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Novartis presents first-of-its-kind histology data with iscalimab (CFZ533) suggesting the extended survival of transplanted organs may be possible

- *Data show 60% of iscalimab-treated transplant patients have normal kidney histology at least 1 year after transplant vs 0% with tacrolimus (current standard of care)*[1]

- *Less than half of donated kidneys last 10 years, so durability is a significant unmet need for patients who are living with or waiting for a transplant*[2]*. More than 100,000 patients are on the US transplant waiting list with a chronic shortfall of donors*[3]

- *Data was presented at the American Transplant Congress (ATC), June 1–5, as a late-breaking abstract*

Basel, June 6, 2019 – Novartis announced today new early stage histology data in kidney transplantation, suggesting that with investigational compound iscalimab (CFZ533) it may be possible to prolong the durability of transplanted kidneys as well as to potentially improve long-term outcomes for kidney transplant patients[1].

“Extending the life of transplanted kidneys would mean fewer patients going back on dialysis or needing a second transplant – relieving pressure on waiting lists that in the US are already three-to-five years long,” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology and Dermatology. “In our journey to reimagine care for patients, I’m excited about the potential of durable transplants becoming a reality.”

The data, presented at the American Transplant Congress (ATC) examines whether calcineurin-free treatment with iscalimab preserves the quality of transplanted kidney grafts. In this analysis, iscalimab demonstrated lower chronic allograft damage index (CADI) scores compared with tacrolimus (current standard-of-care), with normal renal histology seen in three of five patients (60%) on iscalimab vs none of seven on tacrolimus[1]. Low CADI scores have been associated with improved long-term outcomes[4]. The findings, although in a limited number of patients, are to be confirmed in an ongoing Phase IIb trial (Cirrus I, NCT03663335).

About iscalimab (CFZ533)
Iscalimab is a new, fully human, monoclonal antibody preventing cluster of differentiation 40 (CD40) pathway signaling and activation of CD40+ cell types[1]. In a recent multicenter, randomized control trial (NCT02217410), with the primary endpoint of non-inferiority on the composite endpoint, iscalimab therapy showed non-inferiority on a composite clinical endpoint, improved renal function, reduced risk for new onset diabetes and similar safety compared with tacrolimus[5]. The analysis presented at the ATC included patients from this study that underwent either routine biopsies or biopsies as part of a follow-up protocol. The data was reviewed and scored by a blinded pathologist using the established Banff criteria

and CADI. A CADI of 1 or less was considered as 'normal renal histology'. The average CADI at final biopsy was 1.6 ±0.6 for iscalimab and 5.1 ±0.8 for tacrolimus[1].

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References

1. Farkash E, et al. Cni-free Therapy With Iscalimab (anti-cd40 Mab) Preserves Allograft Histology Compared To Standard Of Care After Kidney Transplantation. Presented at the American Transplant Congress (ATC). June 2019.
2. Hart A, et al. OPTN/SRTR 2016 Annual Data Report: Kidney. *Am J Transplant* 2018;18:1–96.
3. University of California San Francisco. The Kidney Project Key Statistics [online]. Available from: https://pharm.ucsf.edu/kidney/need/statistics [Last accessed: May 2019].

4. Yilmaz S, et al. Protocol Core Needle Biopsy and Histologic Chronic Allograft Damage Index (CADI) as Surrogate End Point for Long-Term Graft Survival in Multicenter Studies. *J Am Soc Nephrol* 2003;14:773–779.
5. Novartis data on file. May 2019.

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