Shaping Programs around Commercial Elements
June 27, 2018

Dr. Turck will detail ways to incorporate commercial strategy into every stage of a life science product’s development. He will discuss the market-to-product thought process required for a company and its intellectual property to realize their full potential.

Roland Turck, MD
Managing Partner, TurckBio

Co-Founders:
Michael Welling, Partner, Meridian Risk Management
Joanne Gere, Executive Director
"Bringing together scientists, engineers, and clinicians from many companies and institutions is the best way to stimulate future research collaborations."

Dr. Carla Romney, Fordham University
Welcome!

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Research Community Resources

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Westchester Biotech Project
Building Opportunity Density™
Partnership with the Institute for Life Science Entrepreneurship and CUNY

Innovation in Research

Rare Disease Symposium

Tauopathy Colloquium

CAUTION
WATCH YOUR STEP!

Young Investigators

Consortium on Translational Research in the Microbiome

Westchester Biotech Project
EUROPE
Thank You to our Community Partners, Alliance Partners, and Participants!
WESTCHESTER BIO:
SHAPING PROGRAMS AROUND COMMERCIAL ELEMENTS
WEBINAR JUNE 27, 2018
ROLAND TURCK MD

- Medical Doctor trained in Germany, France and USA
- Former president of the global Specialty Medicine Business Unit and member of the global Executive Committee of Bayer Pharma
- Specialty medicine expert: oncology, neurology, rare diseases, ophthalmology, diagnostic imaging
- Broad and deep operative experience in clinical development and commercialization
- Extensive P&L experience
- Large Pharma and Biotech experience
• Strategy
  • Build and grow a business
  • Build and optimize portfolio and pipeline
• Clinical development strategy for successful reimbursement and commercialization
• Internal and external asset and pipeline review
• Business development: Identification of external opportunities
  • In- and out-licensing
  • M&A opportunities
• Organizational development
• Commercialization strategies
• Execution support
US MARKET – BIGGEST MARKET IN THE WORLD WILL CONTINUE TO THRIVE

• Unmet need
• New technologies
• Innovation rewarded
• Solid IP
• Professional regulatory environment
• Sustainable growth (costs are managed inefficiently but are still being contained)
SPECIALTY MEDICINE WILL CONTINUE TO DRIVE GROWTH

• Abundancy of new technologies continues to drive growth

• Most will be specialty medicine drugs

• Most assets will originate from biotech
REIMBURSEMENT FOR SPECIALTY MEDICINE DRUGS IS FAVORABLE

- Specialty medicine drugs will continue to be funded generously in the US

  • CMS mandate:
    - Part D Plans are generally required to cover “all or substantially all drugs.”
      - Anti-neoplastic drugs
    - Cover at least 2 drugs in each category
      - Orphan drugs
  
  • Commercial payers and providers will make their own judgement about benefits of a drug
    - Hurdle for what is considered meaningful benefit continues to go up

![Chart showing availability and reimbursement status of 49 cancer medicines launched globally 2010-2014.](chart.png)
TIME FOR INCREMENTAL INNOVATION IS OVER, BREAKTHROUGHS THRIVE

• Incremental innovation (me-toos) is dead
  • No longer receive premium pricing
  • Face major commercial hurdles
  • ROI problematic

• The paradigm is “breakthrough innovation”

• Patient centricity: not statistical significance matters but meaningful patient benefit
  ➢ Cancer: OS, cure, QoL
ONCOLOGY SETTING THE TREND – AWAY FROM BLOCKBUSTER MODEL

- Price
- Market share
- Scientific rationale
- Effect
- Safety

Personalized (TRKfus gene)
- Specific mutations
- Across cancers
- Biomarker driven

Targeted (VEGF)
- Target present in some but not all cancers
- Effective and better tolerated

Chemotherapy
- Many cancers
- Effective but not well tolerated
TRADITIONAL SEQUENTIAL DEVELOPMENT MODEL

- Model designed for old incremental innovation model
- Well defined development program

Today:
- Specialty medicine, target small subsegments, countless development options to shape a product
- Fast to market developments
- FDA less of a hurdle than competition and reimbursement
- P2/P3 data are the data a company will launch with
• Assess what is needed to compete successfully
  • Competition
  • Payers
  • (International)
• Match with FDA requirements
• Design development program accordingly – shape the product
• Fast(er) to market development strategies
• Align with investor thinking
CLINICAL DEVELOPMENT MINDSET NEEDS TO SHIFT

- Development programs need to focus on reimbursement and commercial needs as well as FDA requirements

- Differentiation! Creativity!
  - PD-(L)1 inhibitors vs. Hep C medication
  - Understand and leverage specific properties of an asset
  - Creativity to find the right indications and patient subsegments
  - Rigorous proof of concept trial design
  - Leverage technology in trial design

- Clinical and commercial capabilities must merge – commercial input into development programs early
DEVELOPMENT NEEDS TO FOCUS ON INNOVATION AND DIFFERENTIATION

Best launches:

- 1<sup>st</sup> in class
- 2<sup>nd</sup> in class
- Differentiated

Success is clearly driven by the degree of meaningful innovation
SOME GOOD DRUGS FAIL IN DEVELOPMENT

Issues:

• “Large indication trap”
  • High costs, long trials, competition
  • e.g. nivolumab 1L NSCLC

• Phase 3 not based on Phase 2 data or on not pre-specified subgroup results
  • e.g. solanezumab

• Ignore safety signals
  • e.g. SGN-33

• Endpoints not supported by trial design (OS in earlier stage trials)

• Portfolio logic: “best of a bad breed”
  • Genetech vs. others

• Go where everyone else goes – lack of differentiation
  • e.g. PD-(L)1 inhibitors
SOME AVERAGE DRUGS SUCCEED IN DEVELOPMENT

Opportunities:

• Biomarker defined subsegments where asset works best
  • Expand from there (e.g. ALKi)

• Orphan indications with high need and few options
  • e.g. Merkel cell carcinoma / Bavencio

• Combinations of active assets in particular IO
  • Be careful about great MoA with little or no single agent activity (e.g. IDO)

• Non standard but FDA approvable endpoints
  • e.g. apalutamide MFS

• Underserved settings
  • e.g. Maintenance in high risk patients with meaningful surrogate endpoint
DEVELOPMENT STRATEGIES

• PoC trials
  • Show that your drug works, design trial accordingly
    • Single agent if it can show a “trend break” (e.g. oncology) for a meaningful endpoint (e.g. ORR)
    • Controlled trial
    • Targeted population leveraging MoA
  • Vast majority of P1 and P2 trials does everything but

• Trial design strategy
  • Large vs. small indications
  • All comer vs. biomarker and other enriched population
    • Identify options early on and test
  • Endpoints (FDA, clinical relevance, payer relevance)
  • Sequence of programs: indication expansion strategy

• Find your niche!
  • Leverage what is unique about your asset
  • Meaningful impact on patients lives
  • Limited competition
  • Manageable trial program
SUMMARY

• The US market offers unique opportunities but is also challenging
• Innovation and differentiation in specialty medicine drives growth and success
• Development mindset needs to broaden from a regulatory to an innovation focus
• Thinking backwards from what is needed to be commercially successful and design the development program accordingly is critical
QUESTIONS?

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Stay in Touch!

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