Reference Material for Mesenchymal Stromal Cell Critical Quality Attribute Assays

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Strict quality standards apply to medicinal products, including mesenchymal stromal cells (MSCs). There are already internationally recognized quality standards for the 'safety' aspect, which ensure that the medicinal product is not contaminated with bacteria, viruses, fungi or similar.

In addition, the manufacturer must ensure that the medicine is what it is supposed to be and works, as it should. This means that the manufacturer must carry out tests to verify the purity, efficacy and identity of the cellular medicinal product. For such a test, however, the manufacturer needs reference material, also known as a standard, which proves that the results of the analyses are correct and which serves as a benchmark for the medicinal product. To date, such reference materials for testing the identity, purity and efficacy of mesenchymal stromal cells are not available on a large scale.

Therefore, in this project we will develop, produce and test reference materials that allow the comparative verification of the identity, purity and efficacy of mesenchymal stromal cells, thus ensuring their quality for cell therapies.

We will provide reference material that is produced on a large scale. It is used as a reference standard for MSC positive/negative markers, which can be used for identity and purity testing. The reference material should also make it possible to test the efficacy of the drug in functional tests in comparison with the standard. The comparable quality achieved in this way will help to overcome regulatory obstacles that currently hinder the development and commercialization of cell therapies with mesenchymal stromal cells.