Cell Bank and Process Development Services for Vaccine Production

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About Nuvonis

- Nuvonis is biotech company based in Vienna, Austria, providing **innovative cell banks** and technical support for **vaccine process development**
- The Nuvonis team is **highly experienced** in cell line and process optimization for vaccine production
- The **proprietary and fully characterized Nuvonis Vero cells** are cultivated without animal derived media or protease additives and are non-tumorigenic beyond the end of production passage. This cell bank can be licensed for viral vaccine and vector manufacturing
- We are offering a proprietary and **efficient virus purification process** for the generation of high purity vaccine bulk drug substance with low host cell DNA and protein impurities

Nuvonis‘ Vero Cell Banks for Manufacturing

- Master Cell Bank (MCB) and Working Cell Bank (WCB) cells are produced under **serum and animal-free** media conditions. Cells are passaged using **animal-free enzyme** formulations
- The use of a two-tiered cell banking system allows **unlimited production of** both **MCB** and **WCB vials**
- **Proven non-tumorigenicity** at EOP passage level 160 allows flexibility in terms of process scale-up
- Nuvonis’ GMP MCB and WCB cell banks can be **licensed at attractive terms**

Nuvonis‘ Vero Cell Banks are Fully Characterized

- Nuvonis‘ Vero Cell Banks have been tested according to national and international guidelines (US FDA cGMP – 21 Code of Federal Regulations, European Pharmacopoeia and ICH guidelines)

- The characterization includes
  - *Sterility, Mycoplasma, Endotoxin*
  - *Adventitious Viruses, Identity*
  - *Tumorigenicity at passage 160 (End of Production Cells)*

Nuvonis‘ Virus Purification Process

- Nuvonis has developed a **simple and highly efficient purification** procedure based on a combined precipitation step
- This purification method leads to **increased virus yield** (up to 90%) and **low** host cell protein and DNA **impurity levels**

Summary: Purification of Influenza Viruses

- **Optimized Combination Approach:**
  - *Clarification by depth filtration or centrifugation*
  - *Benzonase treatment*
  - *PEG precipitation*

- **Recoveries and Purity:**
  - *Infectious titer yield: 75% (average)*
  - *DNA depletion: > 99%*
  - *Total protein depletion: ~95%*

- **IP filed:** December 2016

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