Biopharmaceutical Innovation: The Complexity of The R&D Process

WIPO IGC 21
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Markus Boehringer, Roche
Many fascinating projects –

idea

Xeloda

medical innovation

improved healthcare

better quality of life

Pegasys
many fascinating projects – a layman’s perspective

idea

some bioactive compounds

some testing

formulation

improved healthcare

better quality of life
many fascinating projects –

the reality is different

highly complex multidisciplinary R&D

frontier science & high-technology

idea

medical innovation

Pegasys

Xeloda
many fascinating projects –
the reality is different

highly complex multidisciplinary R&D

frontier science & high-technology

high cost
long-term
high risk

medical innovation

Pegasis

Xeloda
many fascinating projects –
but only a few are successful
project lead molecule

drug candidate prep for clin tests

clin development:
Phase I  Phase II  Phase III

medical innovation

R
concept

D
STOP

idea
**R**
- concept
  - project
    - lead molecule
  - drug candidate
    - prep for clin tests

**D**
- clin development:
  - Phase I
  - Phase II
  - Phase III

US$ 1‘300‘000‘000
cumulated costs / successfully launched drug

sustainability of R&D
Pharma R&D metrics of success

Research

- New Med Proposal
- Target Assess
- Lead Ident
- Lead Opt
- Enable

10 ideas

1 project

ca 100-300 people needed in research to produce 1 clin.cand. / year

Clin. development

- Phase I
- Phase II
- Phase III
- Reg
- to Market

>2 time

- 60
- 40
- 25
- 15
- 10
- 4.5
- 2
- 1.5
- 1

0.07

>10 years of patent life expired
The Classical Perception of Drug Discovery

- chemistry
- biology
- pharmacology
Drug Discovery Today

A highly networked multi-disciplinary environment!
A multitude of cost intensive technologies!
Additional Complexity: Multidimensional Optimization
Why so complex?
Why these high costs?

“Low hanging fruits are gone” – technologies, translational approaches to overcome

**Increasing demands:**
e.g. T2D: need to demonstrate not just glucose lowering, but benefit on mortality and morbidity.
⇒ longer studies, more patients, higher costs

**Natural products:**
- Scientifically of value
- Complex optimization required!!
  (oral bioavailability, PK, selectivity, …)
- Complex synthesis!!
- Reliability of supply
Pharmaceutical R&D: Summary

Still many unmet medical needs - complex - frontier science - high-tech - expensive - high-risk

$<\frac{1}{60}\$ • Less than 1 out of 60 research projects started will deliver a drug to the market.

$<\frac{1}{10}\$ • Less than 1 out of 10 molecules starting in clinical trials makes it to the market.

$>10$ yrs • More than 10 years from project start to entering the market.

$<10$ yrs • Period of patent protection for a drug entering the market: less than 10 years.

$1.3$ bil USD • The costs for bringing 1 new drug to the market: USD $1'300'000'000$. 
THANK YOU!