



May 13, 2020

Captain Krista Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
Department of Health and Human Services (HHS)
5600 Fishers Lane, Parklawn Building, Mail Stop 10C-03
Rockville, Maryland 20857

Re: Discontinuing Limited Distribution System for PROGRAF® (tacrolimus) ampules and granules and ASTAGRAF XL® (tacrolimus extended-release capsules)

Dear Captain Pedley:

Astellas Pharma US, Inc. (“Astellas”) markets PROGRAF® (tacrolimus) 5 mg/mL (National Drug Code (NDC): 0469-3016-01) for injection; 0.5 mg (NDC: 0469-0607-73), 1 mg (NDC: 0469-0617-73), and 5 mg (NDC: 0469-0657-73) capsules; and 0.2 mg (NDC: 0469-1230-50) and 1 mg (NDC: 0469-1330-50) granules (tacrolimus for oral suspension) (collectively “Prograf”), a calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving allogeneic liver, kidney, or heart transplants, in combination with other immunosuppressants (collectively “organ transplant(s)”). Astellas also markets ASTAGRAF XL® (tacrolimus extended-release capsules) 0.5 mg (NDC: 0469-0647-73), 1 mg (NDC: 0469-0677-73), and 5 mg (NDC: 0469-0687-73) capsules (collectively “Astagraf”), a calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants in adult and pediatric patients (collectively “kidney transplant(s)").

In June 2019, with OPA approval, Astellas implemented a limited distribution plan for all strengths and formulations of Prograf and Astagraf due to another manufacturer’s anticipated shortage of its generic tacrolimus products.

In December 2019, with OPA approval, Astellas removed the limited distribution system on all strengths of Prograf capsules. We left the limited distribution system in effect for Prograf ampules, Prograf granules, and Astagraf because, at that time, Astellas did not have sufficient additional stock of those products to meet a significant increased market demand.



Over the past five months, we have gained improved visibility into the demand for these products. In addition, Astellas has expedited and increased product deliveries from manufacturing facilities. As such, we project that we will have sufficient inventory to support market demand for all products.

For these reasons, we are removing the limited distribution system that has been in effect for Prograf ampules, Prograf granules, and Astagraf. Please feel free to share this information with 340B covered entities and other interested parties as you think appropriate. If there are other questions, please call 1-800-727-7003.

Sincerely,

Astellas Pharma US, Inc.