Accelerate Biotechnology

Rapid response, low-cost manufacturing of viral vaccines against emerging infectious disease threats

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Batavia Biosciences

**HIP-Vax® Technology**

- **Batavia Biosciences**
  - Centre of Excellence biopharmaceutical CDMO with facilities in the Netherlands (Leiden) and USA (Woburn, MA)
  - 14 years of experience in process development and clinical manufacturing
  - HIP-Vax® established for viral & vector vaccines using $60m in grants and contracts since 2016 from Gates Foundation, CEPI, DTRA

- **HIP-Vax® delivers low CoGs: <$1 per dose for vaccines**
  - High cell density production based on innovative fixed-bed bioreactors (scale-X)
  - Reduced facility footprint (CAPEX)
  - Reduced labor and consumables (OPEX)
  - Reduced bioprocessing timelines
  - Commercial manufacturing at lab scale (1000L output in 50-100L harvest)

- **Technology applicable to multiple product modalities**
  - Viral & vector vaccines (e.g. based on Vero and MRC-5)
  - Virotherapies, such as gene therapy or oncolytic vectors (e.g. based on HEK293)
  - Recombinant proteins (based on CHO)
HIP-Vax® highly intensified manufacturing technology

**Biological materials**
- GMP Cell substrates:
  - Vero
  - MRC-5
  - HEK293
- GMP vaccine seeds:
  - Measles EZ
  - Rubella Wistar
  - WHO Sabin Polio type 1
  - WHO Sabin Polio type 2
  - WHO Sabin Polio type 3

**Highly intensified manufacturing**
- Based on innovative, fixed-bed manufacturing equipment
- Achieves ~20-fold increased process intensification compared to current technologies
- Output at 50L scale equivalent to 1000L

**Platform approach**
- Generic platform processes developed for multiple vaccine modalities (eg: VSV, MV, Adeno)
- Reduces time to clinical POC to <6 months and to commercial manufacturing in <10 months

**Low COGs**
- Production in small footprint, low-cost facility reduces CAPEX and hurdle to manufacture
- High yields, short production times & low FTE requirement reduces OPEX
- COGs below 1 Euro per dose

**High output**
- High vaccine output per year (hundreds of millions of doses)
- Flexibility to deliver multiple vaccines from single facility & respond quickly to outbreak threats

Cells, virus seeds, and process available for partners through licensing
A low cost manufacturing process for technology transfer

Available for inactivated Polio, Measles and Rubella and Rota

- Technology developed under global access commitment
  - Licensed to developing country vaccine manufacturers
  - Obligation to deliver % of manufactured product to GAVI and UNICEF agencies at defined price

- Technology Transfer include
  - Process know-how
  - Biological materials (GMP cell lines and GMP seeds), for Rota and Rubella a license agreement with respectively Wistar and MCRI needed
  - Safety and containment (for Polio) documentation
  - Equipment and consumables provided by Univercells. For Rota initial process developed using CF’s, initial data using Scale-X bioreactor is available
New clinical & commercial manufacturing facility in 2024

Facility located in Leiden, NL (12,000m², 5 Floors)
- Design, engineering & permitting completed, constructors engaged and procurement ongoing
- Construction to start early Q2 2023
- Expected facility qualification completed H2 2024

Manufacture of Viral Vaccines and Virotherapy Products
- 6 Drug substance manufacturing suites (2 clinical, 4 commercial)
- Clinical and commercial drug product aseptic filling & packaging, warehouse, QC, goods in/out
- Up to 20 clinical batches, 88 commercial batches (150-200M doses) per year
- Based on scale-X / HIP-Vax at 600M² scale, with capability for standard 1000L scale STR manufacturing
Take away points

- HIP-Vax intensifies the manufacturing of vaccines
- Cost of Goods less than $1 per dose
- Robust and scalable platform
- Cell substrates and Virus seeds available for partners through licensing
- Commercial manufacturing facility ready at the end of 2024
Thank you for your time

Feedback
We value your input and would like to hear your thoughts on the presentation,

Next steps
Let's take a moment to discuss and map out the next steps towards our shared goal.

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