	1	1	Sply, chemo	29	CR (98 m - rel)	20
	5	47	PTCLnos	LN BM Liv	5	1	Chemo	12	CR (150 m - no rel)	2
	6	53	PTCLnos	LN BM skin	2	1	Chemo, cort	25	PR (7 m)	10
	7	37	LB T	LN BM	4	1	Chemo	4	Prog	0,5
	8	42	T LGL	Blood only	1	1	Cort, Gamma	10	NR	3
LGL	9	58	T LGL	BM LN	2	10	Cort, Danazol	34	CR (136 m - no rel)	33
	10	41	T LGL	BM Spl	1	7	Cort, MTX	10	NR	3
	11	82	T LGL	BM	1	1	Cort, Gamma	10	NR	3
	12	63	ATC LGL	BM Liv Int Spl	1	1	Sply, cort	44	CR (45 m - rel)	44

Ongoing prospective trial :

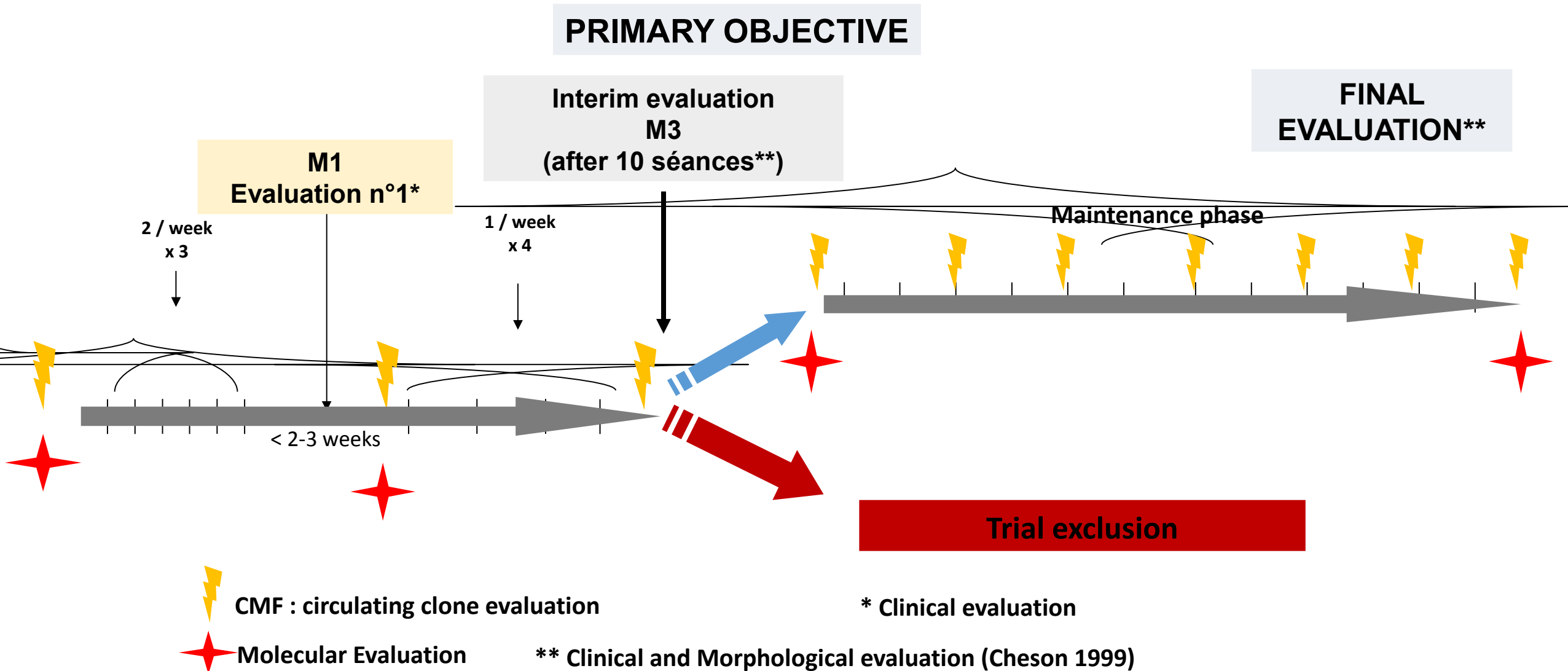
Inclusion criteria:

- **Relapsing non épidermotropic LMNH T**
 - AITL & PTCL nos
 - post ASCT (≥ 6 mois)
- **With quantifiable circulating clone in Flow cytometry :**
 - Centralization in Grenoble
- **ECOG 0 à 2**
- Proliferation rate : doubling time > 3 weeks
- No bulky disease (> 7 cm)
- \pm B Symptoms

OBJECTIVES

- **Primary objective:**
 - **Overall Response Rate after 10 ECP courses**
- **Secondary objectives:**
 - CR rate
 - Clone disappearance rate (CMF & molecular biology)
 - Survival analysis:
 - **OS, PFS, DFS,**
 - response duration

Treatment schedule (PTCL NOS and AILT)



STATISTICAL ANALYSIS PLAN

- **3 steps plan (phase II trial)**
 - 2 interim futility analysis
- Inefficacy if ORR $\leq 15\%$
- Efficacy if ORR is $\geq 35\%$
- α risk = 0.05 et β risk= 80%

	condition	PTCLnos	AITT
Stage 1		9	9
Stage 2	1 response	+ 9	stop
Stage 3	> 3 responses	+ 10	
total	> 7 responses	28	

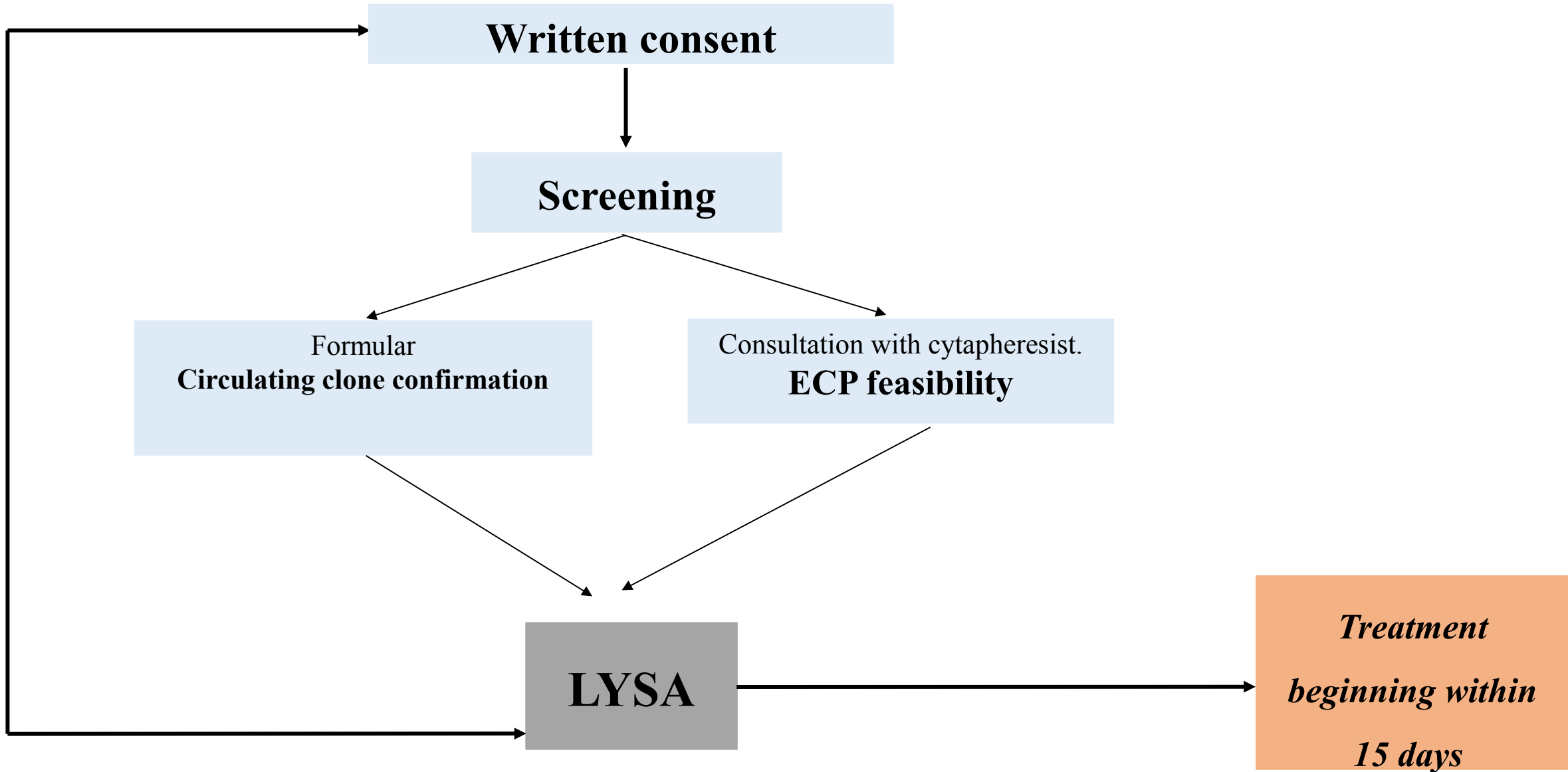
ECP PROCEDURES

- **THERAKOS ECP SEPARATOR :**
 - Cellex separator
- **Venous access :** decision by the local cytopheresist
 - Peripheral access recommended
 - Central catheter only when necessary
- **Anticoagulation :** still in discussion
 - CE approbation: HNF
 - Citrate : routinely used

PARTICIPATING CENTER



INCLUSION PROCESS





Hematology Unit

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Pr JY Cahn

Pr F Garban

Pr S Park

Dr L Molina

Dr S Courby

Dr B Pegourié

Thank you for your attention



ECP Team

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LYSA/LYSARC consortium

