11 October 2023
EMA/CAT/247792/2023
Human Medicines Division

CAT quarterly highlights and approved ATMPs
October 2023

This report provides information on Advanced Therapy Medicinal Products (ATMPs) approvals and extension of indications of authorised ATMPs, as well as statistical data on product-related activities.

The period covered by this report is: August – October 2023.

Advanced therapy medicinal products approvals
No approvals of ATMPs in the period covered by this report

Extension of indication of authorised ATMPs
No extensions of indications in the period covered by this report

Overview of product-related activities
The Committee discussed ongoing evaluation procedures for ATMPs and other related procedures as summarised in the following tables:
### Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP

<table>
<thead>
<tr>
<th></th>
<th>2009-2020</th>
<th>2021</th>
<th>2022</th>
<th>2023*</th>
<th>Total</th>
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<tbody>
<tr>
<td>Submitted MAAs</td>
<td>32</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>38</td>
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<tr>
<td>Positive draft Opinion</td>
<td>18¹</td>
<td>2</td>
<td>6</td>
<td>0</td>
<td>26#</td>
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<tr>
<td>Negative draft opinions</td>
<td>4 i,ii,iii</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Withdrawals</td>
<td>8 ii, iv</td>
<td>0</td>
<td>1v</td>
<td>1vi</td>
<td>10</td>
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<tr>
<td>Ongoing MAAs</td>
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¹ Corresponding to 25 ATMPs (see List of authorised ATMPs)

<table>
<thead>
<tr>
<th></th>
<th>2009-2020</th>
<th>2021</th>
<th>2022</th>
<th>2023*</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Scientific recommendation on advanced therapy classification¹</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Submitted</td>
<td>489</td>
<td>66</td>
<td>51</td>
<td>39</td>
<td>645</td>
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<tr>
<td>Adopted</td>
<td>483</td>
<td>61</td>
<td>46</td>
<td>45</td>
<td>635</td>
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</table>

¹ More information on the scientific recommendation on advanced therapy classification and the summaries of ATMP classification can be found on the [ATMP classification webpage](#).

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

### Variations (Type II) for authorised ATMP

<table>
<thead>
<tr>
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<th>2009-2020</th>
<th>2021</th>
<th>2022</th>
<th>2023*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive opinion</td>
<td>78</td>
<td>32</td>
<td>47</td>
<td>40</td>
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### Scientific advice procedure for ATMPs

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<thead>
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<th>2009-2020</th>
<th>2021</th>
<th>2022</th>
<th>2023*</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Number of procedures</td>
<td>442</td>
<td>64</td>
<td>53</td>
<td>46</td>
<td>605</td>
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### PRIME² Eligibility for ATMPs

<table>
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<th>2016-2020</th>
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<th>Total</th>
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<tbody>
<tr>
<td>Discussed</td>
<td>91</td>
<td>14</td>
<td>10</td>
<td>11</td>
<td>126</td>
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<tr>
<td>Granted</td>
<td>39</td>
<td>7</td>
<td>4</td>
<td>8</td>
<td>58</td>
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* Period: January-October 2023  
+ Period: January-September 2023

¹ More information on the scientific recommendation on advanced therapy classification and the summaries of ATMP classification can be found on the [ATMP classification webpage](#).

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

² PRIority MEdicines (PRIME) scheme. PRIME was set up in March 2016 to provide early and enhanced scientific and regulatory support to medicines that have the potential to significantly address patients’ unmet medical needs. More information can be found at the [PRIME webpage](#).
## List of authorised ATMPs

<table>
<thead>
<tr>
<th>NAME</th>
<th>Type of ATMP</th>
<th>Authorisation Date</th>
<th>Orphan</th>
<th>PRIME</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chondrocelect</td>
<td>TEP</td>
<td>5/10/2009</td>
<td>No</td>
<td>No</td>
<td>MA withdrawn July 2016</td>
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<tr>
<td>Glybera</td>
<td>GTMP</td>
<td>25/10/2012</td>
<td>Yes</td>
<td>No</td>
<td>MA not renewed (MA ended Oct. 2017)</td>
</tr>
<tr>
<td>MACI</td>
<td>TEP, combined ATMP</td>
<td>27/06/2013</td>
<td>No</td>
<td>No</td>
<td>MA not renewed (MA ended June 2018)</td>
</tr>
<tr>
<td>Provenge</td>
<td>CTMP</td>
<td>6/09/2013</td>
<td>No</td>
<td>No</td>
<td>MA withdrawn May 2015</td>
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<tr>
<td>Holoclar</td>
<td>TEP</td>
<td>17/02/2015</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Imlygic</td>
<td>GTMP</td>
<td>16/12/2015</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Strimvelis</td>
<td>GTMP</td>
<td>26/05/2016</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Zalmoxis</td>
<td>CTMP</td>
<td>18/08/2016</td>
<td>Yes</td>
<td>No</td>
<td>MA withdrawn Oct. 2019</td>
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<tr>
<td>Spherox</td>
<td>TEP</td>
<td>10/07/2017</td>
<td>No</td>
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<tr>
<td>Alofisal</td>
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<td>23/03/2018</td>
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<td>No</td>
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<tr>
<td>Yescarta</td>
<td>GTMP</td>
<td>23/08/2018</td>
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<td>Kymriah</td>
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<td>Luxturna</td>
<td>GTMP</td>
<td>22/11/2018</td>
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<td>No</td>
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<tr>
<td>Zynteglo</td>
<td>GTMP</td>
<td>29/05/2019</td>
<td>Yes</td>
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<td>MA withdrawn March 2022</td>
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<td>Zolgensma</td>
<td>GTMP</td>
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<td>Libmeldy</td>
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<td>Tecartus</td>
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<td>Skysona</td>
<td>GTMP</td>
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<td>Yes</td>
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<td>Abecma</td>
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<td>Carvykti</td>
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<td>Upstaza</td>
<td>GTMP</td>
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<tr>
<td>NAME</td>
<td>Type of ATMP</td>
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<td>Orphan</td>
<td>PRIME</td>
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<td>Roctavian</td>
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<td>Ebvallo</td>
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<td>Hemgenix</td>
<td>GTMP</td>
<td>20/02/2023</td>
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More information on authorised products can be found on: [www.ema.europa.eu](http://www.ema.europa.eu) (type in the product name in the search box)

**Abbreviations:** ATMP: advanced therapy medicinal product; GTMP: gene therapy medicinal product; CTMP: cell therapy medicinal product; TEP: tissue engineered product; MA: Marketing authorisation