

Understanding the Pricing and Reimbursement Outcomes of Advanced Therapy Medicinal Products in Spain

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OBJECTIVE

- > The objective of this study was to assess the key factors influencing the pricing and reimbursement (P&R) outcomes of Advanced Therapy Medicinal Products (ATMPs) in Spain.

METHODOLOGY

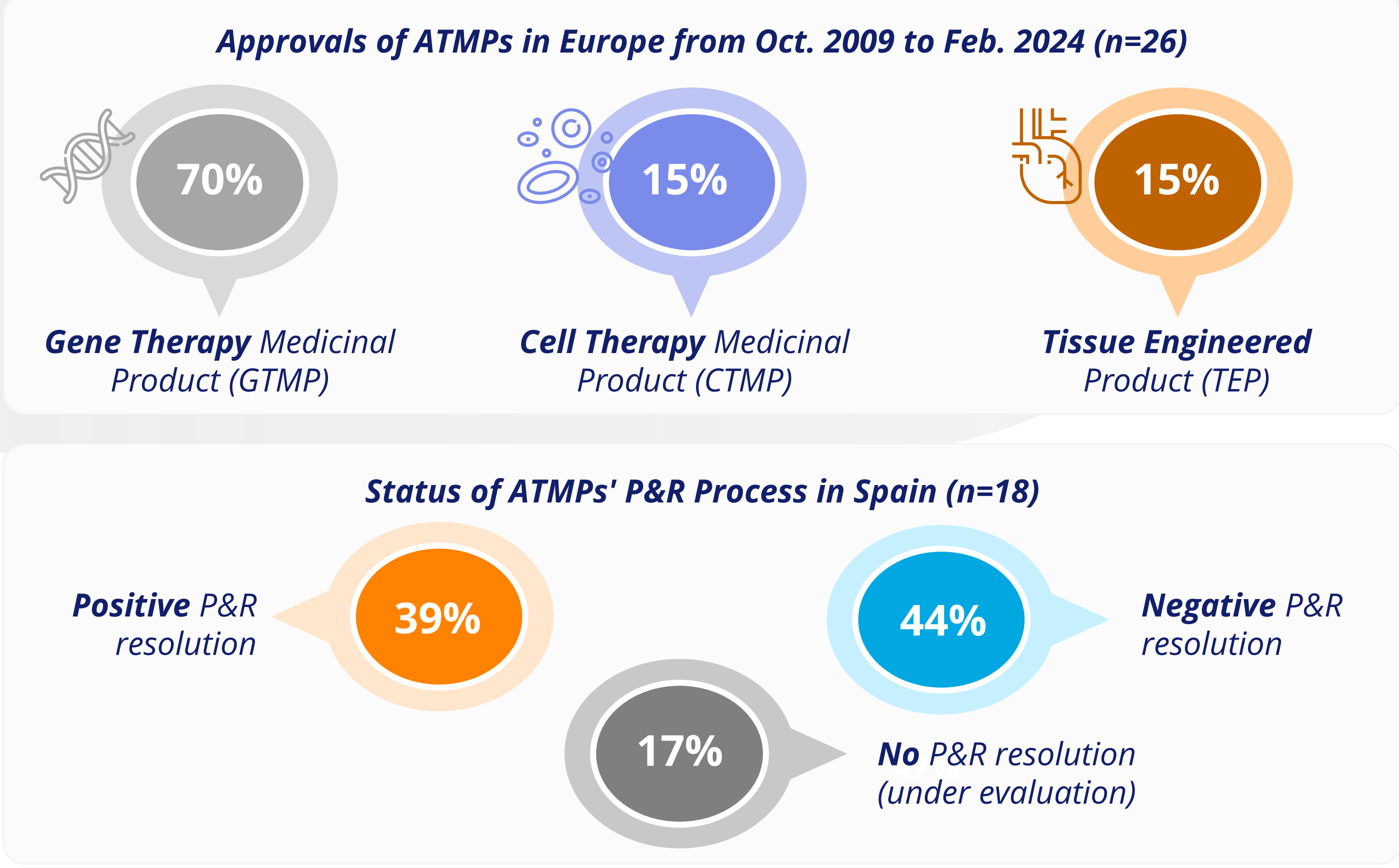
- > Secondary research was developed to analyse the ATMPs approved in Europe from October 2009 to February 2024 that entered the P&R process in Spain, and how different factors could impact drug availability and timeframes^{1,2}.

RESULTS

ATMPs Situation in Spain

- > A total of 26 ATMPs were approved in Europe. Of these, **18 initiated the P&R process in Spain**^{1,3}: 7 (39%) received a positive resolution, 8 (44%) a negative, and 3 (17%) were under evaluation (Figure 1^{1,3})

Figure 1. ATMPs' Overview



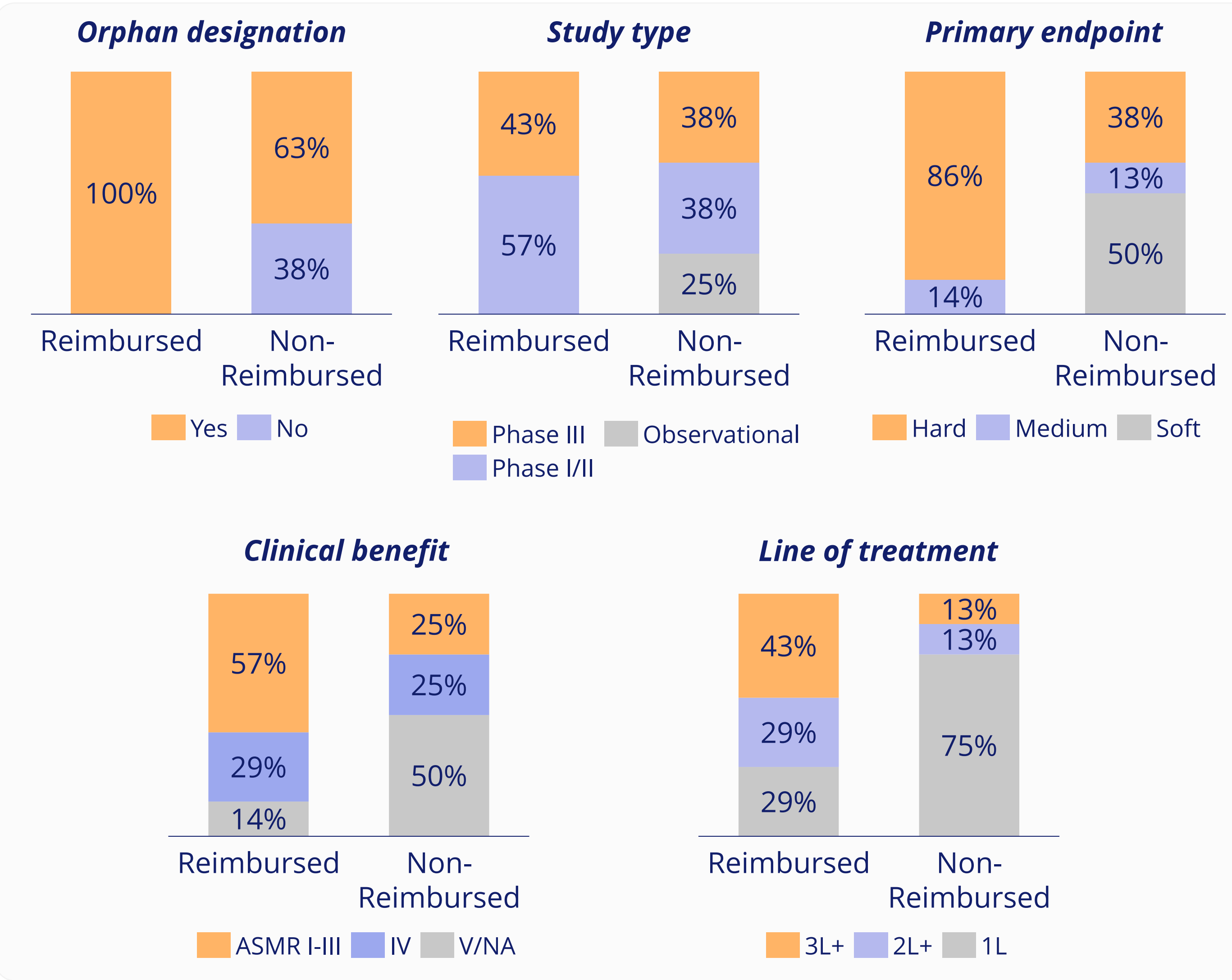
ATMPs with a P&R Resolution in Spain (n=15)

- > Most of the ATMPs were **gene therapies** (80%), with an **orphan designation** (80%), and were authorised **under exceptional circumstances or conditional approval** (87%)^{1,3}
- > The approval was based on **phase I/II** (47%) or **phase III** (40%) clinical trials, predominantly **open-label** (94%), **non-comparative** (87%), and **non-randomized** (80%)^{1,3}
- > A big proportion were **antineoplastic/immunomodulatory agents** (53%), evaluated with **hard outcome measures** (60%) and as a **first-line treatment** (54%)^{1,3}
- > Among the **reimbursed therapies** (n=8), all of them were subject to **price discounts** (range: 4-38%), and 86% had **restricted access** to the reimbursed indication and payment-by-results agreements⁴⁻⁶

Analysis of Reimbursed and Non-Reimbursed ATMPs in Spain

- > Comparisons between reimbursed and non-reimbursed therapies reveal the following points (Figure 2^{1,3}):
 - a) All reimbursed therapies were granted **orphan designation**, indicating their focus on rare conditions, compared to 63% of the non-reimbursed therapies
 - b) All reimbursed therapies were **approved based on phase I-III clinical studies**, versus 75% of the non-reimbursed therapies
 - c) Notably, 86% of reimbursed therapies were studied using a **robust clinical variable** as a primary endpoint versus 38%
 - d) In terms of clinical benefit, 57% of reimbursed ATMPs **demonstrated a clear clinical advantage** (ASMR level in France) versus 25%
 - e) 43% were treatments for **third-line or later** (3L+), suggesting a focus on patients with advanced diseases versus 13%

Figure 2. Comparisons between Reimbursed (n=7) and Non-Reimbursed ATMPs (n=8)



- > The average **time from European approval to P&R resolution** was 21 months for reimbursed therapies, compared to 27 months for non-reimbursed therapies (Figure 3^{1,3})

Figure 3. P&R Timelines for ATMPs in Spain



CONCLUSION

- > This analysis highlights the importance of making innovative therapies accessible while upholding stringent standards for clinical evidence and cost-effectiveness. The findings indicate that improving the efficiency of the approval process and implementing flexible reimbursement models could enhance patient access to advanced therapies in Spain

REFERENCES

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