



## Immunosuppressant CellCept, Approved for Additional Indication of Prevention of Graft-Versus-Host Disease in Hematopoietic Stem-Cell Transplantation

TOKYO, June 25, 2021 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that it obtained approval from the Ministry of Health, Labour and Welfare (MHLW) for immunosuppressant CellCept® Capsules 250, and CellCept® Powder for Oral Suspension 31.8% (generic name: mycophenolate mofetil) for the additional indication of prevention of graft-versus-host disease (GVHD) in hematopoietic stem-cell transplantation (adults and children).

The Review Committee on Unapproved Drugs and Indications with High Medical Needs held on December 9, 2020 concluded that public knowledge-based application should be applicable for CellCept for the prevention of GVHD in hematopoietic stem-cell transplantation. The First Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council held on January 27, 2021 also made a decision that such filing was reasonable. In response, Chugai submitted a public knowledge-based application for the additional indication on February 5, 2021, and thus obtained approval. The Japan Society for Hematopoietic Cell Transplantation (currently the Japanese Society for Transplantation and Cellular Therapy) had requested the development of the additional indication.

GVHD is caused by donor-derived lymphocytes after allogeneic hematopoietic stem-cell transplantation. The normal cells of the patient are considered foreign and are attacked by an immune reaction, which leads to skin symptoms, gastrointestinal symptoms, and liver damage.<sup>1)</sup> CellCept is one of the standard-of-care drugs for GVHD in overseas clinical practice guidelines.<sup>2)</sup>

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### Sources

1. (Reference) Japanese Society for Transplantation and Cellular Therapy. 8-2. Acute Graft-versus-Host Disease Available from: [https://www.jshct.com/modules/patient/index.php?content\\_id=21](https://www.jshct.com/modules/patient/index.php?content_id=21) (accessed in May 2021, Japanese only)
2. Ruutu, T., Gratwohl, A., de Witte, T. et al. Prophylaxis and treatment of GVHD: EBMT–ELN working group recommendations for a standardized practice. *Bone Marrow Transplant* 49, 168–173 (2014).

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