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Session : Concurrent Symposium 13 (Kidney/Pancreas)

Date & Time, Place : November 18 (Sat), 15:30-17:00, Room 5F-1

Session Title : New treatment for antibody-mediated rejection

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## **Imlifidase**

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**Vo Lecture Note (abstract of their lecture contents) Abstract:** Antibody mediated rejection (AMR), characterized by the presence of donor-specific antibodies to HLA, remains one of the most critical problems in renal transplantation, with a significant impact on patient and graft survival. Currently, there is no approved treatment for AMR and patients are often treated with a combination of therapies such as high dose IVIg  $\pm$  rituximab or PE with low dose IVIg  $\pm$  rituximab. Hence, there is a large unmet clinical need for new therapies to treat AMR. Imlifidase is an IgG-degrading enzyme of *Streptococcus pyogenes* that cleaves all four human subclasses of IgG with high efficacy and specificity. Imlifidase was first studied for the desensitization of highly HLA-sensitized patients to enable kidney transplantation. In 2020, imlifidase received conditional approval from the European Medicines Agency for use to desensitize deceased-donor kidney transplant recipients with a positive crossmatch. A Phase 3 trial of imlifidase (ConfIdeS) in highly sensitized (cPRA  $\geq 99.9\%$ ) kidney transplant patients is underway and is expected to conclude in mid-2024. Thus, imlifidase represents a major breakthrough for highly HLA-sensitized kidney transplant candidates, particularly those that have cPRA  $\geq 90\%$ . Imlifidase is also being evaluated in a phase 2 study for kidney transplant recipients who have antibody-mediated rejection (AMR). This study is now completed and results are being analyzed.