

Programa Cooperación Farma-Biotech

Jornada IV: Ámbitos terapéuticos relacionados con respiratorio, dermatología, nefrología, inflamación e infección

CombPath6.0: new biological drug for the treatment of sepsis



Madrid, 12 July 2011

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Content

1. The Company

2. The Product

- a) Therapeutic focus
- b) Innovative mechanisms of action
- c) Differential features facing the market
- d) Current status of development
- e) IPR protection
- f) Pitfalls & Risks to be considered

3. Availability for cooperation

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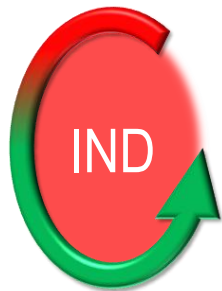
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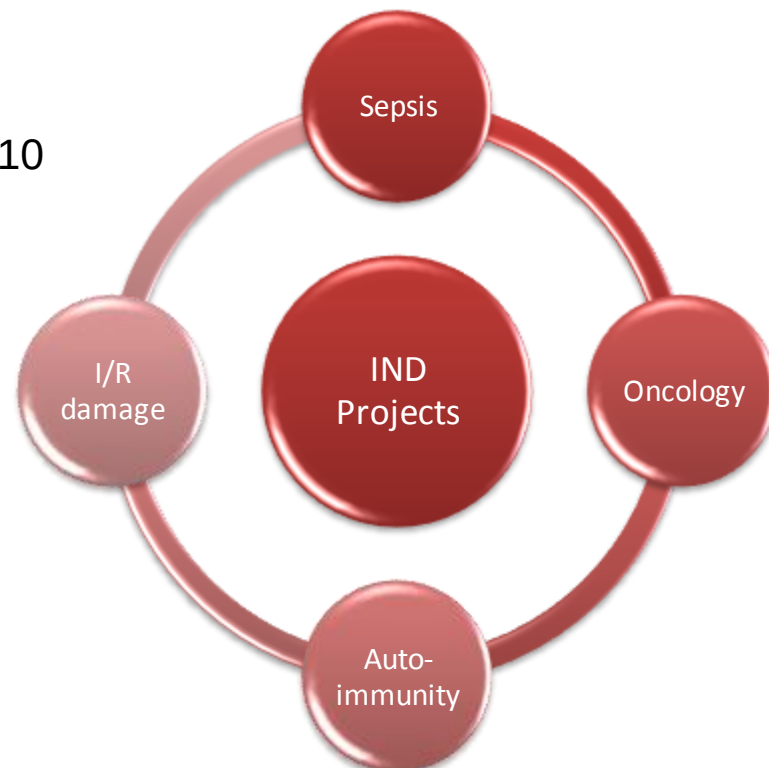
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**ImmunNovative
Developments**

Biotech spin-off company founded in February 2010

Biotech spin-off company
founded in February 2010, developing
Immunology-based biologicals
for the **treatment and prevention** of
life-threatening and clinically relevant
human disorders



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Dr. Josep Lluís Falcó

- Doctor of Chemistry from Institut Químic de Sarrià (URL) and ESERP MBA Master.
- CEO at ImmunNovative Developments.
- 10+ years experience at Sanofi-aventis and Grupo Ferrer as project manager and business developer.
- 1 year experience at Centre for Entrepreneurship, Fundació Bosch i Gimpera.



Dr. Francisco Lozano

- Doctor of Medicine from the University of Barcelona (UB) and a specialist in immunology.
- Senior Consultant, Department of Immunology at the Hospital Clinic of Barcelona.
- Professor of Immunology at the Faculty of Medicine of the UB.
- 20+ years of experience in Immunology.



Ms. Teresa Lloret

- Degree in Chemistry from the University of Barcelona and ESADE MBA Master.
- Project Manager at Fundació Clínic per la Recerca Biomèdica.
- Prior experience in areas of pharma R&D (7 years) and Business Development (3 years).



Mr. Enric Panadès

- Bachelor of Arts from the University of Barcelona (UB).
- Specialized in medical-surgical imaging.
- Sole Administrator at ImmunNovative Developments.

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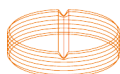


Bioincubadora
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ImmunNovative
Developments

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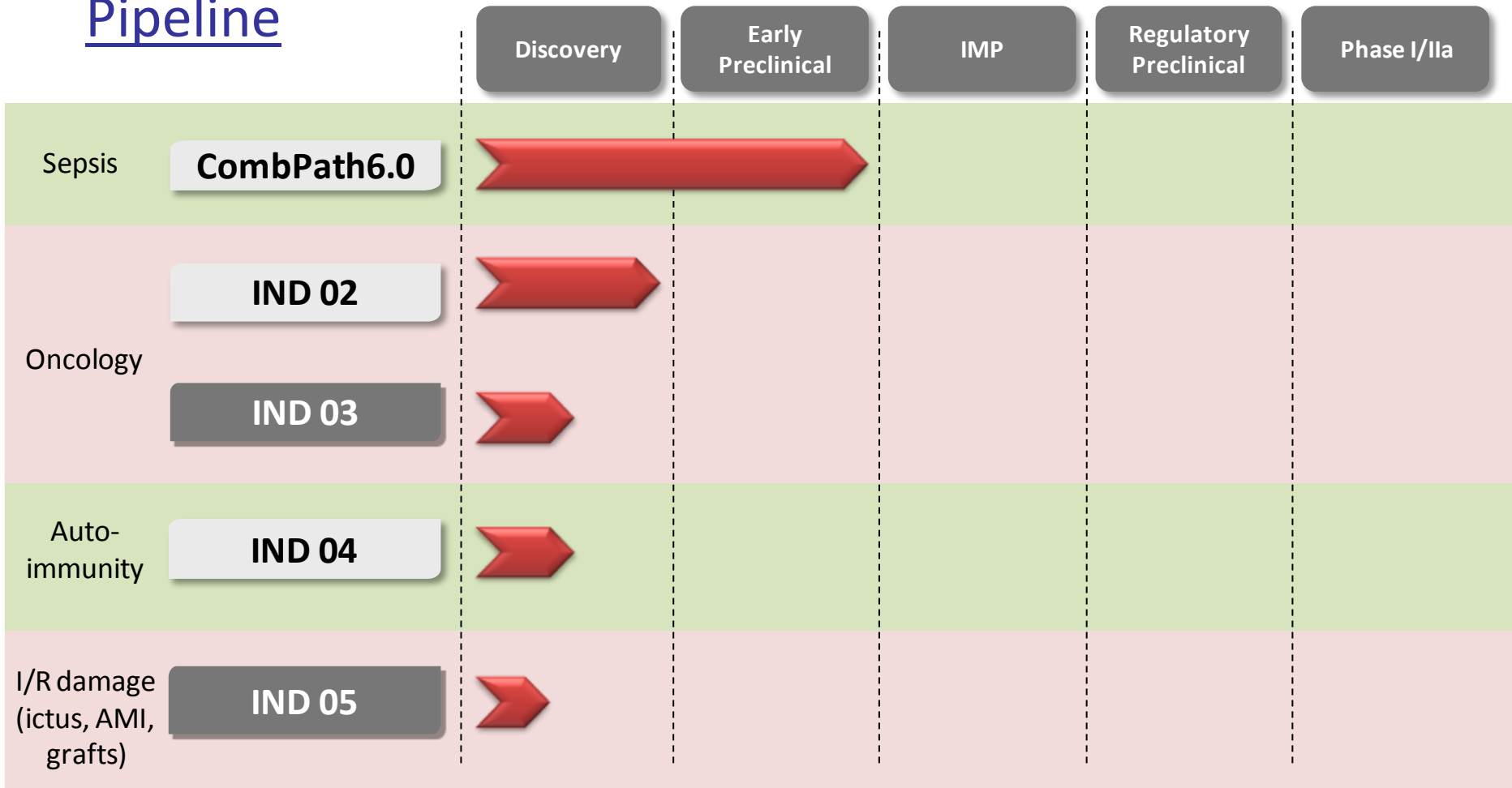
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Pipeline



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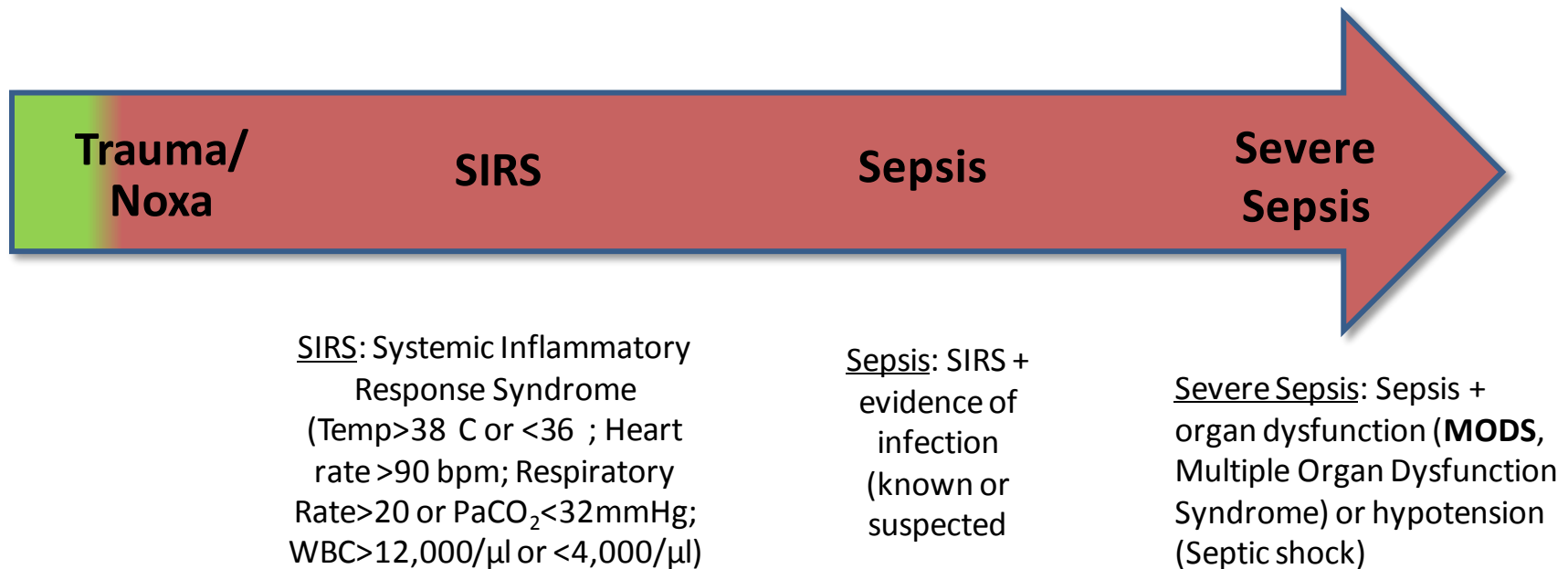
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Therapeutic focus: sepsis

A Systemic Inflammatory Response Sndrome (**SIRS**) mediated by the host immune system to an infection, eventually leading to Multiple Organ Dysfunction (**MOD**), cardiovascular collapse and death.



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Market size: 2.000 M€ worldwide

1.500.000 cases of sepsis per year worldwide

High mortality rate, lack of alternative pharmacological and difficulty in diagnosis

For every hour of delay in diagnosis, mortality increased by 10%

Mortality rate: 30% for sepsis, 50% for severe sepsis

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Sepsis results in a significant economic burden, only in Spain is **€ 345m per year**

It is far superior to that represents the attention to myocardial infarction, a € 80M

It involves **25%** of patients admitted to the **ICU**

The average duration of treatment involves an occupation of **30 days in ICU**

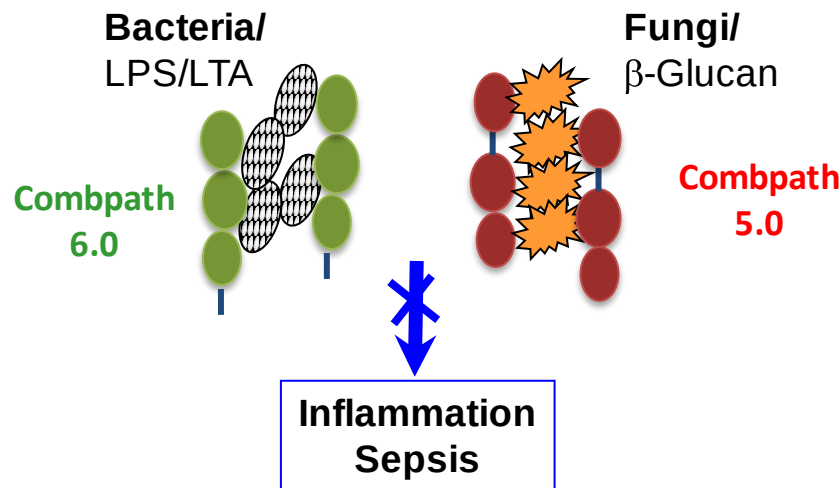
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Innovative Mechanism of Action

Soluble forms of human **lymphocyte surface glycoproteins** having the ability of:

- Sensing and neutralizing microbial components (bacterial, fungal)



Vera J, Fenutria R et al., PNAS 2009;
Sarrias MR, Farnós M et al., PNAS 2007

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Differential features facing the market



Xigris (recombinant C-reactive protein), **launched in 2001**. Limitations in actual practice due to secondary effects, in its fourth year sold \$ 200 million, then decline in 2009 sales to be **161 million**



CytoFab™ (agreement with Protherics in 2006), polyclonal antibody fragment produced by the Australian sheep, developed in 2006. AstraZeneca paid 40 million dollars, 13 of them in form of direct investment in Protherics, plus a commitment of up to 290 million additional associated development milestones and royalties on sales of about two digits). Currently entering **Phase IIb** with 300 patients; scheduled launch **by 2015**.



TAK-242 (Takeda): TLR4 antagonist; discontinued in phase III



E5564 (Eisai): inactive LPS analogue; currently in phase III

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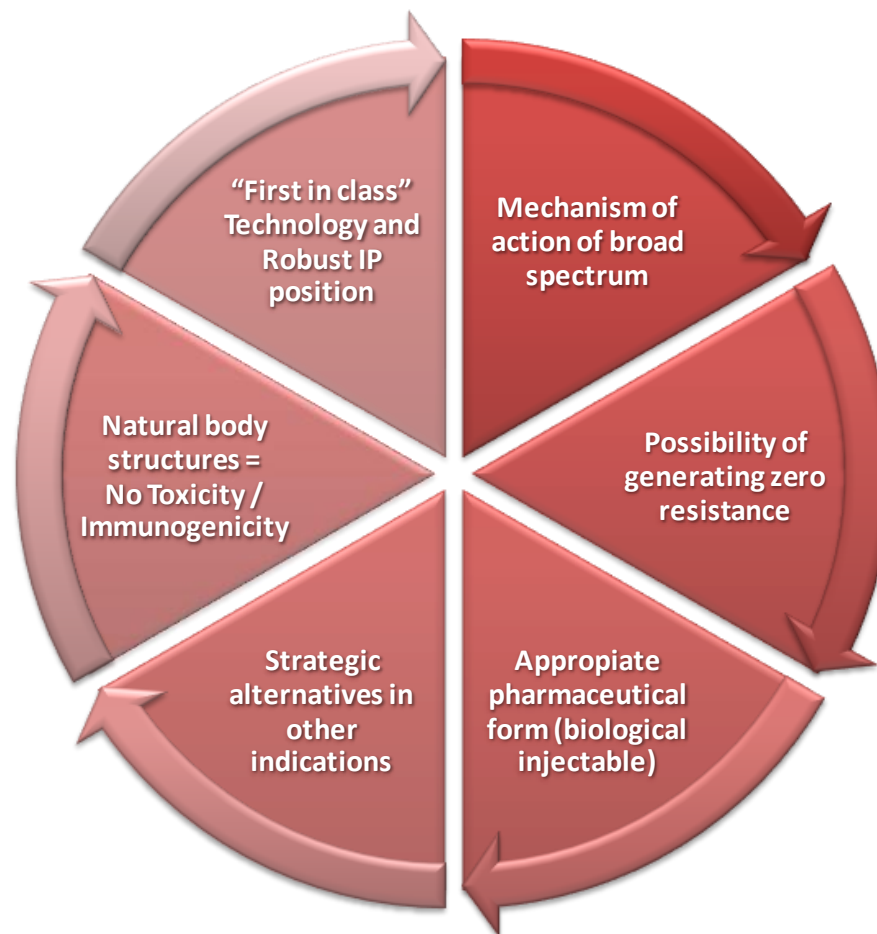
Differential features facing the market

	CombPath Preclinical	Xigris (Lilly) Market - 2001	E5564 (Eisai) Phase III
Therapeutic effect	From early stages of sepsis	Only from late stage of severe stages	From early stages of sepsis
Prophylactic effect	YES	NO	YES
Target	Pathogens G+, G-, fungi	Coagulation	Pathogen G-
Antimicrobial spectrum	Broad	Broad	Restricted
Toxicity risk	Low	Medium (bleeding effect)	Medium
Immunogenicity risk	Low (Human origin)	Low (Human origin)	High (synthetic origin)

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Differential features facing the market



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IPR protection

CombPath6.0:

Patent filed at OEPM on **28.03.2007**

Extended to EU, USA, Canada & Japan on Sept 2009

Freedom to operate finished

Main Claim: Use of CombPath6.0 as medicament for therapeutic and/or preventive treatment, in a mammal including a human, of an infectious disease, or of an inflammatory condition related to an infectious disease, or of an inflammatory disease related to the presence of a product derived from an infectious agent.

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Cooperation Farma-Biotech

VC Investment

Co-Development

Other Collaborations:
- Medical Devices: monitor biomarkers

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dermatología, nefrología, inflamación e infección

Thank you!

Josep Lluís Falcó

Chief Executive Officer

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