

PPIP Meeting

10/29/2020

Fastest 3 Minutes in Pharma

- AZ/Daiichi Sankyo cancer collab Enhertu gains priority review with FDA for Stomach Cancer Indication and is challenging Kadcylla in 2nd line breast cancer
- GSK vaccine sales take hit in Q3 due to COVID- 19, similar story for Novartis blockbuster Cosentyx
 - Net effect of COVID on sales due to avoidance of doctors office??
- Sanofi/SK bio Flu vax suspended in South Korea due to deaths after vaccination
- Merck's Pneumovax23 and Pfizer's Prenar13 are running low in Europe due to surging demand, drugmakers are in a pinch despite efforts to increase supply
- Agios as withdrawn Tibsovo application for EMA Approval
- Biogen looking at potential cost cuts going into FDA AdCom meeting for priority drug Aducanumab and facing pressure from external competition

COVID Updates

- Pfizer interim phase III data on mRNA based COVID-19 vaccine unavailable due lower than expected event rates, may jeopardize launch schedule
 - Other companies in late stage development include Moderna, J&J, and AZ/Novavax
 - Prominent vaccine companies GSK and Sanofi pledge to provide 200 Million Doses to a global vaccination despite not leading the race to market
 - Moderna has finished Phase III enrollment
 - FDA NOT REQUIRING MANUFACTURING INSPECTIONS BEFORE EMERGENCY USE
 - Reports of Conflict between HHS secretary and FDA commission after stricter FDA guidance on vaccination
- Remdesivir(Veklury) received FDA approval for use in COVID-19 requiring hospitalization despite conflicting data from recent WHO clinical trial
- Lilly production plant hit with FDA warning, it produces COVID Ab as well as trulicity, raising quality concerns

Future of Healthcare within Pharma - Shane

- Resources:
 - [A Vision for Medical Affairs in 2025](#)
 - Learn more about future of med affairs within pharma/biotech
 - Envision possible roles/fellowships you may fit into
 - What niche roles in med affairs will be created?
 - [Health 2030: A Prospective Analysis of Health Innovation](#)
 - Learn about areas with high unmet needs
 - Advancements in technology and breakthrough innovations to improve outcomes
 - How will these be priced? How will we determine efficacy and safety (no long term data)? Interpatient variability? Generics??
- Message me if you have any questions or just want to talk!
 - 412-609-1317
 - sjs193@pitt.edu

Unique Opportunity

RACAPITAL

[ABOUT US](#) ▾

[VENTURE](#) ▾

[TECHATLAS](#) ▾

[JOIN US](#)

[KNOWLEDGE](#) ▾

[COVID-19](#)

[FAQ](#)

[CONTACT](#) ▾

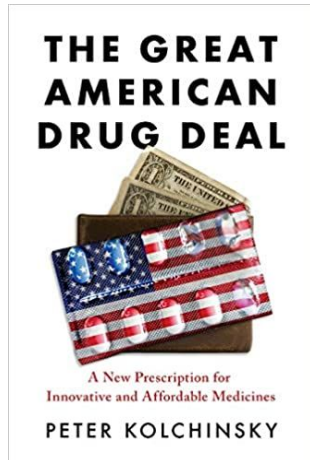
[HOME](#) / [COURSES](#) / **FALL 2020**

The Business of Biotechnology: Virtual Short Course, Fall 2020

OPTIONAL LIVE SESSIONS: NOVEMBER 5, 12, & 19, 5-7 PM ET



- Free to sign up until November 2
- Great way to learn about pharmaceutical industry
- Optional live sessions
- Only requirement is a \$17 book on amazon
 - Free if you have audible



<https://www.racap.com/courses/the-business-of-biotechnology-Fall-2020>

Questions?