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Meeting with J&J of 11 March 2021

Key takeaway:

- Will try to keep up with the delivery of agreed doses for Q2 or at least very close to that number.

- Key bottleneck are materials and disposables

Present J& J:

- [redacted]

GROW

- Hubert Gambs
- [redacted]

Objective of the meeting: making sure that J&J can deliver what was agreed. In view of ramping up production, understand what bottlenecks are and how TF can be helpful in this respect.

State of play

- J&J: were investing in R&D in vaccines, not big manufacturer in vaccine, first vaccine EBOLA production done by CMOs.
- Also had to set up a network of supply chain. Core facility in Leiden, engaged with external partners, building up network around the world
- Some delays with start up with one of the sites in the US (for early delivery to the EU, therefore pressure for Q2)
- Still commit to deliver 200 Mio, second half of April, as close as possible to what was agreed in Q2
- Nine sites in basic network, added Sanofi in France (from end Q3/Q4), Merck in US, tie in of facility of Leiden. <u>Now stopped for a few weeks, then functioning again in April.</u>

Current bottleneck is not fill&finish, much more worried about materials and disposables.

Merck only foreseen to support the US.

Need for a global supply chain, fully integrated supply chain up and running from Q3, but probably already in Q2.

Drug substance: from plant in Leiden. <u>For the volumes in the second quarter, part of that volume is coming or has come from the US (f&f) and part is coming from Leiden.</u>
<u>Drug substance produced in the US, no issues expected for DPA, will go through South-Africa</u>. US will not activate executive orders or FDA for drug orders.
Reference to call with US COVID coordinator; to ensure free flow of good between US and EU.

Fill&Finish: plan was Catalent running in Q3, until then fill&finish in the USA, but now J&J will have it done by Aspen in South-Africa. Delivery second half of April, mapped out day by day; critical path leads us to 22 April, looking at further opportunities to accelerate further. In one week time, J&J may be more sure.

For the regulator aspects, J&J is waiting for some exemptions, working with DG SANTE on this.

It will not be possible to cooperate with Nordic Bavaria in Denmark: this is not going ahead

Reif Jorge should be up and running in Q3.

IDT, clinical fillers in Germany in final stages of signing. Issue may be material and components, to ensure continuity of materials, come from three different suppliers, encouraging suppliers to make products available: bags, systems used around those bags, performance validation tests would be needed if they go to another bag. <u>TF will reach out to these three suppliers, see if they can be prioritised</u>. It is a block. TF would need to have exact information on suppliers and the products needed.

J&J made reference to the initiative of last year for ICU medicines, where companies could cooperate in view of upscaling its production. J&J is wondering whether the same could not be done for materials, letter of comfort to work together from DG COMP. It was interesting to have a platform, seeing who has what, and competition wise it was blessed.

Then the matchmaking event was discussed. Suppliers need to have some predictability. Matchmaking of potential suppliers, building it into the matchmaking event and use it more constructively. We should look out to the next six months with other materials. List that could be shared. J& J shared the materials that they would need in the coming month. GROW would contact the companies.

One question: if it could be done competition wise, Merck to give pieces us now, swopping orders. How to best put their supplies that keeps everyone going. Question of changing the order will be checked.

Matchmaking
To complete J&J network of partners, J& J is welcoming at both matchmaking events:

1. Matchmaking to manufacturing companies for APA companies
2. Matchmaking to suppliers

The more specific the better, TF expect big participation of companies that are active in the sector.

J&J wishes to have another meeting with TF next week. In a week from now, J&J will now more.

Global company, everyone benefits if there are shipments from EU to US and from US to EU. Export authorisation scheme: could also prevent them from delivering things as quickly as possible.