Trilateral Symposium (WHO - WIPO - WTO)
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Topics to be covered and main focus

Topics to be covered

• Biotech/pharma industry developed effective new treatment options and novel technologies
• Exception: Growing threat by multidrug resistant bacteria - a result of stupid mistakes we should not repeat
• Industry trends and critical success factors enabling this achievement
• What could be the next breakthroughs, provided the innovation power is not hampered?

Focus on the needs of the true innovators that provide innovative technologies and medicine addressing novel pathways and/or provide new mode of action mechanisms. Such researchers, entrepreneurs, companies and their investors:

• Engage in a long-term journey (often project timelines are in the range of 10-20 years)
• Face significant attrition risk (only 1 in 100 research projects may lead to a successful product)
• Require substantial funds (hundreds of millions USD to several billion USD for one new product)

Today's presentation will however not be addressing the strategies of individual companies and the prospects or pricing of individual products.
Innovative treatment options address critical medical needs

Innovations in medical treatments have significantly improved

• Life expectancy

• Life quality (alleviating or preventing pain, disfigurement, functional decline, disability, and premature death)

• Survival rate

• Treatment efficiency (lowered disease complications)

• Productivity rate
Innovative treatment options address critical medical needs

Breast cancer death rate has dropped by > 50% in 20 years

Source: Cancer Research UK

For other cancer types the drop was less pronounced so far (typically 15-35%) but death rates dropped across the board (e.g. ovarian cancer, prostate cancer, bowel cancer)
Innovative treatment options address critical medical needs

• Globally, vaccination prevented almost 6 million deaths annually

• The life expectancy of treated HIV-positive individuals improved strongly and is now close to that of the general population in the United States

• Antibiotics have not only saved patients’ lives, but have also played a role in achieving major advances in medicine and surgery

• In the United States the age-adjusted annual heart disease mortality rate fell by more than 50% from 1950 to 1996, and by a further 22% from 1990 to 2013

• The impact of better glucose control has resulted in life expectancy improving substantially in people with type 1 and type 2 diabetes over recent decades

• Immuno-oncology led to more targeted and effective oncology treatment options with significantly lower side effects

Source: OECD Health Policy Studies, Pharmaceutical Innovation and Access to Medicines
Innovative treatment options address critical medical needs

• Even in the challenging area of central nervous system diseases the emergence of treatment options for multiple sclerosis offer a strong signal of hope that such challenging diseases, that are still not fully understood, can also be addressed

• Many orphan diseases have become treatable (e.g. Pulmonary Arterial Hypertension, Cystic Fibrosis) albeit cure typically has remained elusive

• For chronic myeloid leukemia (CML) the estimated 5-year survival rate has improved from less than 20% to >90% in the tyrosine kinase inhibitor era

In the past few years, treatment options have become available that can cure diseases:

• Hepatitis C: used to be a 48 week treatment with 50% success rate new treatment options reach > 90% cure rate with 8 week treatment

• Gene-therapies/CAR-T cell therapies offer personalized treatment solutions

Source: OECD Health Policy Studies, Pharmaceutical Innovation and Access to Medicines
12-14% of healthcare costs relate to drug expenditures

**Source:** Fitch solutions, July 2019, courtesy McKinsey
Composition of drug expenditures (example France)

Source: Quintiles IMS MIDAS, Quintiles IMS Institute, September 2016
Area of antibiotics development deteriorated dramatically

**Priority 1: CRITICAL**
- Acinetobacter baumannii, carbapenem-resistant
- Pseudomonas aeruginosa, carbapenem-resistant
- Enterobacteriaceae, carbapenem-resistant, 3rd generation cephalosporin-resistant

**Priority 2: HIGH**
- Enterococcus feecum, vancomycin-resistant
- Staphylococcus aureus, methicillin-resistant, vancomycin intermediate and resistant
- Helicobacter pylori, clarithromycin-resistant
- Campylobacter, fluoroquinolone-resistant
- Salmonella spp., fluoroquinolone-resistant
- Neisseria gonorrhoeae, 3rd generation cephalosporin-resistant, fluoroquinolone-resistant

**Priority 3: MEDIUM**
- Streptococcus pneumoniae, penicillin-non-susceptible
- Haemophilus influenzae, ampicillin-resistant
- Shigella spp., fluoroquinolone-resistant


*Courtesy of Polyphor Ltd*
A global crisis that we have generated ourselves

We informed investors and pharma companies that they will make no profit

• “Antibiotics pricing will be kept low to enable developing countries to have access”
• “Novel antibiotics that can kill resistant bacteria shall be shelved/kept as a reserve, so that we are prepared for a potential future epidemic”
• “The bacterial infections problem will resolve itself if we implement rigorous hygiene measures in hospitals”

Investors responded in a very logical manner as they

• Stopped investing in this field
• Sold shares of companies that continued to invest in antibiotics R&D
• Pressured management teams to exit the area
• Dissolved functional antibiotics R&D teams

Today we fight to provide minimal funding through foundations, philanthropies and public/private partnerships. However, this corresponds to a fraction of the > 1 billion USD that used to be invested by private investors annually in the past.
Remaining companies fight at all levels

1. Avoid infection
   - 1a. Boost immune modulation
   - 1b. Decolonise/ Avoid colonisation

2. Get diagnosed
   - 2a. Quickly identify pathogen origin and precise strain

3. Quench infection
   - 3a. Inhibit/kill pathogen
   - 3b. Increase kinetic of pharmacologic effect
   - 3c. Promote immune system efficacy
   - 3d. Break existing resistance
   - 3e. Circumvent metabolic evasion

4. Fight infection damage
   - 4a. Avoid tissue damage
   - 4b. Avoid microbiota dysbiosis

5. Avoid treatment failure
   - 5a. Avoid resistance acquisition
   - 5b. Avoid resistance gene transfer

6. Avoid contagion/transmission
   - 6a. Avoid pathogen transfer

Before infection  |  During infection  |  After infection

*Courtesy of the Beam Alliance*
But very few offer the prospect of a new mode of action.
We must acknowledge the value of antibiotics

To address the threat of multi-drug resistant bacteria we must

• Recognize the value of novel antibiotics that can kill resistant bacteria
• Understand that they can cure, counter the spread of resistant bacteria, massively reduce the costs associated with complications/deaths related to multi-drug resistant bacteria
• Signal to investors that such antibiotics will be reimbursed at a significantly higher price
• Signal to investors that such antibiotics are desperately needed and will be applied in order to save lives, reduce healthcare cost and counter the spreading of resistant bacteria

In return we will be able to

• Address the threat caused by multidrug resistant bacteria
• Save lives and reduce healthcare costs related to complications and deaths caused by such bacteria
• Ensure a high compliance in the application of such novel antibiotics (high pricing will reduce risk of non-compliant application)
• Reengage private investors and pharma companies
Large pharma companies tap into external innovation

Share of top 10 pharma companies as sponsors of phase I-III clinical trials based on all commercial trials started in a given year

Total annual revenue by product sourcing strategy

$bn

Cross-functional industry network is constantly adapting...
… offering new investment and partnering opportunities

Biotech companies stay independent:

- build their commercial organizations
- partner with distributors team up with partners that have access to patients
- combine drug and medical device or service provider

Some Biotech companies are fully financed, eliminating the need for small incremental financing rounds

CRO share research risk
CMOs take over production sites
Clinical trials are outsourced and even financed by partners
Service providers start sharing risks and benefit
Business models not relying on product development but on data analysis and AI
Investors go it alone, build virtual project teams rather than companies
Critical success factors - early stage financing

From 2007 – 2018, Venture Kick invested CHF 3.16 million in 48 Swiss biotech startups. This amount was amplified 159 fold by grants and VC investments.

This model works as long as investors are convinced that the successful investments generate so much profit that they can cover the costs of failed projects and still make a profit.

pro memoria, ca.:
1:100 research projects
1:10 clinical stage projects
Critical success factors - talent formation and mobility

Source: Instead, GTCI Report 2017
Critical success factors - high impact patents, effective TTOs

Bubble size represents the number of active patents per country of inventor origin, reporting year 2016

Source: IPI, Swiss Biotech Report 2017
Innovation trends open up new opportunities

Global pipeline composition, directional technology outlook

Monoclonal antibodies: >1’770
Cell & gene therapies: >540

Number of assets in pipeline, 2017

~880
Clinical trials in progress in 2017

~$140Bn
Forecasted global sales, 2030

Source: McKinsey analysis, Statista, clinicaltrials.gov, Evaluate Pharma July 2018

1 E.g., Nanotechnologies, bioelectronics, virus particles
2 Currently ~60% of global clinical pipeline
### Innovation trends open up new opportunities

#### Novel technologies

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Source: Courtesy McKinsey analysis
Global pharma/biotech clinical development pipeline

Source: Courtesy McKinsey analysis
Innovation incentives will remain critical

From treatments to cure and from blockbuster to precision medicine

• Gene-/cell therapies bear the potential to cure diseases and provide therapies that are very targeted, precise and personalized
• This poses a challenge as the R&D cost/patients is very high at this point in time and the reimbursement will not be based on repetitive use of the treatment over a long period of time
• Personalized medicine will increasingly be based on multi-omics selection including genomics, metabolomics, microbiome profiling, proteomics, etc.

From single data points to real world data (access to data a key question)

• Big data collection, consolidation and analysis will be powerful tools to optimize patient selection, accelerate and focus drug development and facilitate international co-operation
• New business models are established in healthcare which are not based on medical treatments but rather on the gathering and interpretation of data.

Investors will look carefully to the signals the world community is giving them as to whether investment in healthcare innovation remains attractive.
Currently, private investors/companies invest > 150 billion USD every year!
Contact us to follow up!

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