

WEBINAR

ACTICOR
BIOTECH

Results of the Phase 1b/2a Study, ACTIMIS, in Patients with Acute Ischemic Stroke

February 2022

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ACTICOR BIOTECH, develops a first-in-class drug for cardiovascular emergencies



Founded in 2013. Result of 10 years of French research (Inserm) listed on Euronext Growth in November 2021



Glencimab, a product for major cardiovascular pathologies: stroke, pulmonary embolism and myocardial infarction, the leading cause of death in the world



Proof of efficacy and safety in stroke patients



An expert drug development team of 20 people (France - USA) with world leaders in the sector

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Reminder: ACTIMIS - Phase 1b/2a

Evaluate the safety of glenzocimab within 4.5 hours of an AIS, in addition to the standard of care

Design

Phase 1b



60 patients recruited
(48 glenzocimab, 12 placebo)



125 mg

250 mg

500 mg



1 000 mg

Phase 2a



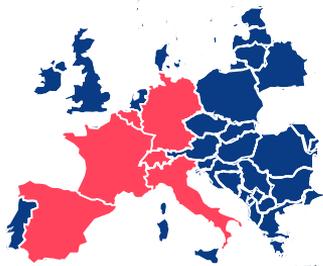
100 patients recruited



1000 mg



placebo



6 European centers

Selection of the optimal dose of 1000 mg
Confirmation of good tolerance in patients

Preliminary safety results

- ✓ Safety: serious adverse events (SAE), intracerebral hemorrhage (ICH)

Key Secondary End Points

Efficacy – Neurology

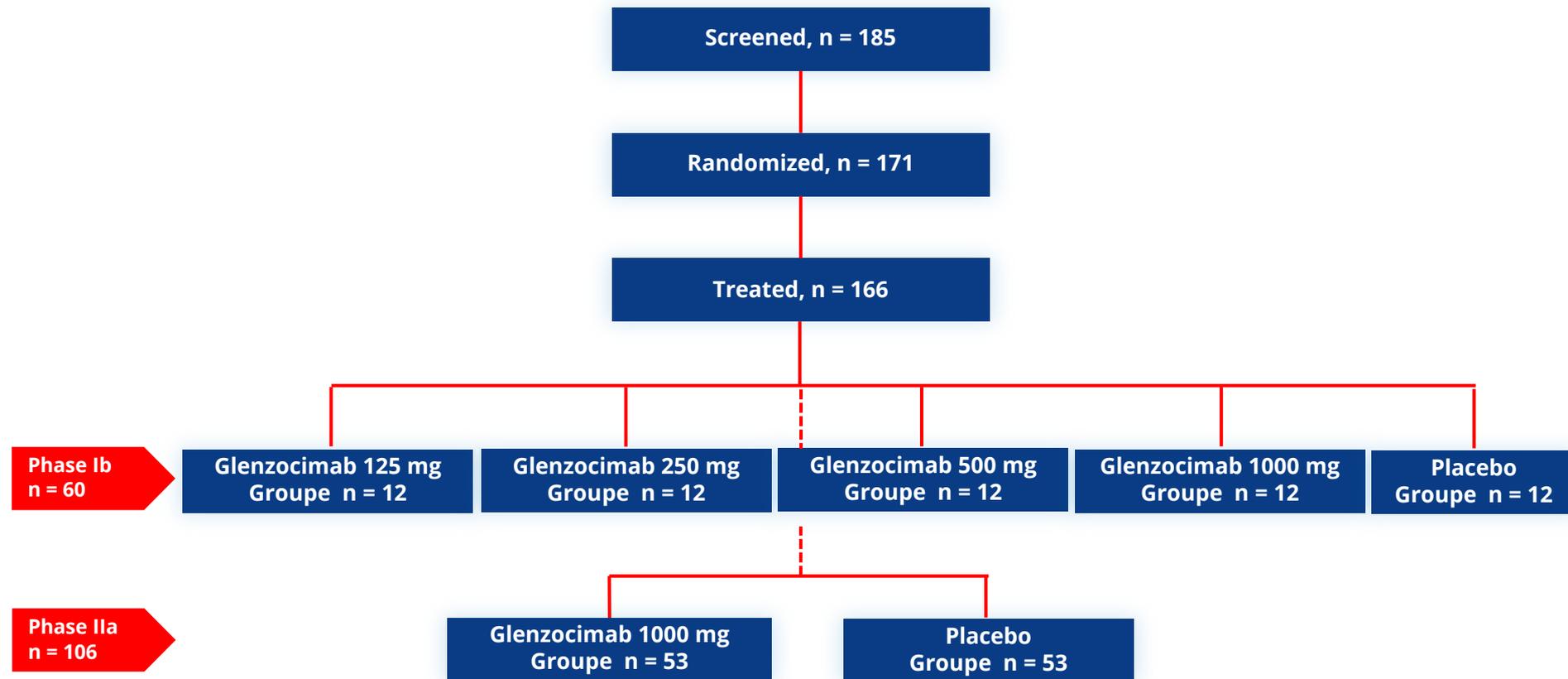
- ✓ Short-term recovery: NIHSS¹ at 24hrs vs baseline NIHSS
- ✓ Final recovery at discharge: mRS at Day 90

Résultats préliminaires en termes d'innocuité

First 60 patients in Phase 1b:

- ✓ No increase in bleeding with alteplase +/- TM
- ✓ No dose-response relationship on safety

Disposition of Patients



Positive results of the ACTIMIS study - Phase 1b/2a

- ✓ Primary endpoint met: Very favorable safety profile of glenzocimab
- ✓ Reduction in intracranial hemorrhage (ICH) and mortality in the glenzocimab group

Safety Profil

- Intracranial hemorrhage (ICH)
- Other adverse events
- Death

Efficacy

- Evolution of the NIHSS score (*National Institute of Health Stroke Score*)
- mRS Score (*Modified Ranking Scale*)
- Death

Safety - No IntraCranial Hemorrhages (ICH) at 1000mg

DECREASE OF s-ICH and ns-ICH

Symptomatic ICH incidence

Phase Ib & IIa

- 1/101 (1%) glenzocimab all doses
- 0/65 (0%) *glenzocimab 1000 mg*
- 5/65 (8%) placebo

Non-symptomatic ICH incidence

Phase Ib & IIa

- 31/101 (31%) glenzocimab all doses
- 20/65 (31%) *glenzocimab 1000 mg*
- 31/65 (48%) placebo

Major finding

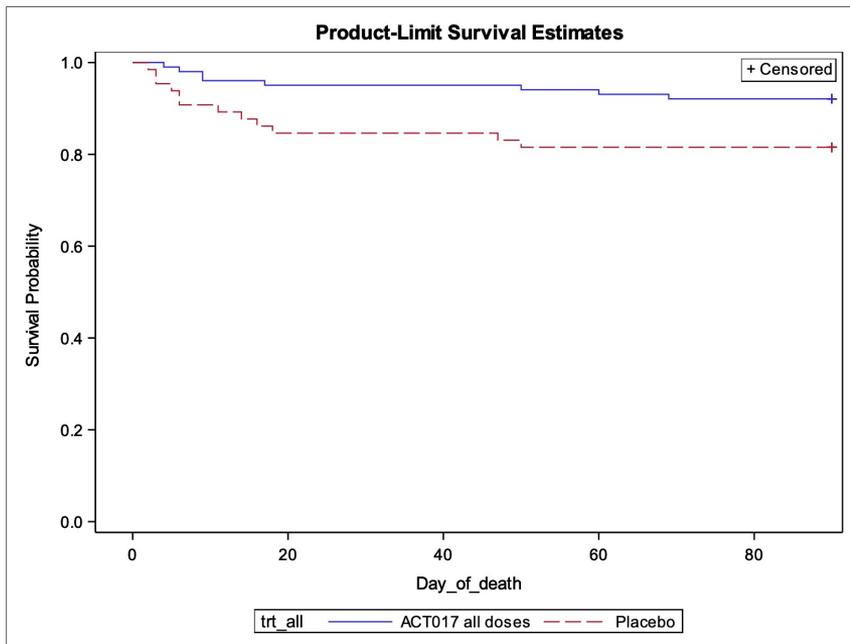


No s-ICHs in glenzocimab 1000 mg group in both Phases Ib & IIa



Lower rate of ns-ICHs in glenzocimab 1000 mg group in both Phases Ib & IIa

Safety - Unexpected improvement of Survival



Test of Equality over Strata			
Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	4.3952	1	0.0360
Wilcoxon	4.5772	1	0.0324
-2Log(LR)	4.5131	1	0.0336

Analysis - Kaplan-Meier Curve

All dose glenzocimab vs Placebo (Phase Ib + IIa)

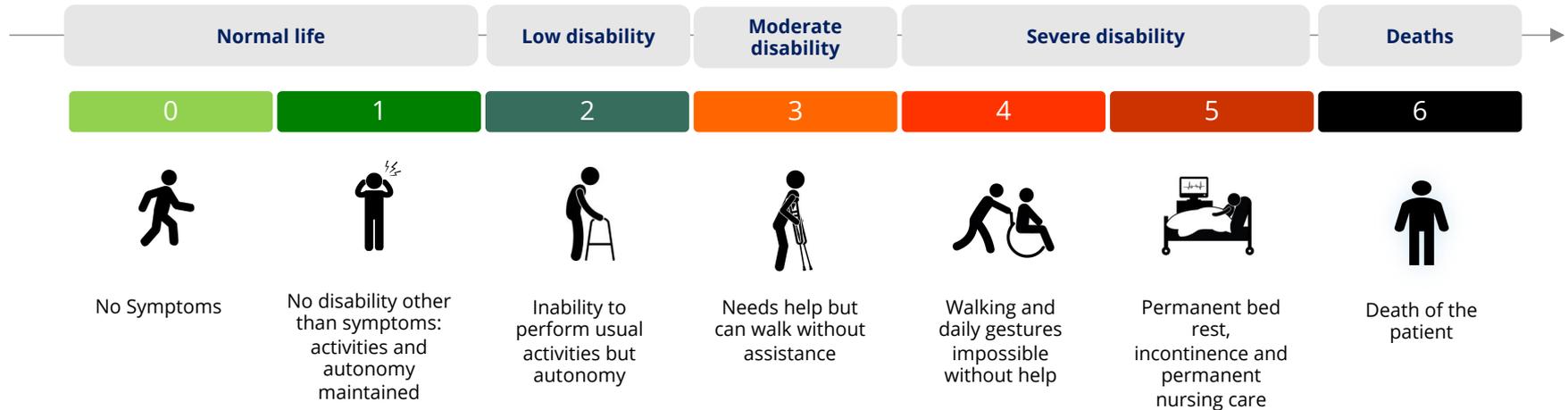
Decreased number of deaths in the glenzocimab group compared to placebo (8% vs. 19%)

Safety: Discussion and Conclusion

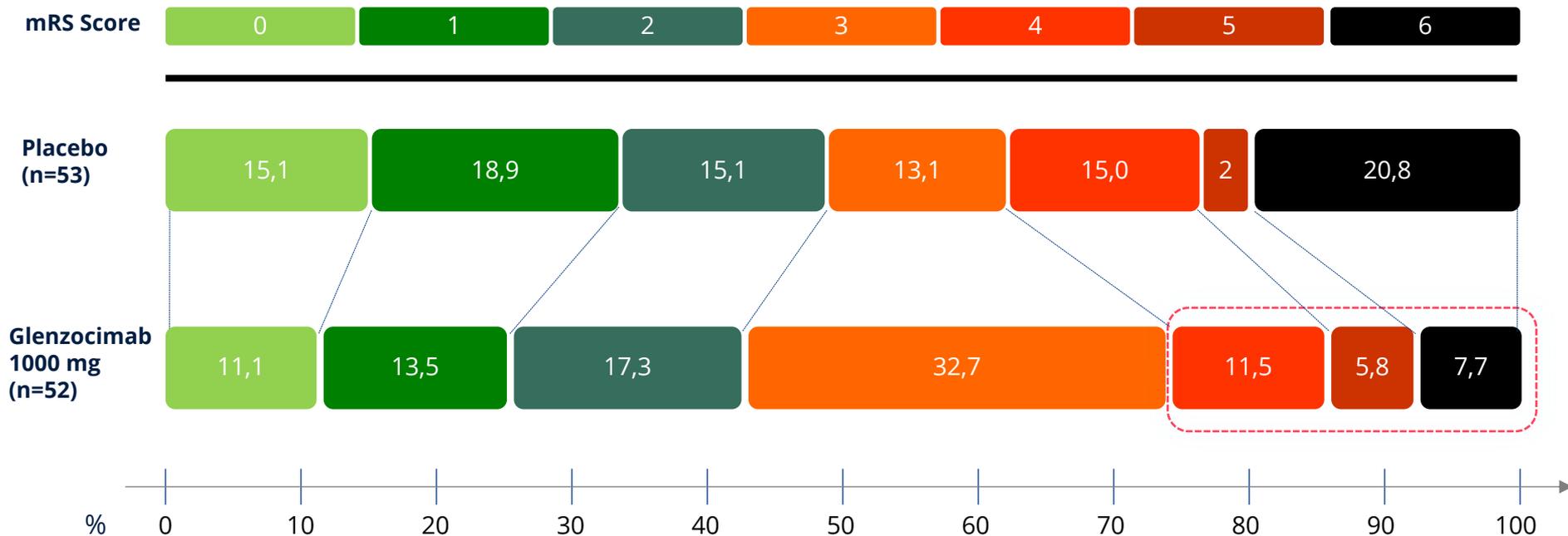
- ✓ Symptomatic and non-symptomatic intracranial hemorrhages under SOC were comparable to published data
- ✓ Symptomatic and non-symptomatic intracranial hemorrhages were seen less frequently with glenzocimab 1000 mg than with placebo
- ✓ Fewer all-cause deaths and fewer stroke-related deaths were reported under glenzocimab 1000 mg

Glenzocimab 1000 mg showed a very favorable safety profile, particularly in terms of hemorrhagic events and deaths Including in patients aged above 80 years (40% of the population)

Efficacy : the mRS score assesses the level of disability

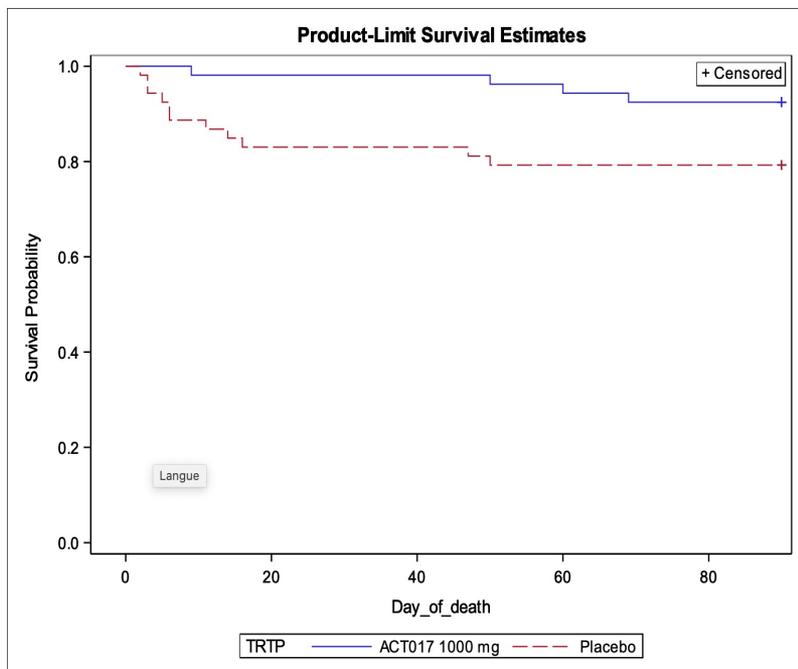


Efficacy: mRS score at day 90 by study treatment group – Glenzocimab 1000 mg (n= 52) / placebo (n=53)



Glenzocimab results in a reduction in severe disability (mRS 4, 5 and 6): 25% versus 38%.

Efficacy : survival analysis



Summary of the Number of Censored and Uncensored Values					
Stratum	TRTP	Total	Failed	Censored	Percent Censored
1	ACT017 1000 mg	53	4	49	92.45
2	Placebo	53	11	42	79.25
Total		106	15	91	85.85

Test of Equality over Strata			
Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	4.1174	1	0.0424
Wilcoxon	4.4495	1	0.0349
-2Log(LR)	4.5612	1	0.0327

Analyse - Courbe Kaplan-Meier

Glenzocimab 1000 mg vs. Placebo (Phase IIa)

3 times reduction of mortality with glenzocimab

Efficacy : Discussion and Conclusion

- ✓ Stroke-related deaths were significantly 3 times less frequent in patients treated with glenzocimab 1000mg that in patients receiving the SOC only.
- ✓ Favorable trend in terms of 90-day functional status assessed by mRS with the most severe categories (mRS 4-5 i.e., major disability), and 6 (i.e., death) shifting favorably between SOC alone and glenzocimab.

In this study, Glenzocimab 1000mg :
- showed a dramatic benefit in terms of death rate (divided by 3)
- decreased the proportion of patients with the most severe level of handicap.

Conclusions

- ✓ 1st proof of efficacy of glenzocimab in patients !
- ✓ Very good safety profile
- ✓ Decrease of HIC and deaths
- ✓ Decrease of percentage of most severe patients mRS 4, 5 & 6

Unexpected and unprecedented significant reduction of mortality in stroke patients