Phase 2b AML Study
Topline Data
December 11, 2017

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Development pipeline founded on the ERYCAPS platform

Mode of action	Product Candidate/ PROGRAM	Drug substance	Indication	Discovery	Pre-clinical	Phase 1	Phase 2	Phase 2b	Phase 3/ Pivotal	Application for Regulatory Approval	Commercial Rights
Cancer metabolism **Tumor starvation**	eryaspase (GRASPA®(1))	Asparaginase	Pancreatic Cancer								erytech
			ALL								RECORDATI Europe; TEVA Israel (2)
			AML								erytech US & RoW
			Other solid tumors								
	ery-methionase	Methionine-γ-lyase	Solid tumors								
	eryminase	Arginine deiminase	Solid tumors								erytech
Enzyme therapies	ERYZYME	Therapeutic enzymes	Metabolic diseases								
Immuno-therapy	ERYMMUNE	Tumor antigens	TBD								

Arrow indicates most advanced study within an indication or program; more detail is provided in subsequent slides

(1) Brand name for eryaspase in Europe and Israel
(2) Initially in ALL only

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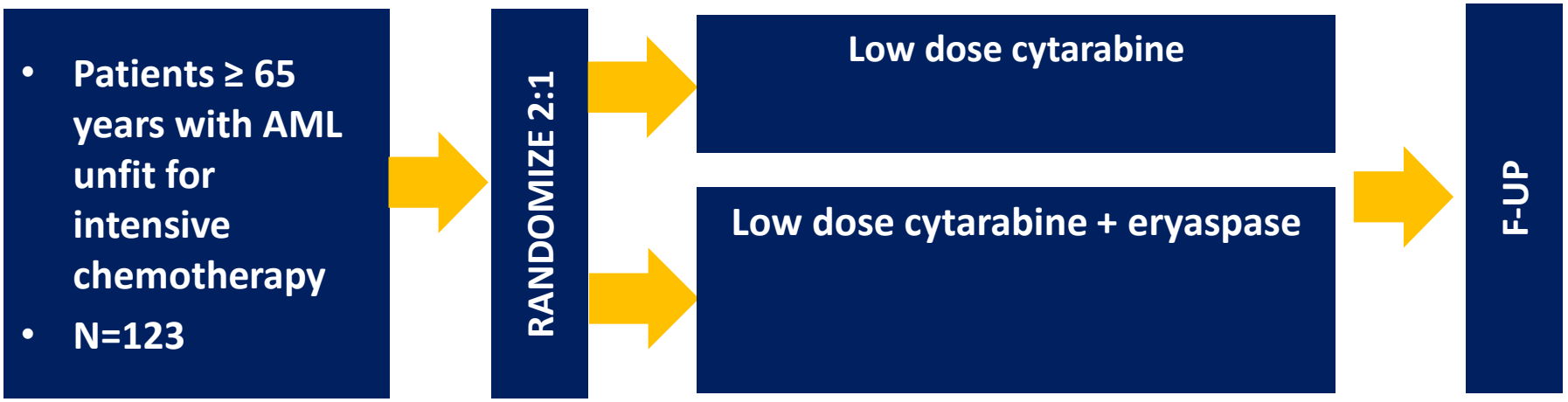
Acute myeloid leukemia (AML) and eryaspase

- Approximately 40,000 new cases of AML are diagnosed in Europe and the United States annually
- AML is a particularly aggressive cancer with a five-year survival rate around 27%; less than 10% in patients over the age of 65
- AML affects mainly older individuals; median age at diagnosis is ~67 years
- L-asparaginases are well established in acute lymphoblastic leukemia (ALL), but the toxicity profile has limited use in AML and solid tumors
- With eryaspase, the L-asparaginase is encapsulated inside donor-derived red blood cells. Its lower toxicity profile is believed to hold the potential to provide L-asparaginase to patients that are unable to tolerate non-encapsulated products, including fragile AML patients

AML Phase 2b study design



- 30 clinical centers in Europe
- Primary Endpoint: overall survival (OS)
- Key Secondary Endpoints: response rate, progression free survival, duration of response, quality of life, number of hospitalizations, safety, PK-PD and immunogenicity

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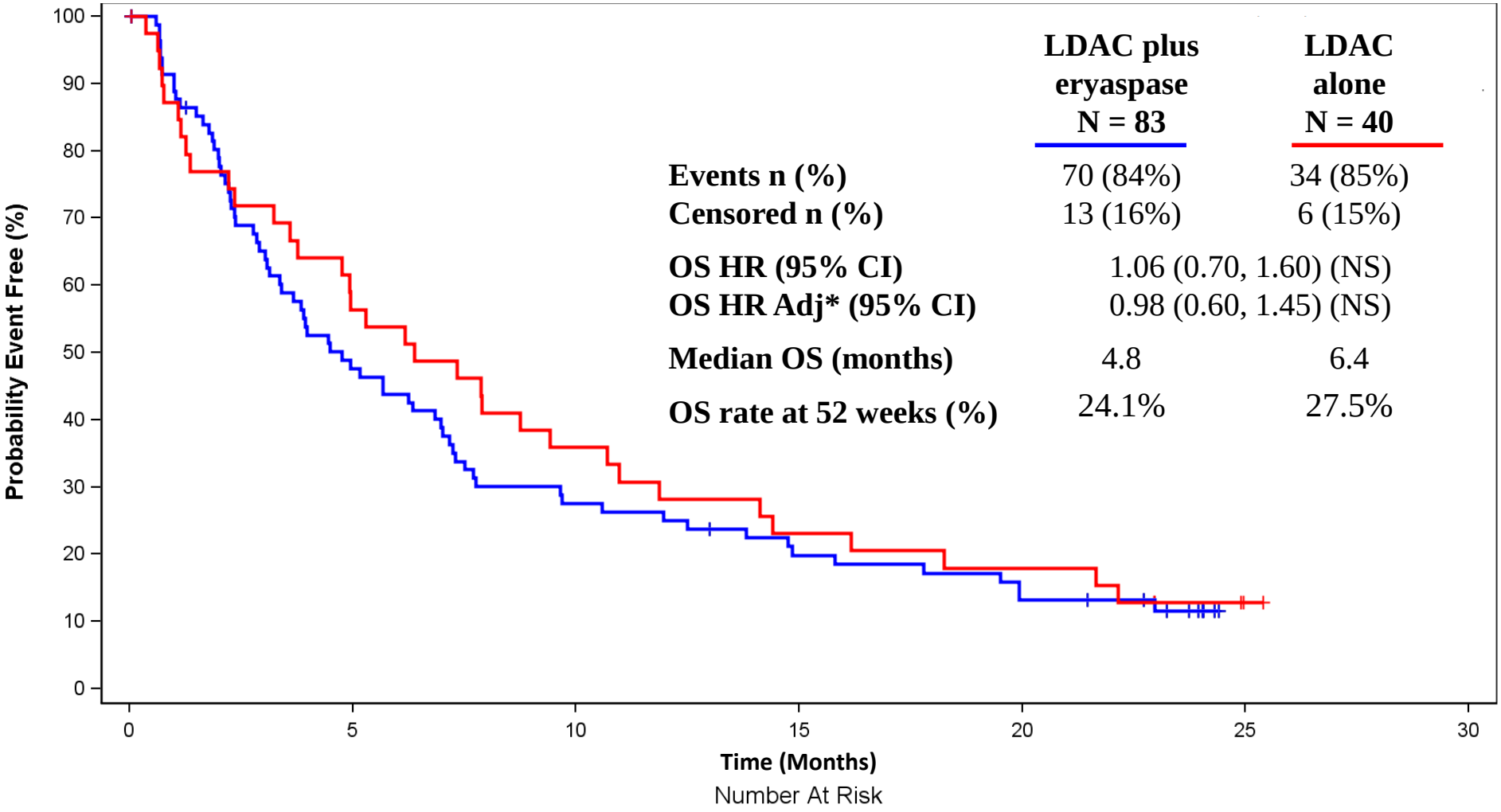
Baseline characteristics and patient disposition

Status	LDAC plus eryaspase N=83	LDAC alone N=40
Gender: Male - Female	55% - 45%	60% - 40%
Median age at randomization	78 yrs	77 yrs
ECOG Performance Status (PS): 0 – 1/2	24% - 76%	28% - 72%
Median duration on treatment (weeks; range)	5.1 (0.1,100)	5.9 (0.9,106)
Main reasons for discontinuation of treatment:		
Disease progression	48%	60%
Adverse event	42%	33%
Consent withdrawal	6%	3%
Other	4%	5%

Primary endpoint not met



	LDAC plus eryaspase N = 83	LDAC alone N = 40
Events n (%)	70 (84%)	34 (85%)
Censored n (%)	13 (16%)	6 (15%)
OS HR (95% CI)	1.06 (0.70, 1.60) (NS)	
OS HR Adj* (95% CI)	0.98 (0.60, 1.45) (NS)	
Median OS (months)	4.8	6.4
OS rate at 52 weeks (%)	24.1%	27.5%

- Adjusted for baseline characteristics (age, karyotype and FAB classification

NS = non-significant

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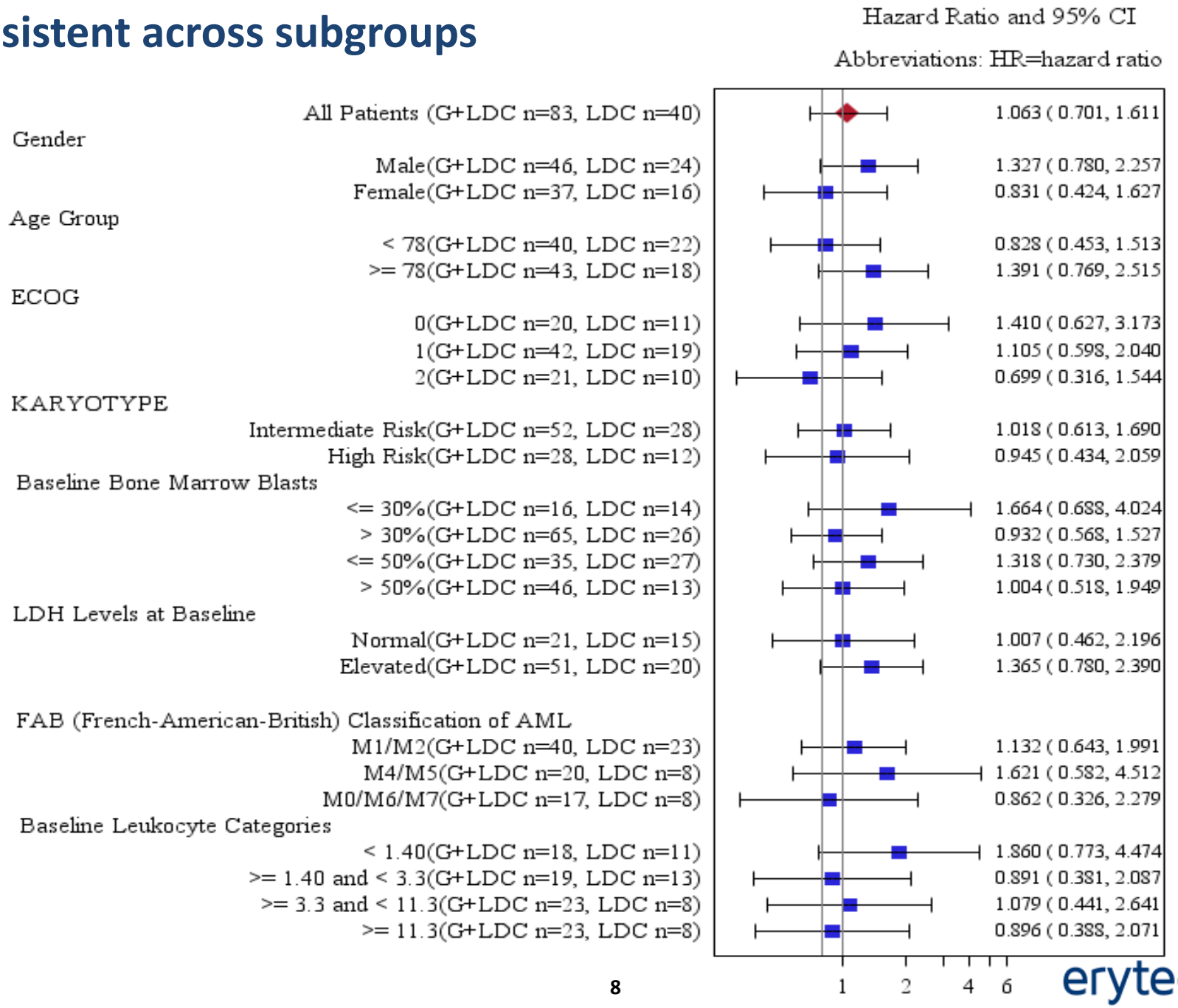
Consistent across subgroups



Acceptable safety profile; no unexpected toxicities

Incidence of treatment emergent adverse events > 20%	eryaspase + LDAC N=81 (%)	LDAC alone N=39 (%)
Patients with at least one TEAE	81 (100.0)	39 (100.0)
Anaemia	62 (76.5)	34 (87.2)
Thrombocytopenia	60 (74.1)	32 (82.1)
Leukopenia	41 (50.6)	19 (48.7)
Neutropenia	35 (43.2)	18 (46.2)
Asthenia	28 (34.6)	18 (46.2)
Blood Potassium Decreased	25 (30.9)	9 (23.1)
Hemorrhagic Events	24 (29.6)	10 (25.6)
Diarrhea	24 (29.6)	9 (23.1)
Pyrexia	21 (25.9)	12 (30.8)
Blood Albumin Decreased	24 (29.6)	6 (15.4)
Blood Calcium Decreased	16 (19.8)	9 (23.1)
Hyponatraemia	17 (21.0)	5 (12.8)
Elevated lipase	17 (21.0)	4 (10.3)
Antithrombin III decreased	17 (21.0)	3 (7.7)
Alloimmunization	17 (21.0)	1 (2.6)

Continuing the AML discussion

- Potential causes for lack of a signal
  - Patient characteristics
  - Disease characteristics

- Next steps
  - Further data interrogation
  - Presentation of full data at an upcoming medical meeting
  - Publication in a medical journal

Key milestones

- ☑ Reporting of full Phase 2b PDAC data
- ☑ Determination of recommended dose in US Phase 1 study in first-line adult ALL
- ☑ Meeting with FDA on PDAC development plan
- ☑ Resubmission of EU marketing authorization application in R/R ALL
- ☑ Reporting of top-line Phase 2b AML results
- ☐ Meeting with EMA on PDAC next steps
- ☐ Meeting with FDA on ALL next steps
- ☐ Initiation of Phase 3 study in second-line PDAC in Europe and the U.S.
- ☐ Initiation of clinical studies in first-line PDAC and other solid tumors
- ☐ Potential launch of Phase 3 study in first-line adult ALL
- ☐ Potential EU marketing authorization on R/R ALL
- ☐ Potential initiation of erymethionase Phase 1 study

THANK YOU

QUESTIONS?

ERYTECH Pharma SA
60 Avenue Rockefeller
69008 Lyon
France

ERYTECH Pharma Inc
1 Main Street
Cambridge, MA 01242
USA

www.erytech.com

investors@erytech.com