One ATMP, Two Hospital Pharmacies, No Compromise !

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GERPAC EUROPEAN SOCIETY OF HOSPITAL PHARMACEUTICAL TECHNOLOGIES

COM25-60207

Background & Importance : Urgent request for a patient

- Rare genetic disease : dystrophic epidermolysis bullosa caused by a COL7A1 mutation → extreme skin fragility
- Treatment with Beremagene geperpavec (B-VEC), a modified HSV-1= **ATMP**

→ **No authorization for preparation within the local hospital pharmacy**

Objective : Implementation of a secure & compliant process for the weekly administration of this ATMP in our hospital, with the support of an authorized pharmacy department

150 km

Material & Methods :

November

- *13/11/2024* : Contact initiated by the dermatologist for continuation of B-VEC in our hospital
- *15/11/2024 :* Contact with the Regional Health Agency (ARS) to identify an authorized pharmacy
  → **Decision to subcontract preparation to Rennes University Hospital : authorization to prepare for other sites already in place & existing preparation agreement**
- *29/11/2024 :* Training with the pharmaceutical company marketing B-VEC

December

- Amendment to the sterile preparation agreement
- Review by the Drug Committee of the costs including transport, subcontracted preparation, and the drug itself. Estimated weekly cost > €24,000

January

- *08/01/25 :* Validation of staff protection procedures and ATMP waste management with the infectious risk team
- *15/01/25 :* First preparation & application at Rennes University Hospital
- *17/01/25 :* Preparation of dummy syringes and training of the nursing team at GHBS
- *22/01/25 :* First application in Lorient

Bibliographic & Regulatory Analysis

Results :

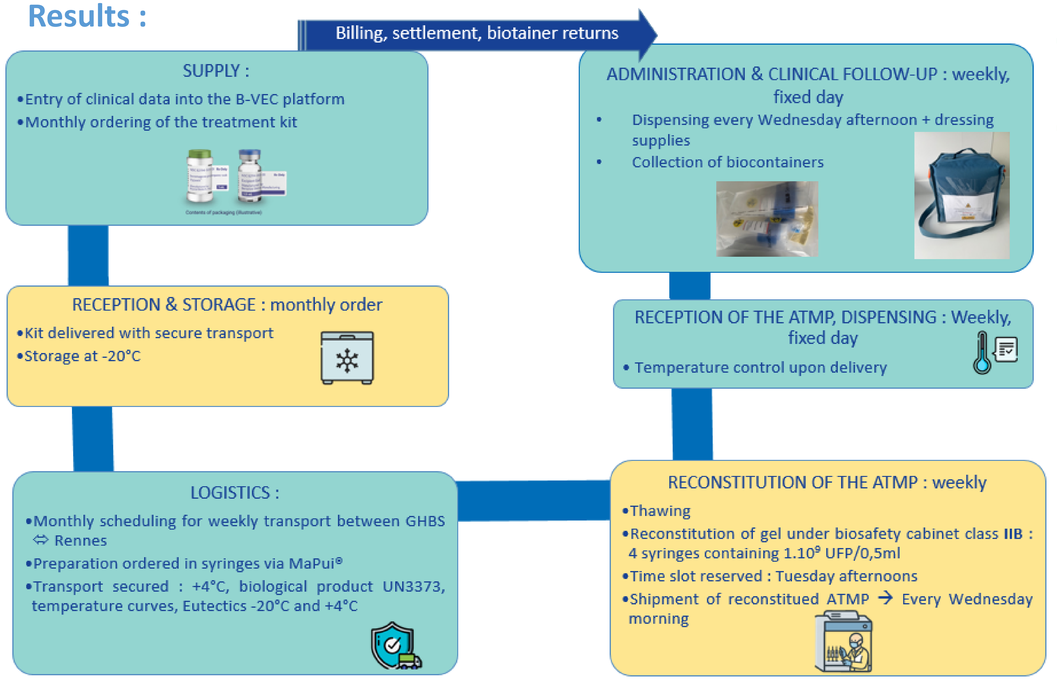

Figure 1 : Workflow established between Rennes University Hospital and GHBS : administrative, logistical & clinical

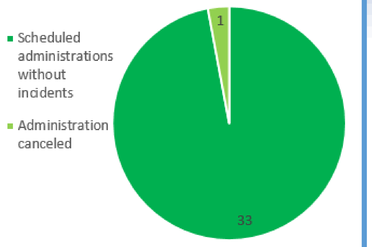

Figure 2 : Overview of administration since January 2025

Strengths :

- ☑ Close coordination with dermatology, day hospital and the pharmacy department
- ☑ Involvement of the hospital pharmacy technician : reception, traceability, dispensing, nurse contact
- ☑ Reduced travel burden for the patient : local care avoided long trips → **Major improvment in quality of life**
- ☑ Treatment effectiveness

Challenges :

- ☑ Strong dependence on the subcontracting institution
- ☑ Significant logistical risks : delays, road incidents
- ☑ Organization requiring strict follow-up and close coordination between both centers, for orders and production planning
- ☑ Additionnal workload for the university hospital, integrating new tasks into an already highly solicited environment

Discussion :

→ Logistical, regulatory, and organizational challenges raised by ATMP administration in a non-accredited center

→ Success of inter-hospital cooperation while ensuring quality and safety standards

→ A delicate balance, especially due to the additional workload borne by the preparing center

With the expansion of ATMPs, there is a need to rethink preparation and distribution models: extending authorizations, regional pooling. Beyond technical constraints, a key question remains: **how to guarantee equitable access to therapeutic innovation for all patients, across the entire territory?**