SYNOPSIS

4th Boston Biotechnology Virtual Summit –

15 OCT 2020 -11AM-01PM US EDT

The 4th Boston/Boston●Paris Biotechnology Summit was held successfully on 15 October. A record of 250 participants registered, mainly from the USA and France but also from Australia, Belgium, Canada, Denmark, Ecuador, Germany, India, Japan, Korea, Spain, Sweden and the UK. Broad representation was seen from academic centers (Biotechnology, Business & Medical), biotechnology companies (close to 50 CEO/C-Level Executives), expert consultants, the FDA, Pharma (AstraZeneca, Bayer Pharmaceuticals, Johnson & Johnson, Merck, MSD, Pierre Fabre, Roche, Stallergenes Greer, Servier, Sanofi Pasteur, Vertex Pharmaceuticals, etc.) and CROs, and diplomatic representatives in the USA were in virtual attendance.

The Organizing & Program Committees convened renowned experts to analyze and discuss the treatment / prevention of Covid-19, as well as its impact on the biotechnology industry. Their Covid-19 expertise ranges from the "trenches" of everyday clinical care to the complexities of public policy & decision making. The event was held in collaboration with Mass Bio *Hub* Conference Services.

Panel ①: Covid-19 Prevention. Full review of vaccines and public prevention policies.
Moderators: S Gharakhanian, Program Chair, Cambridge MA & B Malkin, McDermott, Will & Emery, Washington DC
Speakers:

- Professor B. WALKER, Director, Ragon Institute of MGH, MIT and Harvard. Co-Leader, Massachusetts Consortium for Pathogen Readiness (MassCPR). Professor, Harvard Medical School & MIT, Cambridge MA. Research Associate CAPRISA Center, South Africa.
- Professor J-F DELFRAISSY, Chair of the Covid-19 Scientific Committee advising the Government and President Emmanuel Macron of France.

Panel ②: Finance, Investment & Leadership in the new Covid-19 era.
Moderator: C Le Camus, Vertex Pharmaceuticals, Boston MA.
Speakers :

- P. DOUGLAS, Ed.D. (Harvard University), Published Author on Leadership, Board of Overseers Member, Fmr. Government & Pharmaceutical Executive, and on Boston's Business Journal's Top 10 Executive Coach, Somerville MA.
- S. KORNOWSKI, Pharm D, MBA. Managing Partner, Gurnet Point Capital (GPC), $2 Billion Healthcare Fund, investing long-term capital & supporting entrepreneurs, Cambridge MA.

Panel ③: Covid-19 Treatment. Full review of treatments in clinical trials and medical care.
Moderators: V El Harrar, PPD Biotech & N La Monica, Johnson & Johnson, Boston MA.\

- Professor D. KURITZKES, Chief, Infectious Disease, Brigham & Women's Hospital; Professor, Harvard Medical School, Boston MA.
- Professor K. LACOMBE, Chief, Infectious Diseases, AP-HP St Antoine Hospital; Professor of Infectious Diseases, Sorbonne University Medical Schools, Paris France.

Soheila GHARAKHANIAN, President of Bland of Concept LLC, Summit Producer, opened and expressed her thanks to the Speakers and Moderators … Their engagement, know-how and expertise regarding the pandemic and it's societal and management issues are priceless, cherished and reassuring for all. Since 2017 the Summit has been supported by prominent companies and organizations. She expressed thanks to the generous 2020 Sponsors: McDermott Will Emery, PPD Biotech and CPL Physicians, most of which have been present since the first edition. Four years of collaboration, trust and support means a lot to the Organizing Team.

Dr Pravin CHATURVEDI, Honorary Chair & CEO of Oceanyx Pharmaceuticals, thanked and congratulated the co-founders and organizing team of Shahin and Soheila Gharakhanian for putting together the 4th Boston Biotechnology Summit, as well as the International Program Committee involving many distinguished professionals. (listed on the summit website). He continued "*There is an old adage that states that God always forgives, humans often forgive and nature never forgives. So here we are in 2020, exactly 100 years after the 1919 flu pandemic, dealing with another respiratory virus pandemic. When one reviews the history of medicine, respiratory diseases as a class are not, nor have ever been, under control. Although they are the most frequent cause of death, we do not know how to prevent respiratory diseases and deal with respiratory viruses. It is important to note that respiratory viruses show no correlation between viral load changes and clinical symptoms. Neither are the clinical symptoms predictable. In addition to the challenges of not having an adequate control of respiratory viral infections, we need to remember that public indifference, lack of knowledge of the contagion effect of respiratory viruses as well as their inconsistent periods of incubation have resulted in different infectious sequelae. We have all witnessed numerous strains of the influenza virus epidemics over our lifetimes and we have had limited success (at best) in preventing the contagion effect".* He went on to add *"So today we have assembled a group of experts that will provide some of their insights and knowledge about what we know of COVID-19 and what progress we have made in the ability to detect and diagnose it accurately, the success achieved with various prevention measures including but not limited to isolation and social distancing, and vaccine initiatives and progress towards the development of novel antiviral treatments that will enable better clinical outcomes for those who are infected by COVID and/or are hospitalized with severe infections. Since we have historically not done well with respiratory viruses and their clinical sequelae, we expect that while we may not have novel solutions for the prevention and/or treatment of COVID, we will be able to pose and discuss the Right Questions. In this regard the three panels we have today will discuss the progress made with our vaccine and therapeutic initiatives, and since all of this requires capitalization, we will discuss the funding required to address this global pandemic. Our creative friends from Hollywood made a summer blockbuster about 25 years ago in which planet earth was taken over by aliens that intended to destroy the planet. It needed all of humanity to come together, and COVID has reminded us that during this global pandemic, we need all hands on deck".* Shahin Gharakhanian started the first panel by reminding participants of the dire social consequences of this pandemic, including some references from the press: Boston Business Journal, The Economist Le Monde, Wall Street Journal, etc.

Conclusions of the Presentation by Bruce WALKER

- SARS-CoV-2 causes damage to the immune system and lowers natural antibody responses.
- Vaccine developments for Covid-19 are progressing at an unprecedented speed, building on advances in HIV and other fields.
- Without effective treatments, a vaccine is critical to enabling a broad return to work.
- Vaccines will be "available" as early as late 2020.
- Vaccines will be more "widely available: by the second half of 2021.
- The goal is still to obtain as many vaccines as possible in order to meet global demand.
- Masks, physical distancing and contact tracing are as good as any likely vaccine candidate in development.
- There is much still to be done.

Conclusions of the Presentation by Jean-François DELFRAISSY [Recorded 10.OCT.20, 10 AM EDT]

- The expertise of the Scientific Council and its contribution to decisions by the executive: most of the proposals accepted.
- The "third medical power" is a figment of the imagination of the press. The Council has no influence on material issues such as access to testing or masks.
- The Scientific Council makes every effort to be transparent: publication of opinions and notes, hearings at the National Assembly, the Senate and the Economic, Social and Environmental Council (CESE), and interventions in the press, etc.
- There have been calls for a citizen committee from the Scientific Council, the National Healthcare Commission and the National Commission on Human Rights, but so far the response from the French government has been negative.
- The principal doctrine followed is that of personal responsibility and choices for citizens. Nothing is imposed and everything is voluntary regarding the choices for each measure: schools, testing, isolation after the end of lockdown for positive patients or older people who are at greater risk, etc.

In conclusion, we refer to an article published by R. Horton in *The Lancet* on 4 October 2020 and entitled: Science and the Breakdown of Trust:

"The COVID-19 pandemic is entering its most dangerous phase. There is a mounting breakdown of trust. Not only between politicians and the public. But also among politicians and publics with science and scientists. This breach of faith with science is far more threatening. For the public is slowly turning against those who have sought to guide the political response to COVID-19. As countries face a resurgence of coronavirus transmission, scientific advisers are recommending further restrictions to our liberties. There is now a palpable public reaction against these mandates."
< *Tzvetan Todorov, in his book In Defense of the Enlightenment (2006), was surely right that "debate rather than consensus" characterizes our modern era. We should not be afraid of disagreement* >

Key points from the Presentation by Priscilla DOUGLAS on Leadership

- React
- Relate
- Recalibrate
- Realign
- Re-imagine
- Re-engage
- Re-design

Key points from the Presentation by Sophie KORNOWSKI on Finance & Investment

- Best year for Biopharma financing.
- The strong performance of biotech indices has enabled companies to raise record amounts of capital.
- Biopharma M&A sluggish in 2020 with some activity during Q3.

Key points from the Presentation by Daniel R KURITZKES on Covid-19 Treatments

REMSIDIVIR

- RNA-dependent RNA polymerase inhibitor
  Displays *in vitro* activity against Ebola, SARS, MERS and SARS-CoV-2
- Sub-micromolar EC_{50} against SARS-CoV-2 in vitro
- Effective against SARS-CoV-2 in the NHP model

CORTICOSTEROIDS

- RECOVERY Trial: Effect of dexamethasone on 28-day mortality by level of respiratory support

CONVALESCENT PLASMA

- Anecdotal evidence and uncontrolled trials suggest convalescent plasma *may* provide a benefit in patients with severe COVID-19
- Any benefit appears to be linked to the early administration of high-titer CCP
- Little or no benefit in critically ill (intubated) patients
- Randomized trials ongoing
- IDSA guideline panel only recommends COVID-19 convalescent plasma in the context of a clinical trial
- DHHS COVID-19 Treatment Guidelines state:
  There are insufficient data to recommend either for or against the use of convalescent plasma for the treatment of COVID-19. Convalescent plasma should not be considered standard of care for the treatment of patients with COVID-19.

MONOCLONAL ANTIBODIES:

- Numerous SARS-CoV-2 mAbs have been produced
- These mAbs reduce virus load, protect against infection and/or reduce lung injury in animal models
- Multiple human clinical trials are ongoing for the treatment and prevention of COVID-19
- Preliminary results of phase 1-2 trials with the LY-CoV555 and REGN-CoV2 cocktail are encouraging
- No safety concerns to date
- Phase 3 data required to demonstrate clinical efficacy
- **Applications for EUAs with respect to Lilly and Regeneron mAbs under review**

Selected points from the Presentation by Karine LACOMBE on experience in the medical care of Covid-19. [Recorded 14 OCT 20, 9:30 AM EDT]

Challenges faced by Medicare Care for Covid-19 in Hospitals (France)

- Challenge #1: to identify patients who may rapidly deteriorate following arrival from the emergency room,
- Challenge #2: to manage without any known and effective therapy for many weeks,
- Challenge #3: to maintain other ID activities in the context of wholly "Covid-oriented" activities in the hospital.

Other clinical challenges:

- Neuropsychiatric complications.
- Global health impact: e.g. liver-related deaths.

Summit Conclusions by Shahin GHARAKHANIAN

- We need to re-engineer clinical trials & their road maps; i.e. study design & biometric methodology, regulatory approval, financing and clinical operations, in order to respond to clinical research questions with fewer N and shorter time frames.
- "We need multiple strategies to prevent and treat Covid-19, including PrEP, PEP, and vaccines, since it's highly unlikely that we'll hit a home run on the first trial of any
- intervention" (Celum C et al., NEJM, 10.07.2020)

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