MARKET ACCESS OF ATMPs IN FRANCE : CHALLENGES AND OPPORTUNITIES

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CONTEXT

Advanced Therapy Medicinal Products (ATMP) are costly breakthrough innovations generally responsible for a paradigm shift in the way targeted diseases are treated. They offer a real prospect for the treatment and even cure of diseases previously considered incurable. Most ATMP granted marketing authorization (MA) at an early stage of development based on single arm trial.

OBJECTIVES

The objective of this analysis was to describe the market access of ATMPs in France.

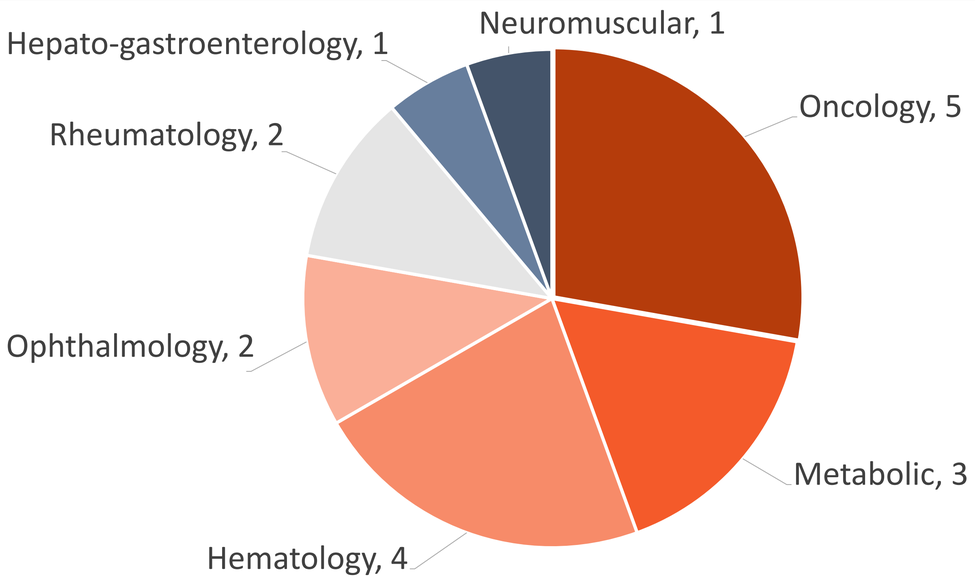
METHODS

We conducted an analysis of ATMP market access in France by collecting information related to EAP, reimbursement and pricing of ATMP published between May 29, 2013 and June 21, 2023.

RESULTS

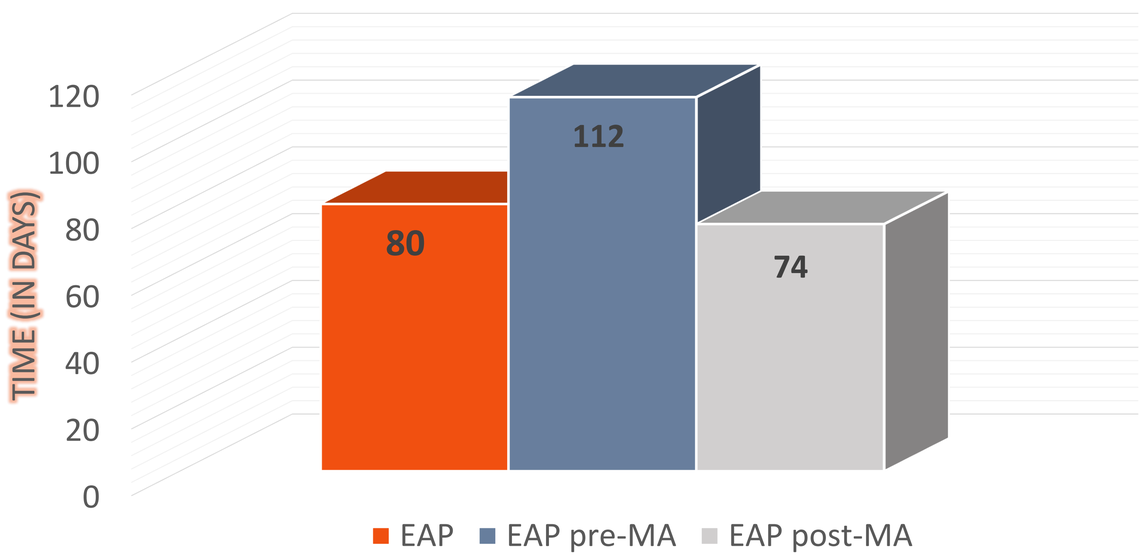
- A total of 18 ATMP were assessed, including 5 (28%) in oncology which is the most represented therapeutic area, 4 (22%) in hematology and 3 (17%) in metabolic diseases.

FIGURE 1. THERAPEUTICS AREAS OF ATMP EVALUATED BY THE HAS



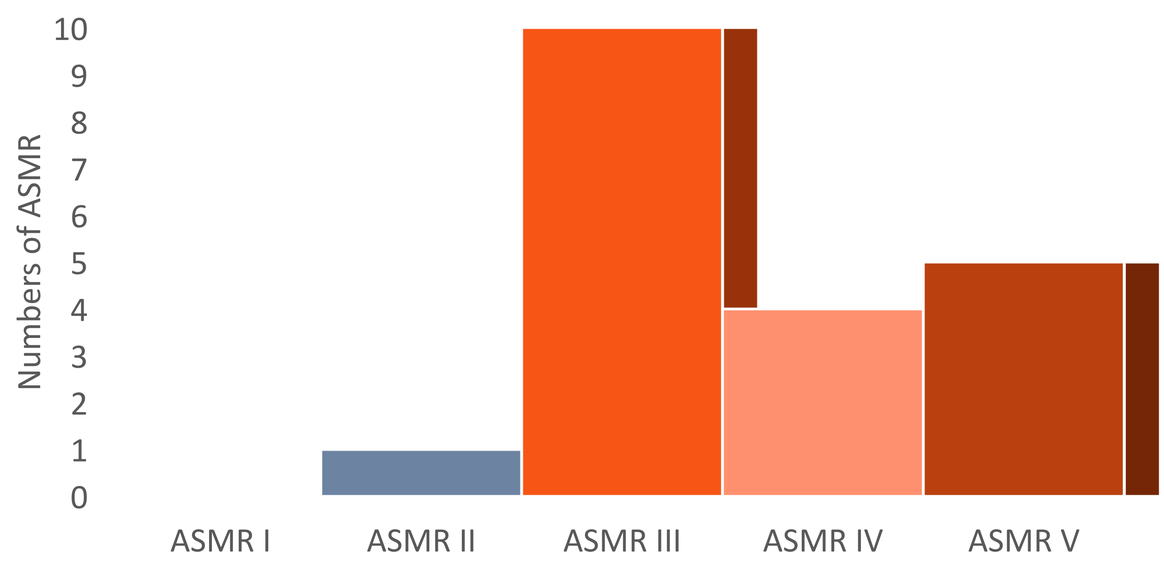
- Since the introduction of the new EAP process (July 2021), 12 EAP application were submitted to the HAS of which 10 (83%) granted an EAP authorization (only 2 before MA). Two applications were rejected because of insufficient clinical data.
- Average delay between administrative admissibility and EAP decision publication was 80 days and was longer for EAP pre-MA (112 days) than for EAP post-MA (74 days).

FIGURE 2. AVERAGE TIME (IN DAYS) BETWEEN ADMINISTRATIVE APPROVAL AND PUBLICATION OF EAP DECISION OF ATMP



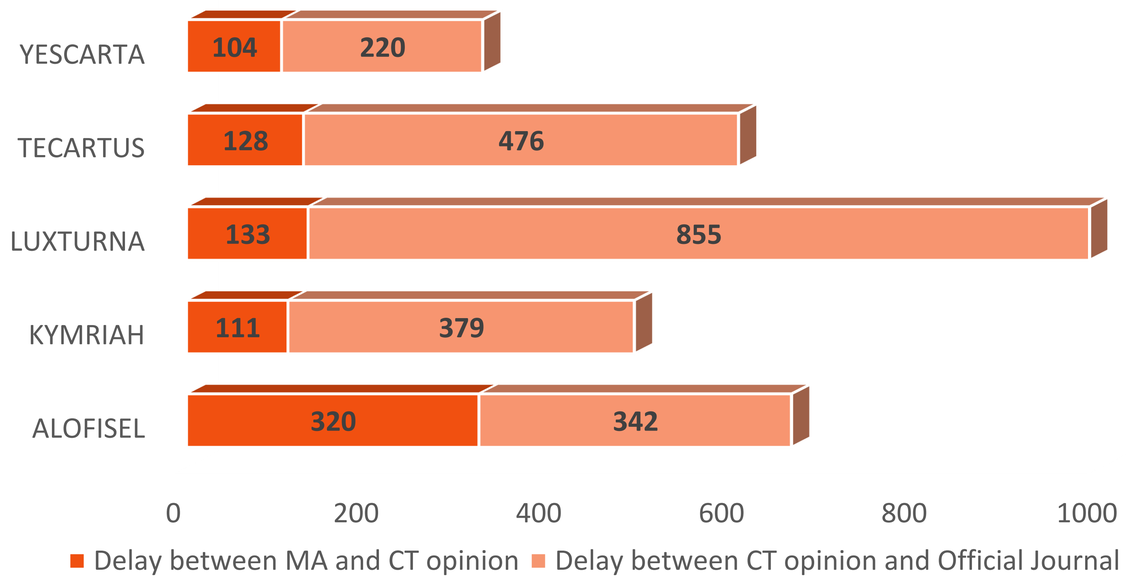
- In terms of reimbursement, 26 appraisals were published of which 20 were accepted for reimbursement (sufficient actual benefit) and 6 were not accepted (insufficient actual benefit).
- Among the 20 ATMP reimbursed, the Transparency Committee (TC) granted 1 (5%) ASMR II (important), 10 (50%) ASMR III (moderate), 4 (20%) ASMR IV (low), and 5 (25%) ASMR V (no clinical added value).

FIGURE 3. ASMR LEVELS GRANTED BY THE HAS



- Of the 16 ATMP evaluated by the HAS, only 5 are already commercialized (costly drug list).
- Regarding pricing, the mean delay between TC appraisal and price publication was around 15 months.

FIGURE 4. THE MEAN DELAY IN DAYS BETWEEN MA, TC OPINION AND OFFICIAL JOURNAL OF 5 ATMP COMMERCIALIZED IN FRANCE



CONCLUSION

EAP represent an opportunity for ATMP in France. The lack of robust comparative clinical data does not appear to be a barrier to launch an EAP. On the other hand, the lack of comparative data is always criticized by the HAS when assessing reimbursement and make it challenging to obtain high levels of ASMR (I-III), which is essential to obtain a level of price in line with the cost of these therapies.

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