APPLICATION FORM for CERTIFICATION of Quality and Non-clinical data for Advanced Therapy Medicinal Products developed by Small and Medium-sized Enterprises (SME)

●●●●●

ANNEXED DOCUMENTS (where appropriate)

☐ **A.1** Table of Content for Module 3 and 4 with an indication of the relevant studies / data submitted for evaluation and certification. (In case of subsequent certification, the new sections should be highlighted)

☐ **A.2** Applicant's proposal and justification on the classification of the product as ATMP.

☐ **A.3** Scientific recommendation on advanced therapy classification given by the CAT (if applicable).

☐ **A.4** Letter of authorisation for communication on behalf of the applicant.

☐ **A.5** Flow-chart indicating all manufacturing and control sites involved in the manufacturing process / development of the ATMP.

☐ **A.6** Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other Community arrangements apply); any proof of authorisation in accordance with Article 8(k) of Directive 2001/83/EC. GMP certificate(s) or other equivalent documents.

☐ **A.7** For combined ATMPs: name, address and contact details of the manufacturer of the medical device.

☐ **A.8** Information on the Non-clinical testing facilities (company name, address, contact details and test performed) and GLP certificates when available.

☐ **A.9** Scientific Advice given by CHMP and/or by member state(s).

☐ **A.10** Copy of the Orphan Designation Decision.

☐ **A.11** Information on the stage of development of the ATMP (Pharmaceutical development, Non-clinical development (specify, e.g. proof of concept studies, toxicity studies), Clinical development (specify, e.g. first in man studies, dose finding studies, pivotal studies)). If clinical trails have been conducted, provide the Investigator's Brochure.

☐ **A.12** Agreed minutes of the pre-submission meeting (if applicable).