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Statement by the DAG-HSZT on the approval status of Belumosudil

In Germany, approximately 3,500 patients undergo allogeneic stem cell transplantation each year, of whom about one-third will develop chronic GvHD requiring systemic drug therapy. Although first-line therapy with corticosteroids and when indicated second-line therapy (usually with ruxolitinib or ECP) mostly enable adequate disease control, approximately 200–300 patients per year require systemic third-line therapy. To date, there is no standard of care for this setting. Since chronic GvHD requiring treatment is associated with relevant morbidity for patients affected, there is undoubtedly an “unmet medical need” in this area.

Belumosudil is an innovative compound for the treatment of severe, refractory chronic GvHD after failure of multiple lines of therapy. Upon submission of Belumosudil to the European Medicines Agency (EMA), in October 2025 the Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion regarding approval, referring to what the EMA considered to be insufficient evidence of clinical benefits at this time.

Belumosudil has already been approved in several countries, including the USA, the UK, and Canada. In Germany, Belumosudil has been used over a longer period of time in clinical trials and a compassionate use program, providing considerable clinical experience. In addition, a number of other retrospective studies have recently been published demonstrating the benefits of Belumosudil complementary to the approval trial (Holtick et al., P6011, ASH 2025; Rodriguez-Rodrigue P4239, ASH 2025; Rodriguez-Rodrigue P6031, ASH 2025; Michonneau et al., Bone Marrow Transplant 60, 779–786 (2025); Bonifazi et al. PS2042 EHA 2025).

Before this background, we are afraid that denial of approval of Belumosudil would result in a significant impairment of care of patients with refractory severe chronic GvHD. In our opinion, the experience gained in trials and real-world practice demonstrates the clear clinical benefit of Belumosudil with an overall favorable risk-benefit ratio in this highly vulnerable patient group.

Therefore, the DAG-HSZT would like to appeal to the EMA to re-evaluate its appraisal of the benefit-risk ratio of Belumosudil, taking into account recent evidence, in order to make the drug available for standard clinical care of patients affected with the burden of refractory severe chronic GVHD.

Prof. Dr. Peter Dreger*
For the Steering Committee of the DAG-HSZT

* P Dreger declares that he has no financial conflicts of interest with regard to the licenscee of belumosudil