Figure: sanofi-aventis logo : because health matters

Incrustation: A leading pharmaceutical group working for health throughout the world

Among the leading international pharmaceutical companies, sanofi-aventis currently has one of the most important research and development budgets.

Incrustation: 7 major therapeutics themes : cardiovascular, thrombosis, central nervous system, oncology, metabolic diseases, internal medicine, vaccines.

Its research activities cover both the search for new, innovative and well-tolerated drugs and a constant search to improve existing therapies.

Incrustation: High quality, innovative international research.

Incrustation: Over 17,600 research staff working at over 20 sites on 3 continents to create new and innovative drugs and vaccines.

These efforts have one goal : the constant improvement of human health.

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Developing a new drug is a highly complex, risky and costly enterprise.

Incrustation: The life cycle of a drug from research to patients :

Incrustation: research: 2 to 4 years, development: 7 to 10 years, launch: 1 year, life.

Incrustation: Preclinical development: 1 to 2 years.

Incrustation: Clinical development: 6 to 8 years.

It takes 15 years on average.

Indeed, of every 10,000 potentially interesting compounds, only one will become a medicinal product.

This long process comprises numerous steps involving many sophisticated techniques.

Incrustation: ***Research***

The first research step consists of testing a large number of compounds on a target implicated in a disease, such as an enzyme or a receptor.

Incrustation: Search for a chemical starting point

These compounds can be naturally occurring or synthesized using combinational chemistry, for example.

Figure: molecule in 3D view

Incrustation: Chemical synthesis

Incrustation: File a patent "as soon as the compound has been identified"

Incrustation: ***Patent***

Incrustation: screening

These compounds are then screened using a battery of pharmacological tests to detect any relevant biological activity.

Incrustation: Pharmalogical research : beneficial effects / adverse effects

Pharmacological research determines the beneficial and adverse effects of the drug candidates using in vitro and in vivo models. It provides information about their potential therapeutic application.

Incrustation: Optimization : potential candidates

Further chemical and pharmacological studies are conducted to optimize these compounds, generating potential candidates for the creation of a medicinal product.

Incrustation: ***Quality, safety, ethics***

Incrustation: Potency, specificity, absorption via oral route, duration of action

The compounds must now be tested on additional in-vitro techniques and in animals, using relevant in vivo models.

Incrustation: Development

Incrustation: Preclinical evaluation: in vitro studies and in vivo animal testing, about 2 years

The first phases of preclinical evaluation take about 2 years, and comprise several simultaneous steps:

Chemical development (generates active substances up to the phase II and III clinical trials), analytical procedures (to test and validate the quality and stability of the product throughout its development), safety studies (evaluate the harmful or adverse effects of a compound in relation to its therapeutic use), metabolism and pharmacokinetics (to investigate the absorption, metabolic and kinetic profile of the drug candidate in living organisms), and finally formulation studies (studies to provide a suitable dosage form for the drug when administered to the patient).

Incrustation: Development

Incrustation: Clinical evaluationin humans: from 6 to 8 years

Clinical evaluation in humans consists of 3 phases.

Incrustation: Tolerance and pharmacokinetics: phase 1

Phase I, in which the drug is administered to healthy human subjects to study its pharmacological activity, tolerance and pharmacokinetic behaviour.

Incrustation: Phase 2: biological activity and clinical research.

Incrustation: Determination of optimal dose in humans. Optimal dose.

Phase II: the biological activity of the drug is confirmed on a small number of patients and the dose and dosage regimen for optimal efficacy are determined.

Incrustation: Phase 3: therapeutic effect and tolerance are confirmed

In phase III, the product is administered to a large number of patients (several hundred to several thousand) to confirm its therapeutic effect and to evaluate its efficacy/safety ratio compared to a placebo or a reference drug.

Incrustation: ***Launch***

Incrustation: The files for registration are prepared and submitted

Incrustation: Marketing authorization / new drug approval

Incrustation: At least one year before approval is granted

Before it can be marketed, the drug should be able to be manufactured on an industrial scale to obtain new drug approval (marketing authorization), granted by the national regulatory bodies concerned, such as the FDA (Food and Drug Administration) in the United States or the Japanese PMDA (Pharmaceutical and Medical Devices Agency) or supranational authorities such as the EMEA (European medicines evaluation agency).

Incrustation: ***Manufacturing***

After marketing authorization has been obtained, the active substance becomes a medicinal product. It is then manufactured industrially, marketed and made available to the medical profession.

Incrustation: ***Pharmacovigilance***

Clinical trials do not end once the product has been released on the market. In fact, the pharmaceutical company continues its studies and research throughout the drug's lifetime through constant evaluation of the safety of the medicinal product and identification of

any other beneficial or adverse effects.

Incrustation: ***Life cycle management***

These clinical trials improve our knowledge and understanding of the product and enhance patient safety. This phase, conducted in close collaboration with health professionals, identifies any unexpected or undesirable effects and provides information for the development of new dosage forms and new therapeutic indications.

Incrustation: Preclinical development: A to 2 years

Incrustation: Clinical development: 5 to 8 years

Drug discovery and product development are an exciting, uncertain and difficult process.

Figure: sanofi-aventis logo : beacause health matters

The life cycle of a drug is a long and extremely expensive process, with many parties involved.

Our goal is to provide doctors and their patients with innovative drugs corresponding to global healthcare requirements.

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