

ImmunNovative Developments (IND)

IND is a biotech spin-off company based on product development for the prevention, diagnosis and treatment of sepsis and other inflammatory immune-based diseases.

Sepsis

Sepsis results in a significant economic burden; only in Spain it represents €345M per year, far superior to myocardial infarction. The average duration of sepsis treatment involves an occupation of 30 days in the Spanish intensive care unit (ICU) and 25% of the patients admitted to the ICU.

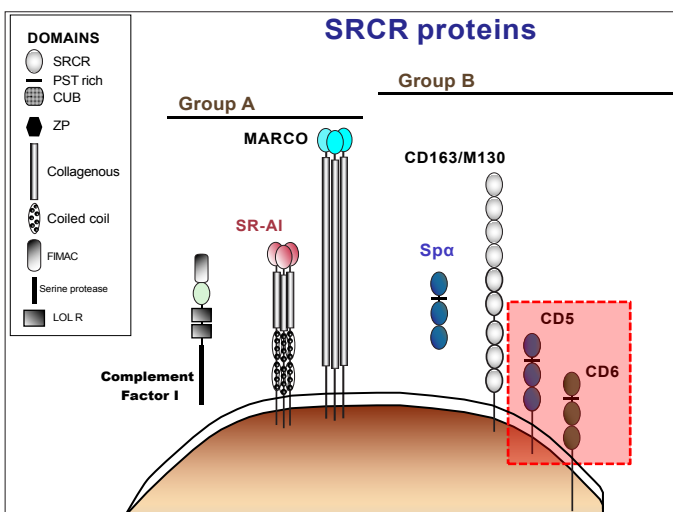
Sepsis presents the following:

- High mortality rate;
- Lack of alternative pharmacology; and
- Difficulty in diagnosis.

For every hour of delay in diagnosis, mortality increased by 10%. There are 1.500.000 cases of sepsis per year and 1/3 of these die.

The Business Model

The inventors have found that CD6 and CD5 are members of the super-family scavenger receptor cysteine-rich (SRCR) expressed in human lymphocytes binds to gram-positive and gram-negative bacteria and to other microbial structures. Therefore, the CD5 and CD6 products are useful for manufacturing a drug for therapeutic and/or preventive treatment of an infectious disease or an inflammatory process related with an infectious disease in humans like systemic inflammatory response syndrome (SIRS), sepsis, severe sepsis and septic shock.



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In vivo Proof-of-concept with CD5 & CD6

The group observed that knockout CD5 mice are more susceptible to septic shock induced by Zymosan. Therefore delayed administration of soluble rhCD5 ameliorates Zymosan-induced septic shock-like syndrome. Furthermore CD6 administration provides 50% more survival in comparison with control and reduction of pro-inflammatory cytokines with post-administration of CD6.

The next steps are:

- Selection of cell line to manufacture CD6 and CD5.
- Proof-of-concept for manufacturing by obtaining a non-GMP scaled-up batch.
- Proof-of-concept in primates: PK, PD and MTD studies.
- GMP-development and preclinical studies.

	Combination CD5+CD6	Xigris (lilly)	E5564 (Eisai)
Therapeutic effect	From early stages to sepsis	only from late stages of severe sepsis	From early stages to sepsis
Prophylactic effect	Yes	No	Yes
Target	Pathogenes, G+, G-, fungi, virus	Coagulation	Pathogen G-
Antimicrobial spectrum	Broad	Broad	Restricted
Toxicity risk	Low	Medium (bleeding effect)	Medium
Immunogenicity risk	Low (human origen)	Low (human origen)	High (synthetic origen)

Financial Opportunity

- First-round financing has been successfully completed.
- IND has been granted research loans and funding from public sources.
- IND seeks additional funding to complete preclinical development and start clinical trials in humans in 24 months.
- Funding need estimation: 5M€ to complete IND filing, phase I clinical trials and start phase II in the next 3 years.
- Genoma España offers its 18% stake of IND to any interested investor willing to capitalize the shares and strategically contribute to its development and business.

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