Promising first-in-human, first-in-class, Phase 1b immunogenicity data of VRON-0200, a novel checkpoint modifier containing immunotheraputic, for HBV functional cure

**BACKGROUND**
- Limited options exist for chronic HBeAg-positive patients
- VRON-0200 targeting core and polymerase (Pol N & C), but not S-antigen

**PURPOSE**
- Evaluate the first-in-human immunogenicity and ongoing safety data in chronically HBV-infected patients successfully vaccinated with VRON-0200

**METHODS**
- This is a Phase 1b, multicenter, multinational, open-label, randomized trial in chronic HBV-infected patients
- Cohort 1a low: N=12, AdC6-primed – low-dose prime
- Cohort 1b low: N=12, AdC6-primed – low-dose prime
- Cohort 1b high: N=12, AdC6-primed – high-dose prime

**RESULTS**
- **Safety and Tolerability**
  - One patient had a leg cramp and flu-like symptoms; another patient had left arm numbness and papular rash, and the third patient had diarrhea

**IMMUNOLOGY**
- **Day 91**
  - For the 5 “responders”, the increase was more pronounced (4.0-fold)

**CONCLUSIONS**
- These are the highest immunogenicity data for any checkpoint modifier-containing vaccine of any kind
- Following a single intramuscular low-dose VRON-0200 vaccination (Cohort 1):
  - **Safety**
    - None had been tolerated with no SAEs or safety concerns
  - **Immunogenicity**
    - Even in patients with limited pre-existing immunity, VRON-0200 showed increases in T cell responses in the majority of treated patients
  - **Day 91**,
    - Several patients maintain T cell responses above their pre-treatment values
  - **Overall**, there was a 2.4-fold increase from baseline
  - **Cohort 1a**;
    - Of the 13 patients, 12 were male; mean age of 46 years, and baseline HBsAg of 244 IU/mL (range: 16–623)

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- **REFERENCES**

**DISCLOSURES**
- **Abbreviations**
  - **ELISPOT**
    - See Table 4 for definitions of peptide pools
  - **ALP**
    - Serum alkaline phosphatase levels
  - **SFU**
    - Spot-forming units
  - **TCR**
    - T cell receptor
  - **TEAE**
    - Treatment-emergent adverse events
  - **Tx**
    - Treatment
  - **ULN**
    - Upper limit normal
  - **vp**
    - Viral particles

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