Phase I clinical trial of a new antifibrinolytic agent, compound CM-352, with an efficient synthesis route, aimed at controlling disabling and lethal bleeding.

Timeline | 10/2023 to 09/2026

Overall Budget | 3.623.834,13 €

ICIQ's Budget | 423.969,38 €

ICIQ People | CSOL

Call | Proyectos en colaboración público-privada 2022

SUMMARY

The consortium is based on the development of a new antifibrinolytic agent, the compound CM-352, with an efficient synthesis route aimed at controlling disabling and lethal bleeding through a new pharmacological strategy based on MMP inhibition, which will provide a much more effective and safer therapeutic approach than current treatments.

By combining catalyst design with hundreds of reaction screening techniques using automated analysis systems, such as the one available at the ICIQ's HTE laboratory, once we have the new synthesis route of the compound, we have planned toxicological studies to request approval to test the compound CM-352 in humans, classified into genetic and pharmacological toxicology.

Finally, the phase I clinical trial will be carried out in the Department of Orthopedic Surgery in primary total knee replacement (TKR) procedures. The phase I clinical trial will be a blind study aimed at investigating the safety, tolerability, and pharmacokinetics of CM-352 in order to verify the safety and feasibility of acute administration of CM-352 in a total of 21 patients. The beneficial results shown by the compound CM-352 will allow us to move on to a phase II study with a focus on severe bleeding in traumatology, where there is currently no treatment with demonstrated clinical efficacy.

Unfortunately, bleeding is a very common complication in different clinical situations, such as surgeries (30% of the 800,000 patients requiring a blood transfusion) or trauma (responsible for 45% of deaths after 24 hours following a traumatic injury). If we confirm our hypotheses and verify the results in the proposed models, we could obtain at least one patent for the development of a new synthesis route. Finally, thanks to the impetus of this help, we will be able to have a product ready for licensing in 2028 in a potential market of more than 11 million cases of severe bleeding in surgical interventions by 2032, which could generate a NPV and IRR of 3 billion and 135.6%, respectively.

WORK PLAN

WORK PACKAGES	Year 1	Year 2	Year 3
WP1. MANAGEMENT OF THE REGULATION OF THE CM-352 MOLECULE AND INTELLECTUAL PROPERTY			
WP2. DEVELOPMENT OF PRE-CLINICAL TOXICITY, EFFICACY, PHARMACOKINETIC AND PHARMACODYNAMIC TESTS			
WP3. NEW CM-352 COMPOUND SYNTHESIS PATHWAY			
WP4. ICIQICIQ4ENSAYO CLÍNICO FASE I EN CIRUGÍA ORTOPÉDICACUNHMPC,.			

CONSORTIA

Hemostatics

Project coordinator

ICIQ

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Reference:CPP2022-009643